ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Aerius 5 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg desloratadine.

Excipient(s) with known effect:
This medicine contains lactose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aerius is indicated in adults and adolescents aged 12 years and older for the relief of symptoms associated with:
- allergic rhinitis (see section 5.1)
- urticaria (see section 5.1)

4.2 Posology and method of administration

Posology
Adults and adolescents (12 years of age and over)
The recommended dose of Aerius is one tablet once a day.

Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or for less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance. In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during the allergen exposure periods.

Paediatric population
There is limited clinical trial efficacy experience with the use of desloratadine in adolescents 12 through 17 years of age (see sections 4.8 and 5.1).

The safety and efficacy of Aerius 5 mg film-coated tablets in children below the age of 12 years have not been established. No data are available.

Method of administration
Oral use.
The dose can be taken with or without food.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1, or to loratadine.

4.4 Special warnings and precautions for use

In the case of severe renal insufficiency, Aerius should be used with caution (see section 5.2).

Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children, being more susceptible to develop new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions were observed in clinical trials with desloratadine tablets in which erythromycin or ketoconazole were co-administered (see section 5.1).

Paediatric population
Interaction studies have only been performed in adults.

In a clinical pharmacology trial, Aerius tablets taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol (see section 5.1). However, cases of alcohol intolerance and intoxication have been reported during post-marketing use. Therefore, caution is recommended if alcohol is taken concomitantly.

4.6 Fertility, pregnancy and lactation

Pregnancy
A large amount of data on pregnant women (more than 1,000 pregnancy outcomes) indicate no malformative nor foeto/ neonatal toxicity of desloratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). As a precautionary measure, it is preferable to avoid the use of Aerius during pregnancy.

Breast-feeding
Desloratadine has been identified in breastfed newborns/infants of treated women. The effect of desloratadine on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Aerius therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
There are no data available on male and female fertility.

4.7 Effects on ability to drive and use machines

Aerius has no or negligible influence on the ability to drive and use machines based on clinical trials. Patients should be informed that most people do not experience drowsiness. Nevertheless, as there is individual variation in response to all medicinal products, it is recommended that patients are advised not to engage in activities requiring mental alertness, such as driving a car or using machines, until they have established their own response to the medicinal product.

4.8 Undesirable effects

Summary of the safety profile
In clinical trials in a range of indications including allergic rhinitis and chronic idiopathic urticaria, at the recommended dose of 5 mg daily, undesirable effects with Aerius were reported in 3 % of patients

in excess of those treated with placebo. The most frequent of adverse reactions reported in excess of placebo were fatigue (1.2 %), dry mouth (0.8 %) and headache (0.6 %).

Paediatric population
In a clinical trial with 578 adolescent patients, 12 through 17 years of age, the most common adverse event was headache; this occurred in 5.9 % of patients treated with desloratadine and 6.9 % of patients receiving placebo.

Tabulated list of adverse reactions
The frequency of the clinical trial adverse reactions reported in excess of placebo and other undesirable effects reported during the post-marketing period are listed in the following table. Frequencies are defined as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reactions seen with Aerius
Metabolism and nutrition disorders	Not known	Increased appetite
Psychiatric disorders	Very rare Not known	Hallucinations Abnormal behaviour, aggression
Nervous system disorders	Common Very rare	Headache Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Cardiac disorders	Very rare Not known	Tachycardia, palpitations QT prolongation
Gastrointestinal disorders	Common Very rare	Dry mouth Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea
Hepatobiliary disorders	Very rare Not known	Elevations of liver enzymes, increased bilirubin, hepatitis Jaundice
Skin and subcutaneous tissue disorders	Not known	Photosensitivity
Musculoskeletal and connective tissue disorders	Very rare	Myalgia
General disorders and administration site conditions	Common Very rare Not known	Fatigue Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria) Asthenia
Investigations	Not known	Weight increased

Paediatric population
Other undesirable effects reported during the post-marketing period in paediatric patients with an unknown frequency included QT prolongation, arrhythmia, bradycardia, abnormal behaviour, and aggression.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

Treatment
In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.

Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

Symptoms
Based on a multiple dose clinical trial, in which up to 45 mg of desloratadine was administered (nine times the clinical dose), no clinically relevant effects were observed.

Paediatric population
The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antihistamines – H_1 antagonist, ATC code: R06A X27

Mechanism of action
Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H_1-receptors because the substance is excluded from entry to the central nervous system.

Desloratadine has demonstrated antiallergic properties from *in vitro* studies. These include inhibiting the release of proinflammatory cytokines such as IL-4, IL-6, IL-8, and IL-13 from human mast cells/basophils, as well as inhibition of the expression of the adhesion molecule P-selectin on endothelial cells. The clinical relevance of these observations remains to be confirmed.

Clinical efficacy and safety
In a multiple dose clinical trial, in which up to 20 mg of desloratadine was administered daily for 14 days, no statistically or clinically relevant cardiovascular effect was observed. In a clinical pharmacology trial, in which desloratadine was administered at a dose of 45 mg daily (nine times the clinical dose) for ten days, no prolongation of QTc interval was seen.

No clinically relevant changes in desloratadine plasma concentrations were observed in multiple-dose ketoconazole and erythromycin interaction trials.

Desloratadine does not readily penetrate the central nervous system. In controlled clinical trials, at the recommended dose of 5 mg daily, there was no excess incidence of somnolence as compared to placebo. Aerius given at a single daily dose of 7.5 mg did not affect psychomotor performance in clinical trials. In a single dose study performed in adults, desloratadine 5 mg did not affect standard measures of flight performance including exacerbation of subjective sleepiness or tasks related to flying.

In clinical pharmacology trials, co-administration with alcohol did not increase the alcohol-induced impairment in performance or increase in sleepiness. No significant differences were found in the

psychomotor test results between desloratadine and placebo groups, whether administered alone or with alcohol.

In patients with allergic rhinitis, Aerius was effective in relieving symptoms such as sneezing, nasal discharge and itching, as well as ocular itching, tearing and redness, and itching of palate. Aerius effectively controlled symptoms for 24 hours.

Paediatric population
The efficacy of Aerius tablets has not been clearly demonstrated in trials with adolescent patients 12 through 17 years of age.

In addition to the established classifications of seasonal and perennial, allergic rhinitis can alternatively be classified as intermittent allergic rhinitis and persistent allergic rhinitis according to the duration of symptoms. Intermittent allergic rhinitis is defined as the presence of symptoms for less than 4 days per week or for less than 4 weeks. Persistent allergic rhinitis is defined as the presence of symptoms for 4 days or more per week and for more than 4 weeks.

Aerius was effective in alleviating the burden of seasonal allergic rhinitis as shown by the total score of the rhino-conjunctivitis quality of life questionnaire. The greatest amelioration was seen in the domains of practical problems and daily activities limited by symptoms.

Chronic idiopathic urticaria was studied as a clinical model for urticarial conditions, since the underlying pathophysiology is similar, regardless of etiology, and because chronic patients can be more easily recruited prospectively. Since histamine release is a causal factor in all urticarial diseases, desloratadine is expected to be effective in providing symptomatic relief for other urticarial conditions, in addition to chronic idiopathic urticaria, as advised in clinical guidelines.

In two placebo-controlled six week trials in patients with chronic idiopathic urticaria, Aerius was effective in relieving pruritus and decreasing the size and number of hives by the end of the first dosing interval. In each trial, the effects were sustained over the 24 hour dosing interval. As with other antihistamine trials in chronic idiopathic urticaria, the minority of patients who were identified as non-responsive to antihistamines was excluded. An improvement in pruritus of more than 50 % was observed in 55 % of patients treated with desloratadine compared with 19 % of patients treated with placebo. Treatment with Aerius also significantly reduced interference with sleep and daytime function, as measured by a four-point scale used to assess these variables.

5.2 Pharmacokinetic properties

Absorption
Desloratadine plasma concentrations can be detected within 30 minutes of administration. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) and a once daily dosing frequency. The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

In a pharmacokinetic trial in which patient demographics were comparable to those of the general seasonal allergic rhinitis population, 4 % of the subjects achieved a higher concentration of desloratadine. This percentage may vary according to ethnic background. Maximum desloratadine concentration was about 3-fold higher at approximately 7 hours with a terminal phase half-life of approximately 89 hours. The safety profile of these subjects was not different from that of the general population.

Distribution
Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no evidence of clinically relevant medicine accumulation following once daily dosing of desloratadine (5 mg to 20 mg) for 14 days.

Biotransformation
The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products cannot be fully excluded. Desloratadine does not inhibit CYP3A4 *in vivo,* and *in vitro* studies have shown that the medicinal product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

Elimination
In a single dose trial using a 7.5 mg dose of desloratadine, there was no effect of food (high-fat, high caloric breakfast) on the disposition of desloratadine. In another study, grapefruit juice had no effect on the disposition of desloratadine.

Renally impaired patients
The pharmacokinetics of desloratadine in patients with chronic renal insufficiency (CRI) was compared with that of healthy subjects in one single-dose study and one multiple dose study. In the single-dose study, the exposure to desloratadine was approximately 2 and 2.5-fold greater in subjects with mild to moderate and severe CRI, respectively, than in healthy subjects. In the multiple-dose study, steady state was reached after Day 11, and compared to healthy subjects the exposure to desloratadine was ~1.5-fold greater in subjects with mild to moderate CRI and ~2.5-fold greater in subjects with severe CRI. In both studies, changes in exposure (AUC and C_{max}) of desloratadine and 3-hydroxydesloratadine were not clinically relevant.

5.3 Preclinical safety data

Desloratadine is the primary active metabolite of loratadine. Non-clinical studies conducted with desloratadine and loratadine demonstrated that there are no qualitative or quantitative differences in the toxicity profile of desloratadine and loratadine at comparable levels of exposure to desloratadine.

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development. The lack of carcinogenic potential was demonstrated in studies conducted with desloratadine and loratadine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core: calcium hydrogen phosphate dihydrate, microcrystalline cellulose, maize starch, talc.
Tablet coating: film coat (containing lactose monohydrate, hypromellose, titanium dioxide, macrogol 400, indigotin (E132)), clear coat (containing hypromellose, macrogol 400), carnauba wax, white wax.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 30°C.
Store in the original package.

6.5 Nature and contents of container

Aerius is supplied in blisters comprised of laminate blister film with foil lidding.
The materials of the blister consist of a polychlorotrifluoroethylene (PCTFE)/Polyvinyl Chloride (PVC) film (product contact surface) with an aluminium foil lidding coated with a vinyl heat seal coat (product contact surface) which is heat sealed.
Packs of 1, 2, 3, 5, 7, 10, 14, 15, 20, 21, 30, 50, 90, 100 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

8. MARKETING AUTHORISATION NUMBERS

EU/1/00/160/001-013
EU/1/00/160/036

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 January 2001
Date of latest renewal: 15 January 2006

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

1. NAME OF THE MEDICINAL PRODUCT

Aerius 2.5 mg orodispersible tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each orodispersible tablet contains 2.5 mg desloratadine.

Excipient(s) with known effect:
This medicine contains mannitol and aspartame (E951).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Orodispersible tablet

Light-red, flat-faced, round, speckled tablets, one side branded with "K"

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aerius is indicated in adults, adolescents aged 12 years and older and children aged 6 – 11 years old for the relief of symptoms associated with:
- allergic rhinitis (see section 5.1)
- urticaria (see section 5.1)

4.2 Posology and method of administration

Posology
Adults and adolescents (12 years of age and over)
The recommended dose of Aerius is two 2.5 mg orodispersible tablets placed in the mouth once a day.

Paediatric population
Children 6 to 11 years of age: the recommended dose of Aerius is one 2.5 mg orodispersible tablet placed in mouth once a day.

The safety and efficacy of Aerius 2.5 mg orodispersible tablets in children below the age of 6 years have not been established. No data are available.

There is limited clinical trial efficacy experience with the use of desloratadine in children 6 through 11 years of age (see section 5.2).

There is limited clinical trial efficacy experience with the use of desloratadine in adolescents 12 through 17 years of age (see sections 4.8 and 5.1).

Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or for less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance. In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during the allergen exposure periods.

Method of administration
Oral use.
The dose can be taken with or without food.
Immediately before use, the blister must be carefully peeled open and the dose of orodispersible tablet removed without crushing it. The dose of orodispersible tablet is placed in the mouth where it will disperse immediately. Water or other liquid is not needed to swallow the dose. The dose must be taken as soon as the blister has been opened.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1, or to loratadine.

4.4 Special warnings and precautions for use

In the case of severe renal insufficiency, Aerius should be used with caution (see section 5.2).

Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children, being more susceptible to develop new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment.

This product contains 1.4 mg of phenylalanine per 2.5 mg dose of Aerius orodispersible tablet. Phenylalanine may be harmful for people with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions were observed in clinical trials with desloratadine tablets in which erythromycin or ketoconazole were co-administered (see section 5.1).

Paediatric population
Interaction studies have only been performed in adults.

In a clinical pharmacology trial, Aerius tablets taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol (see section 5.1). However, cases of alcohol intolerance and intoxication have been reported during post-marketing use. Therefore, caution is recommended if alcohol is taken concomitantly.

4.6 Fertility, pregnancy and lactation

Pregnancy
A large amount of data on pregnant women (more than 1,000 pregnancy outcomes) indicate no malformative nor foeto/ neonatal toxicity of desloratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). As a precautionary measure, it is preferable to avoid the use of Aerius during pregnancy.

Breast-feeding
Desloratadine has been identified in breastfed newborns/infants of treated women. The effect of desloratadine on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Aerius therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
There are no data available on male and female fertility.

4.7 Effects on ability to drive and use machines

Aerius has no or negligible influence on the ability to drive and use machines based on clinical trials. Patients should be informed that most people do not experience drowsiness. Nevertheless, as there is individual variation in response to all medicinal products, it is recommended that patients are advised not to engage in activities requiring mental alertness, such as driving a car or using machines, until they have established their own response to the medicinal product.

4.8 Undesirable effects

Summary of the safety profile
In clinical trials, desloratadine in the syrup formulation was administered to a paediatric population. The overall incidence of adverse reactions was similar between the desloratadine syrup and the placebo groups and did not differ significantly than the safety profile seen in adult patients.

In clinical trials in a range of indications including allergic rhinitis and chronic idiopathic urticaria, at the recommended dose of 5 mg daily, undesirable effects with Aerius tablets were reported in 3 % of patients in excess of those treated with placebo. The most frequent of adverse events reported in excess of placebo were fatigue (1.2 %), dry mouth (0.8 %) and headache (0.6 %).

Paediatric population
In a clinical trial with 578 adolescent patients, 12 through 17 years of age, the most common adverse event was headache; this occurred in 5.9 % of patients treated with desloratadine and 6.9 % of patients receiving placebo.

Tabulated list of adverse reactions
The frequency of the clinical trial adverse reactions reported in excess of placebo and other undesirable effects reported during the post-marketing period are listed in the following table. Frequencies are defined as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reactions seen with Aerius
Metabolism and nutrition disorders	Not known	Increased appetite
Psychiatric disorders	Very rare Not known	Hallucinations Abnormal behaviour, aggression
Nervous system disorders	Common Very rare	Headache Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Cardiac disorders	Very rare Not known	Tachycardia, palpitations QT prolongation
Gastrointestinal disorders	Common Very rare	Dry mouth Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea
Hepatobiliary disorders	Very rare Not known	Elevations of liver enzymes, increased bilirubin, hepatitis Jaundice
Skin and subcutaneous tissue disorders	Not known	Photosensitivity
Musculoskeletal and connective tissue disorders	Very rare	Myalgia

System Organ Class	Frequency	Adverse reactions seen with Aerius
General disorders and administration site conditions	Common Very rare Not known	Fatigue Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria) Asthenia
Investigations	Not known	Weight increased

Paediatric population
Other undesirable effects reported during the post-marketing period in paediatric patients with an unknown frequency included QT prolongation, arrhythmia, bradycardia, abnormal behaviour, and aggression.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

Treatment
In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.

Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

Symptoms
Based on a multiple dose clinical trial, in which up to 45 mg of desloratadine was administered (nine times the clinical dose), no clinically relevant effects were observed.

Paediatric population
The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antihistamines – H_1 antagonist, ATC code: R06A X27

Mechanism of action
Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H_1-receptors because the substance is excluded from entry to the central nervous system.

Desloratadine has demonstrated antiallergic properties from *in vitro* studies. These include inhibiting the release of proinflammatory cytokines such as IL-4, IL-6, IL-8, and IL-13 from human mast cells/basophils, as well as inhibition of the expression of the adhesion molecule P-selectin on endothelial cells. The clinical relevance of these observations remains to be confirmed.

Clinical efficacy and safety

In a multiple dose trial, Aerius orodispersible tablets were well tolerated.

At the recommended dose, Aerius 5 mg orodispersible tablet was found to be bioequivalent to the Aerius 5 mg conventional tablet formulation of desloratadine. Therefore, the efficacy of Aerius orodispersible tablet is expected to be the same as with the Aerius tablet formulation.

In a multiple dose clinical trial, in which up to 20 mg of desloratadine was administered daily for 14 days, no statistically or clinically relevant cardiovascular effect was observed. In a clinical pharmacology trial, in which desloratadine was administered at a dose of 45 mg daily (nine times the clinical dose) for ten days, no prolongation of QTc interval was seen.

No clinically relevant changes in desloratadine plasma concentrations were observed in multiple-dose, ketoconazole and erythromycin interaction trials.

Desloratadine does not readily penetrate the central nervous system. In clinical trials, at the recommended dose of 5 mg daily, there was no excess incidence of somnolence as compared to placebo. Aerius tablets given at a single daily dose of 7.5 mg did not affect psychomotor performance in clinical trials. In a single dose study performed in adults, desloratadine 5 mg did not affect standard measures of flight performance including exacerbation of subjective sleepiness or tasks related to flying.

In clinical pharmacology trials, co-administration with alcohol did not increase the alcohol-induced impairment in performance or increase in sleepiness. No significant differences were found in the psychomotor test results between desloratadine and placebo groups, whether administered alone or with alcohol.

In patients with allergic rhinitis, Aerius tablets were effective in relieving symptoms such as sneezing, nasal discharge and itching, as well as ocular itching, tearing and redness, and itching of palate. Aerius tablets effectively controlled symptoms for 24 hours.

Paediatric population

The efficacy of Aerius tablets has not been clearly demonstrated in trials with adolescent patients 12 through 17 years of age.

In addition to the established classifications of seasonal and perennial, allergic rhinitis can alternatively be classified as intermittent allergic rhinitis and persistent allergic rhinitis according to the duration of symptoms. Intermittent allergic rhinitis is defined as the presence of symptoms for less than 4 days per week or for less than 4 weeks. Persistent allergic rhinitis is defined as the presence of symptoms for 4 days or more per week and for more than 4 weeks.

Aerius was effective in alleviating the burden of seasonal allergic rhinitis as shown by the total score of the rhino-conjunctivitis quality of life questionnaire. The greatest amelioration was seen in the domains of practical problems and daily activities limited by symptoms.

Chronic idiopathic urticaria was studied as a clinical model for urticarial conditions, since the underlying pathophysiology is similar, regardless of etiology, and because chronic patients can be more easily recruited prospectively. Since histamine release is a causal factor in all urticarial diseases, desloratadine is expected to be effective in providing symptomatic relief for other urticarial conditions, in addition to chronic idiopathic urticaria, as advised in clinical guidelines.

In two placebo-controlled six week trials in patients with chronic idiopathic urticaria, Aerius was effective in relieving pruritus and decreasing the size and number of hives by the end of the first dosing interval. In each trial, the effects were sustained over the 24 hour dosing interval. As with other antihistamine trials in chronic idiopathic urticaria, the minority of patients who were identified as non-responsive to antihistamines was excluded. An improvement in pruritus of more than 50 %

was observed in 55 % of patients treated with desloratadine compared with 19 % of patients treated with placebo. Treatment with Aerius also significantly reduced interference with sleep and daytime function, as measured by a four-point scale used to assess these variables.

5.2 Pharmacokinetic properties

Absorption
Desloratadine plasma concentrations can be detected within 30 minutes of administration. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) and a once daily dosing frequency. The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

In a series of pharmacokinetic and clinical trials, 6 % of the subjects reached a higher concentration of desloratadine. The prevalence of this poor metaboliser phenotype was comparable for adult (6 %) and paediatric subjects 2- to 11-year old (6 %), and greater among Blacks (18 % adult, 16 % paediatric) than Caucasians (2 % adult, 3 % paediatric) in both populations however the safety profile of these subjects was not different from that of the general population.

In a multiple-dose pharmacokinetic study conducted with the tablet formulation in healthy adult subjects, four subjects were found to be poor metabolisers of desloratadine. These subjects had a C_{max} concentration about 3-fold higher at approximately 7 hours with a terminal phase half-life of approximately 89 hours.

Distribution
Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no evidence of clinically relevant medicine accumulation following once daily dosing of desloratadine (5 mg to 20 mg) for 14 days.

Biotransformation
The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products cannot be fully excluded. Desloratadine does not inhibit CYP3A4 *in vivo,* and *in vitro* studies have shown that the medicinal product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

In single-dose crossover studies of Aerius 5 mg orodispersible tablets with Aerius 5 mg conventional tablets, the formulations were bioequivalent. Aerius 2.5 mg tablets has not been evaluated in paediatric patients however in conjunction with the dose finding studies in paediatrics, the pharmacokinetics data for Aerius orodispersible tablets supports the use of the 2.5 mg dose in paediatric patients 6 to 11 years of age.

Elimination
The presence of food prolongs T_{max} for desloratadine from 2.5 to 4 hours and T_{max} for 3-OH-desloratadine from 4 to 6 hours. In a separate study, grapefruit juice had no effect on the disposition of desloratadine. Water had no effect on the bioavailability of Aerius orodispersible tablets.

Renally impaired patients
The pharmacokinetics of desloratadine in patients with chronic renal insufficiency (CRI) was compared with that of healthy subjects in one single-dose study and one multiple dose study. In the single-dose study, the exposure to desloratadine was approximately 2 and 2.5-fold greater in subjects with mild to moderate and severe CRI, respectively, than in healthy subjects. In the multiple-dose study, steady state was reached after Day 11, and compared to healthy subjects the exposure to desloratadine was ~1.5-fold greater in subjects with mild to moderate CRI and ~2.5-fold greater in subjects with severe CRI. In both studies, changes in exposure (AUC and C_{max}) of desloratadine and 3-hydroxydesloratadine were not clinically relevant.

5.3 Preclinical safety data

Desloratadine is the primary active metabolite of loratadine. Non-clinical studies conducted with desloratadine and loratadine demonstrated that there are no qualitative or quantitative differences in the toxicity profile of desloratadine and loratadine at comparable levels of exposure to desloratadine.

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development. The collective analysis of preclinical and clinical irritation studies for the orodispersible tablet indicate that this formulation in unlikely to pose risk for local irritation with clinical use. The lack of carcinogenic potential was demonstrated in studies conducted with desloratadine and loratadine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

microcrystalline cellulose
pregelatinized starch
sodium starch glycolate
magnesium stearate
butylated methacrylate copolymer
crospovidone
sodium hydrogen carbonate
citric acid
colloidal silicon dioxide
ferric oxide
mannitol
aspartame (E951)
flavour Tutti-Frutti

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in the original package.

6.5 Nature and contents of container

Aerius orodispersible tablets are supplied in unit dose blisters comprised of laminate blister film with foil lidding.

The blister materials consist of a four layer aluminum foil laminate cold form blister film and a paper backed laminated aluminum foil lidding film.
The cold form blister film is composed of polyvinyl chloride (PVC) film adhesively laminated to an oriented polyamide (OPA) film, adhesively laminated to aluminum foil, adhesively laminated to polyvinyl chloride (PVC) film.
Packs of 5, 6, 10, 12, 15, 18, 20, 30, 50, 60, 90 and 100 orodispersible tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

8. MARKETING AUTHORISATION NUMBERS

EU/1/00/160/037-048

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 January 2001
Date of latest renewal: 15 January 2006

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

1. NAME OF THE MEDICINAL PRODUCT

Aerius 5 mg orodispersible tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each orodispersible tablet contains 5 mg desloratadine.

Excipient(s) with known effect:
This medicine contains mannitol and aspartame (E951).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Orodispersible tablet

Light-red, flat-faced, round, speckled tablets, one side branded with "A"

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aerius is indicated in adults and adolescents aged 12 years and older for the relief of symptoms associated with:
- allergic rhinitis (see section 5.1)
- urticaria (see section 5.1)

4.2 Posology and method of administration

Posology
Adults and adolescents (12 years of age and over)
The recommended dose of Aerius is one 5 mg orodispersible tablet placed in the mouth once a day.

Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or for less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance. In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during the allergen exposure periods.

Paediatric population
The safety and efficacy of Aerius 5 mg orodispersible tablets in children below the age of 12 years have not been established. No data are available.

There is limited clinical trial efficacy experience with the use of desloratadine in adolescents 12 through 17 years of age (see sections 4.8 and 5.1).

Method of administration
Oral use.
The dose can be taken with or without food.
Immediately before use, the blister must be carefully peeled open and the dose of orodispersible tablet removed without crushing it. The dose of orodispersible tablet is placed in the mouth where it will

disperse immediately. Water or other liquid is not needed to swallow the dose. The dose must be taken as soon as the blister has been opened.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1, or to loratadine.

4.4 Special warnings and precautions for use

In the case of severe renal insufficiency, Aerius should be used with caution (see section 5.2).

Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children, being more susceptible to develop new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment.

This product contains 2.9 mg of phenylalanine per 5 mg dose of Aerius orodispersible tablet. Phenylalanine may be harmful for people with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions were observed in clinical trials with desloratadine tablets in which erythromycin or ketoconazole were co-administered (see section 5.1).

Paediatric population
Interaction studies have only been performed in adults.

In a clinical pharmacology trial, Aerius tablets taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol (see section 5.1). However, cases of alcohol intolerance and intoxication have been reported during post-marketing use. Therefore, caution is recommended if alcohol is taken concomitantly.

4.6 Fertility, pregnancy and lactation

Pregnancy
A large amount of data on pregnant women (more than 1,000 pregnancy outcomes) indicate no malformative nor foeto/ neonatal toxicity of desloratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). As a precautionary measure, it is preferable to avoid the use of Aerius during pregnancy.

Breast-feeding
Desloratadine has been identified in breastfed newborns/infants of treated women. The effect of desloratadine on newborns/infants is unknown. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Aerius therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
There are no data available on male and female fertility.

4.7 Effects on ability to drive and use machines

Aerius has no or negligible influence on the ability to drive and use machines based on clinical trials. Patients should be informed that most people do not experience drowsiness. Nevertheless, as there is individual variation in response to all medicinal products, it is recommended that patients are advised not to engage in activities requiring mental alertness, such as driving a car or using machines, until they have established their own response to the medicinal product.

4.8 Undesirable effects

Summary of the safety profile
In clinical trials in a range of indications including allergic rhinitis and chronic idiopathic urticaria, at the recommended dose of 5 mg daily, undesirable effects with Aerius tablets were reported in 3 % of patients in excess of those treated with placebo. The most frequent of adverse reactions reported in excess of placebo were fatigue (1.2 %), dry mouth (0.8 %) and headache (0.6 %).

Paediatric population
In a clinical trial with 578 adolescent patients, 12 through 17 years of age, the most common adverse event was headache; this occurred in 5.9 % of patients treated with desloratadine and 6.9 % of patients receiving placebo.

Tabulated list of adverse reactions
The frequency of the clinical trial adverse reactions reported in excess of placebo and other undesirable effects reported during the post-marketing period are listed in the following table. Frequencies are defined as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reactions seen with Aerius
Metabolism and nutrition disorders	Not known	Increased appetite
Psychiatric disorders	Very rare Not known	Hallucinations Abnormal behaviour, aggression
Nervous system disorders	Common Very rare	Headache Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Cardiac disorders	Very rare Not known	Tachycardia, palpitations QT prolongation
Gastrointestinal disorders	Common Very rare	Dry mouth Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea
Hepatobiliary disorders	Very rare Not known	Elevations of liver enzymes, increased bilirubin, hepatitis Jaundice
Skin and subcutaneous tissue disorders	Not known	Photosensitivity
Musculoskeletal and connective tissue disorders	Very rare	Myalgia
General disorders and administration site conditions	Common Very rare Not known	Fatigue Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria) Asthenia
Investigations	Not known	Weight increased

Paediatric population
Other undesirable effects reported during the post-marketing period in paediatric patients with an unknown frequency included QT prolongation, arrhythmia, bradycardia, abnormal behaviour, and aggression.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

Treatment
In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.

Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

Symptoms
Based on a multiple dose clinical trial, in which up to 45 mg of desloratadine was administered (nine times the clinical dose), no clinically relevant effects were observed.

Paediatric population
The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antihistamines – H_1 antagonist, ATC code: R06A X27

Mechanism of action
Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H_1-receptors because the substance is excluded from entry to the central nervous system.

Desloratadine has demonstrated antiallergic properties from *in vitro* studies. These include inhibiting the release of proinflammatory cytokines such as IL-4, IL-6, IL-8, and IL-13 from human mast cells/basophils, as well as inhibition of the expression of the adhesion molecule P-selectin on endothelial cells. The clinical relevance of these observations remains to be confirmed.

Clinical efficacy and safety
In a multiple dose trial, Aerius orodispersible tablets were well tolerated.

At the recommended dose, Aerius 5 mg orodispersible tablet was found to be bioequivalent to the Aerius 5 mg conventional tablet formulation of desloratadine. Therefore, the efficacy of Aerius orodispersible tablet is expected to be the same as with the Aerius tablet formulation.

In a multiple-dose clinical trial, in which up to 20 mg of desloratadine was administered daily for 14 days, no statistically or clinically relevant cardiovascular effect was observed. In a clinical pharmacology trial, in which desloratadine was administered at a dose of 45 mg daily (nine times the clinical dose) for ten days, no prolongation of QTc interval was seen.

No clinically relevant changes in desloratadine plasma concentrations were observed in multiple-dose, ketoconazole and erythromycin interaction trials.

Desloratadine does not readily penetrate the central nervous system. In clinical trials, at the recommended dose of 5 mg daily, there was no excess incidence of somnolence as compared to placebo. Aerius tablets given at a single daily dose of 7.5 mg did not affect psychomotor performance in clinical trials. In a single dose study performed in adults, desloratadine 5 mg did not affect standard measures of flight performance including exacerbation of subjective sleepiness or tasks related to flying.

In clinical pharmacology trials, co-administration with alcohol did not increase the alcohol-induced impairment in performance or increase in sleepiness. No significant differences were found in the psychomotor test results between desloratadine and placebo groups, whether administered alone or with alcohol.

In patients with allergic rhinitis, Aerius tablets were effective in relieving symptoms such as sneezing, nasal discharge and itching, as well as ocular itching, tearing and redness, and itching of palate. Aerius tablets effectively controlled symptoms for 24 hours.

Paediatric population
The efficacy of Aerius tablets has not been clearly demonstrated in trials with adolescent patients 12 through 17 years of age.

In addition to the established classifications of seasonal and perennial, allergic rhinitis can alternatively be classified as intermittent allergic rhinitis and persistent allergic rhinitis according to the duration of symptoms. Intermittent allergic rhinitis is defined as the presence of symptoms for less than 4 days per week or for less than 4 weeks. Persistent allergic rhinitis is defined as the presence of symptoms for 4 days or more per week and for more than 4 weeks.

Aerius was effective in alleviating the burden of seasonal allergic rhinitis as shown by the total score of the rhino-conjunctivitis quality of life questionnaire. The greatest amelioration was seen in the domains of practical problems and daily activities limited by symptoms.

Chronic idiopathic urticaria was studied as a clinical model for urticarial conditions, since the underlying pathophysiology is similar, regardless of etiology, and because chronic patients can be more easily recruited prospectively. Since histamine release is a causal factor in all urticarial diseases, desloratadine is expected to be effective in providing symptomatic relief for other urticarial conditions, in addition to chronic idiopathic urticaria, as advised in clinical guidelines.

In two placebo-controlled six week trials in patients with chronic idiopathic urticaria, Aerius was effective in relieving pruritus and decreasing the size and number of hives by the end of the first dosing interval. In each trial, the effects were sustained over the 24 hour dosing interval. As with other antihistamine trials in chronic idiopathic urticaria, the minority of patients who were identified as non-responsive to antihistamines was excluded. An improvement in pruritus of more than 50 % was observed in 55 % of patients treated with desloratadine compared with 19 % of patients treated with placebo. Treatment with Aerius also significantly reduced interference with sleep and daytime function, as measured by a four-point scale used to assess these variables.

5.2 Pharmacokinetic properties

Absorption
Desloratadine plasma concentrations can be detected within 30 minutes of administration. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) and a once daily dosing frequency. The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

In a series of pharmacokinetic and clinical trials, 6 % of the subjects reached a higher concentration of desloratadine. The prevalence of this poor metaboliser phenotype was greater among Black adults than Caucasian adults (18 % vs. 2 %) however the safety profile of these subjects was not different from that of the general population.

In a multiple-dose pharmacokinetic study conducted with the tablet formulation in healthy adult subjects, four subjects were found to be poor metabolisers of desloratadine. These subjects had a C_{max} concentration about 3-fold higher at approximately 7 hours with a terminal phase half-life of approximately 89 hours.

Distribution
Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no evidence of clinically relevant medicine accumulation following once daily dosing of desloratadine (5 mg to 20 mg) for 14 days.

Biotransformation
The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products cannot be fully excluded. Desloratadine does not inhibit CYP3A4 *in vivo,* and *in vitro* studies have shown that the medicinal product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

In single-dose crossover studies of Aerius 5 mg orodispersible tablets with Aerius 5 mg conventional tablets, the formulations were bioequivalent.

Elimination
The presence of food prolongs T_{max} for desloratadine from 2.5 to 4 hours and T_{max} for 3-OH-desloratadine from 4 to 6 hours. In a separate study, grapefruit juice had no effect on the disposition of desloratadine. Water had no effect on the bioavailability of Aerius orodispersible tablets.

Renally impaired patients
The pharmacokinetics of desloratadine in patients with chronic renal insufficiency (CRI) was compared with that of healthy subjects in one single-dose study and one multiple dose study. In the single-dose study, the exposure to desloratadine was approximately 2 and 2.5-fold greater in subjects with mild to moderate and severe CRI, respectively, than in healthy subjects. In the multiple-dose study, steady state was reached after Day 11, and compared to healthy subjects the exposure to desloratadine was ~1.5-fold greater in subjects with mild to moderate CRI and ~2.5-fold greater in subjects with severe CRI. In both studies, changes in exposure (AUC and C_{max}) of desloratadine and 3-hydroxydesloratadine were not clinically relevant.

5.3 Preclinical safety data

Desloratadine is the primary active metabolite of loratadine. Non-clinical studies conducted with desloratadine and loratadine demonstrated that there are no qualitative or quantitative differences in the toxicity profile of desloratadine and loratadine at comparable levels of exposure to desloratadine.

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development. The collective analysis of preclinical and clinical irritation studies for the orodispersible tablet indicate that this formulation is unlikely to pose risk for local irritation with clinical use. The lack of carcinogenic potential was demonstrated in studies conducted with desloratadine and loratadine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

microcrystalline cellulose
pregelatinized starch
sodium starch glycolate
magnesium stearate
butylated methacrylate copolymer
crospovidone
sodium hydrogen carbonate
citric acid
colloidal silicon dioxide
ferric oxide
mannitol
aspartame (E951)
flavour Tutti-Frutti

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in the original package.

6.5 Nature and contents of container

Aerius orodispersible tablets are supplied in unit dose blisters comprised of laminate blister film with foil lidding.

The blister materials consist of a four layer aluminum foil laminate cold form blister film and a paper backed laminated aluminum foil lidding film.
The cold form blister film is composed of polyvinyl chloride (PVC) film adhesively laminated to an oriented polyamide (OPA) film, adhesively laminated to aluminum foil, adhesively laminated to polyvinyl chloride (PVC) film.
Packs of 5, 6, 10, 12, 15, 18, 20, 30, 50, 60, 90 and 100 orodispersible tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

8. MARKETING AUTHORISATION NUMBERS

EU/1/00/160/049-060

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 January 2001
Date of latest renewal: 15 January 2006

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

1. NAME OF THE MEDICINAL PRODUCT

Aerius 0.5 mg/ml oral solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of oral solution contains 0.5 mg desloratadine.

Excipient(s) with known effect:
This medicinal product contains 150 mg/ml of sorbitol

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Aerius is indicated in adults, adolescents and children over the age of 1 year for the relief of symptoms associated with:
- allergic rhinitis (see section 5.1)
- urticaria (see section 5.1)

4.2 Posology and method of administration

Posology
Adults and adolescents (12 years of age and over)
The recommended dose of Aerius is 10 ml (5 mg) oral solution once a day.

Paediatric population
The prescriber should be aware that most cases of rhinitis below 2 years of age are of infectious origin (see section 4.4) and there are no data supporting the treatment of infectious rhinitis with Aerius.

Children 1 through 5 years of age: 2.5 ml (1.25 mg) Aerius oral solution once a day.

Children 6 through 11 years of age: 5 ml (2.5 mg) Aerius oral solution once a day.

The safety and efficacy of Aerius 0.5 mg/ml oral solution in children below the age of 1 year have not been established. No data are available.

There is limited clinical trial efficacy experience with the use of desloratadine in children 1 through 11 years of age and adolescents 12 through 17 years of age (see sections 4.8 and 5.1).

Intermittent allergic rhinitis (presence of symptoms for less than 4 days per week or for less than 4 weeks) should be managed in accordance with the evaluation of patient's disease history and the treatment could be discontinued after symptoms are resolved and reinitiated upon their reappearance. In persistent allergic rhinitis (presence of symptoms for 4 days or more per week and for more than 4 weeks), continued treatment may be proposed to the patients during the allergen exposure periods.

Method of administration
Oral use.
The dose can be taken with or without food.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1, or to loratadine.

4.4 Special warnings and precautions for use

Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children, being more susceptible to develop new seizures under desloratadine treatment. Healthcare providers may consider discontinuing desloratadine in patients who experience a seizure while on treatment.

Paediatric population
In children below 2 years of age, the diagnosis of allergic rhinitis is particularly difficult to distinguish from other forms of rhinitis. The absence of upper respiratory tract infection or structural abnormalities, as well as patient history, physical examinations, and appropriate laboratory and skin tests should be considered.

Approximately 6 % of adults and children 2- to 11-year old are phenotypic poor metabolisers of desloratadine and exhibit a higher exposure (see section 5.2). The safety of desloratadine in children 2- to 11-years of age who are poor metabolisers is the same as in children who are normal metabolisers. The effects of desloratadine in poor metabolisers < 2 years of age have not been studied.

In the case of severe renal insufficiency, Aerius should be used with caution (see section 5.2).

This medicinal product contains sorbitol; thus, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically relevant interactions were observed in clinical trials with desloratadine tablets in which erythromycin or ketoconazole were co-administered (see section 5.1).

Paediatric population
Interaction studies have only been performed in adults.

In a clinical pharmacology trial, Aerius tablets taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol (see section 5.1). However, cases of alcohol intolerance and intoxication have been reported during post-marketing use. Therefore, caution is recommended if alcohol is taken concomitantly.

4.6 Fertility, pregnancy and lactation

Pregnancy
A large amount of data on pregnant women (more than 1,000 pregnancy outcomes) indicate no malformative nor foeto/ neonatal toxicity of desloratadine. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). As a precautionary measure, it is preferable to avoid the use of Aerius during pregnancy.

Breast-feeding
Desloratadine has been identified in breastfed newborns/infants of treated women. The effect of desloratadine on newborns/infants is unknown. A decision must be made whether to discontinue

breast-feeding or to discontinue/abstain from Aerius therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility
There are no data available on male and female fertility.

4.7 Effects on ability to drive and use machines

Aerius has no or negligible influence on the ability to drive and use machines based on clinical trials. Patients should be informed that most people do not experience drowsiness. Nevertheless, as there is individual variation in response to all medicinal products, it is recommended that patients are advised not to engage in activities requiring mental alertness, such as driving a car or using machines, until they have established their own response to the medicinal product.

4.8 Undesirable effects

Summary of the safety profile

Paediatric population
In clinical trials in a paediatric population, the desloratadine syrup formulation was administered to a total of 246 children aged 6 months through 11 years. The overall incidence of adverse events in children 2 through 11 years of age was similar for the desloratadine and the placebo groups. In infants and toddlers aged 6 to 23 months, the most frequent adverse reactions reported in excess of placebo were diarrhoea (3.7 %), fever (2.3 %) and insomnia (2.3 %). In an additional study, no adverse events were seen in subjects between 6 and 11 years of age following a single 2.5 mg dose of desloratadine oral solution.

In a clinical trial with 578 adolescent patients, 12 through 17 years of age, the most common adverse event was headache; this occurred in 5.9 % of patients treated with desloratadine and 6.9 % of patients receiving placebo.

Adults and adolescents
At the recommended dose, in clinical trials involving adults and adolescents in a range of indications including allergic rhinitis and chronic idiopathic urticaria, undesirable effects with Aerius were reported in 3 % of patients in excess of those treated with placebo. The most frequent of adverse events reported in excess of placebo were fatigue (1.2 %), dry mouth (0.8 %) and headache (0.6 %).

Tabulated list of adverse reactions
The frequency of the clinical trial adverse reactions reported in excess of placebo and other undesirable effects reported during the post-marketing period are listed in the following table. Frequencies are defined as very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reactions seen with Aerius
Metabolism and nutrition disorders	Not known	Increased appetite
Psychiatric disorders	Very rare Not known	Hallucinations Abnormal behaviour, aggression
Nervous system disorders	Common Common (children less than 2 years) Very rare	Headache Insomnia Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures

System Organ Class	Frequency	Adverse reactions seen with Aerius
Cardiac disorders	Very rare Not known	Tachycardia, palpitations QT prolongation
Gastrointestinal disorders	Common Common (children less than 2 years) Very rare	Dry mouth Diarrhoea Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea
Hepatobiliary disorders	Very rare Not known	Elevations of liver enzymes, increased bilirubin, hepatitis Jaundice
Skin and subcutaneous tissue disorders	Not known	Photosensitivity
Musculoskeletal and connective tissue disorders	Very rare	Myalgia
General disorders and administration site conditions	Common Common (children less than 2 years) Very rare Not known	Fatigue Fever Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria) Asthenia
Investigations	Not known	Weight increased

Paediatric population
Other undesirable effects reported during the post-marketing period in paediatric patients with an unknown frequency included QT prolongation, arrhythmia, bradycardia, abnormal behaviour, and aggression.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

4.9 Overdose

The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

Treatment
In the event of overdose, consider standard measures to remove unabsorbed active substance. Symptomatic and supportive treatment is recommended.

Desloratadine is not eliminated by haemodialysis; it is not known if it is eliminated by peritoneal dialysis.

Symptoms
Based on a multiple dose clinical trial in adults and adolescents, in which up to 45 mg of desloratadine was administered (nine times the clinical dose), no clinically relevant effects were observed.

Paediatric population
The adverse event profile associated with overdosage, as seen during post-marketing use, is similar to that seen with therapeutic doses, but the magnitude of the effects can be higher.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antihistamines – H_1 antagonist, ATC code: R06A X27

Mechanism of action
Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H_1-receptors because the substance is excluded from entry to the central nervous system.

Desloratadine has demonstrated antiallergic properties from *in vitro* studies. These include inhibiting the release of proinflammatory cytokines such as IL-4, IL-6, IL-8, and IL-13 from human mast cells/basophils, as well as inhibition of the expression of the adhesion molecule P-selectin on endothelial cells. The clinical relevance of these observations remains to be confirmed.

Clinical efficacy and safety

Paediatric population
Efficacy of Aerius oral solution has not been investigated in separate paediatric trials. However, the safety of desloratadine syrup formulation, which contains the same concentration of desloratadine as Aerius oral solution, was demonstrated in three paediatric trials. Children, 1-11 years of age, who were candidates for antihistamine therapy received a daily desloratadine dose of 1.25 mg (1 through 5 years of age) or 2.5 mg (6 through 11 years of age). Treatment was well tolerated as documented by clinical laboratory tests, vital signs, and ECG interval data, including QTc. When given at the recommended doses, the plasma concentrations of desloratadine (see section 5.2) were comparable in the paediatric and adult populations. Thus, since the course of allergic rhinitis/chronic idiopathic urticaria and the profile of desloratadine are similar in adults and paediatric patients, desloratadine efficacy data in adults can be extrapolated to the paediatric population.
Efficacy of Aerius syrup has not been investigated in paediatric trials in children less than 12 years of age.

Adults and adolescents
In a multiple dose clinical trial, in adults and adolescents, in which up to 20 mg of desloratadine was administered daily for 14 days, no statistically or clinically relevant cardiovascular effect was observed. In a clinical pharmacology trial, in adults and adolescents, in which desloratadine was administered to adults at a dose of 45 mg daily (nine times the clinical dose) for ten days, no prolongation of QTc interval was seen.

Desloratadine does not readily penetrate the central nervous system. In controlled clinical trials, at the recommended dose of 5 mg daily for adults and adolescents, there was no excess incidence of somnolence as compared to placebo. Aerius tablets given at a single daily dose of 7.5 mg to adults and adolescents did not affect psychomotor performance in clinical trials. In a single dose study performed in adults, desloratadine 5 mg did not affect standard measures of flight performance including exacerbation of subjective sleepiness or tasks related to flying.

In clinical pharmacology trials in adults, co-administration with alcohol did not increase the alcohol-induced impairment in performance or increase in sleepiness. No significant differences were found in the psychomotor test results between desloratadine and placebo groups, whether administered alone or with alcohol.

No clinically relevant changes in desloratadine plasma concentrations were observed in multiple-dose ketoconazole and erythromycin interaction trials.

In adult and adolescent patients with allergic rhinitis, Aerius tablets were effective in relieving symptoms such as sneezing, nasal discharge and itching, as well as ocular itching, tearing and redness, and itching of palate. Aerius effectively controlled symptoms for 24 hours. The efficacy of Aerius tablets has not been clearly demonstrated in trials with adolescent patients 12 through 17 years of age.

In addition to the established classifications of seasonal and perennial, allergic rhinitis can alternatively be classified as intermittent allergic rhinitis and persistent allergic rhinitis according to the duration of symptoms. Intermittent allergic rhinitis is defined as the presence of symptoms for less than 4 days per week or for less than 4 weeks. Persistent allergic rhinitis is defined as the presence of symptoms for 4 days or more per week and for more than 4 weeks.

Aerius tablets were effective in alleviating the burden of seasonal allergic rhinitis as shown by the total score of the rhino-conjunctivitis quality of life questionnaire. The greatest amelioration was seen in the domains of practical problems and daily activities limited by symptoms.

Chronic idiopathic urticaria was studied as a clinical model for urticarial conditions, since the underlying pathophysiology is similar, regardless of etiology, and because chronic patients can be more easily recruited prospectively. Since histamine release is a causal factor in all urticarial diseases, desloratadine is expected to be effective in providing symptomatic relief for other urticarial conditions, in addition to chronic idiopathic urticaria, as advised in clinical guidelines.

In two placebo-controlled six week trials in patients with chronic idiopathic urticaria, Aerius was effective in relieving pruritus and decreasing the size and number of hives by the end of the first dosing interval. In each trial, the effects were sustained over the 24 hour dosing interval. As with other antihistamine trials in chronic idiopathic urticaria, the minority of patients who were identified as non-responsive to antihistamines was excluded. An improvement in pruritus of more than 50 % was observed in 55 % of patients treated with desloratadine compared with 19 % of patients treated with placebo. Treatment with Aerius also significantly reduced interference with sleep and daytime function, as measured by a four-point scale used to assess these variables.

5.2 Pharmacokinetic properties

Absorption

Desloratadine plasma concentrations can be detected within 30 minutes of desloratadine administration in adults and adolescents. Desloratadine is well absorbed with maximum concentration achieved after approximately 3 hours; the terminal phase half-life is approximately 27 hours. The degree of accumulation of desloratadine was consistent with its half-life (approximately 27 hours) and a once daily dosing frequency. The bioavailability of desloratadine was dose proportional over the range of 5 mg to 20 mg.

In a series of pharmacokinetic and clinical trials, 6 % of the subjects reached a higher concentration of desloratadine. The prevalence of this poor metaboliser phenotype was comparable for adult (6 %) and paediatric subjects 2- to 11-year old (6 %), and greater among Blacks (18 % adult, 16 % paediatric) than Caucasians (2 % adult, 3 % paediatric) in both populations.

In a multiple-dose pharmacokinetic study conducted with the tablet formulation in healthy adult subjects, four subjects were found to be poor metabolisers of desloratadine. These subjects had a C_{max} concentration about 3-fold higher at approximately 7 hours with a terminal phase half-life of approximately 89 hours.

Similar pharmacokinetic parameters were observed in a multiple-dose pharmacokinetic study conducted with the syrup formulation in paediatric poor metaboliser subjects 2- to 11-year old diagnosed with allergic rhinitis. The exposure (AUC) to desloratadine was about 6-fold higher and the C_{max} was about 3 to 4 fold higher at 3-6 hours with a terminal half-life of approximately 120 hours. Exposure was the same in adult and paediatric poor metabolisers when treated with age-appropriate

doses. The overall safety profile of these subjects was not different from that of the general population. The effects of desloratadine in poor metabolizers < 2 years of age have not been studied.

In separate single dose studies, at the recommended doses, paediatric patients had comparable AUC and C_{max} values of desloratadine to those in adults who received a 5 mg dose of desloratadine syrup.

Distribution
Desloratadine is moderately bound (83 % - 87 %) to plasma proteins. There is no evidence of clinically relevant active substance accumulation following once daily adult and adolescent dosing of desloratadine (5 mg to 20 mg) for 14 days.

In a single dose, crossover study of desloratadine, the tablet and the syrup formulations were found to be bioequivalent. As Aerius oral solution contains the same concentration of desloratadine, no bioequivalence study was required and it is expected to be equivalent to the syrup and tablet.

Biotransformation
The enzyme responsible for the metabolism of desloratadine has not been identified yet, and therefore, some interactions with other medicinal products cannot be fully excluded. Desloratadine does not inhibit CYP3A4 *in vivo,* and *in vitro* studies have shown that the medicinal product does not inhibit CYP2D6 and is neither a substrate nor an inhibitor of P-glycoprotein.

Elimination
In a single dose trial using a 7.5 mg dose of desloratadine, there was no effect of food (high-fat, high caloric breakfast) on the disposition of desloratadine. In another study, grapefruit juice had no effect on the disposition of desloratadine.

Renally impaired patients
The pharmacokinetics of desloratadine in patients with chronic renal insufficiency (CRI) was compared with that of healthy subjects in one single-dose study and one multiple dose study. In the single-dose study, the exposure to desloratadine was approximately 2 and 2.5-fold greater in subjects with mild to moderate and severe CRI, respectively, than in healthy subjects. In the multiple-dose study, steady state was reached after Day 11, and compared to healthy subjects the exposure to desloratadine was ~1.5-fold greater in subjects with mild to moderate CRI and ~2.5-fold greater in subjects with severe CRI. In both studies, changes in exposure (AUC and C_{max}) of desloratadine and 3-hydroxydesloratadine were not clinically relevant.

5.3 Preclinical safety data

Desloratadine is the primary active metabolite of loratadine. Non-clinical studies conducted with desloratadine and loratadine demonstrated that there are no qualitative or quantitative differences in the toxicity profile of desloratadine and loratadine at comparable levels of exposure to desloratadine.

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development. The lack of carcinogenic potential was demonstrated in studies conducted with desloratadine and loratadine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

sorbitol,
propylene glycol,
sucralose E 955,
hypromellose 2910,

sodium citrate dihydrate,
natural and artificial flavour (bubblegum),
citric acid anhydrous,
disodium edetate,
purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not freeze. Store in the original package.

6.5 Nature and contents of container

Aerius oral solution, is supplied in 30, 50, 60, 100, 120, 150, 225 and 300 ml size Type III amber glass bottles closed with a plastic child resistant (C/R) screw closure having a multi-ply polyethylene-faced liner. All packages except the 150 ml package are supplied with a measuring spoon marked for doses of 2.5 ml and 5 ml. For the 150 ml package, a measuring spoon or an oral measuring syringe is provided, marked for doses of 2.5 ml and 5 ml.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

8. MARKETING AUTHORISATION NUMBERS

EU/1/00/160/061-069

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 January 2001
Date of latest renewal: 15 January 2006

10. DATE OF REVISION OF THE TEXT

Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

ANNEX II

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

A. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release for film-coated tablets

SP Labo N.V.
Industriepark 30
2220 Heist-op-den-Berg
Belgium

Name and address of the manufacturer responsible for batch release for orodispersible tablet

SP Labo N.V.
Industriepark 30
2220 Heist-op-den-Berg
Belgium

Name and address of the manufacturer responsible for batch release for oral solution

SP Labo N.V.
Industriepark 30
2220 Heist-op-den-Berg
Belgium

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Medicinal product subject to medical prescription.

C. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

- **Periodic Safety Update Reports**

The marketing authorisation holder shall submit periodic safety update reports for this product in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.

D. CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

- **Risk Management Plan (RMP)**

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:
- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX OF 1, 2, 3, 5, 7, 10, 14, 15, 20, 21, 30, 50, 90, 100 TABLETS

1. NAME OF THE MEDICINAL PRODUCT

Aerius 5 mg film-coated tablets
desloratadine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 5 mg desloratadine.

3. LIST OF EXCIPIENTS

Contains lactose.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

1 film-coated tablet
2 film-coated tablets
3 film-coated tablets
5 film-coated tablets
7 film-coated tablets
10 film-coated tablets
14 film-coated tablets
15 film-coated tablets
20 film-coated tablets
21 film-coated tablets
30 film-coated tablets
50 film-coated tablets
90 film-coated tablets
100 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Swallow the tablet whole with water.
Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. Store in the original package.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/160/001 1 tablet
EU/1/00/160/002 2 tablets
EU/1/00/160/003 3 tablets
EU/1/00/160/004 5 tablets
EU/1/00/160/005 7 tablets
EU/1/00/160/006 10 tablets
EU/1/00/160/007 14 tablets
EU/1/00/160/008 15 tablets
EU/1/00/160/009 20 tablets
EU/1/00/160/010 21 tablets
EU/1/00/160/011 30 tablets
EU/1/00/160/012 50 tablets
EU/1/00/160/036 90 tablets
EU/1/00/160/013 100 tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Aerius

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BOX OF 1, 2, 3, 5, 7, 10, 14, 15, 20, 21, 30, 50, 90, 100 TABLETS

1. NAME OF THE MEDICINAL PRODUCT

Aerius 5 mg tablet
desloratadine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX OF 5, 6, 10, 12, 15, 18, 20, 30, 50, 60, 90, 100 ORODISPERSIBLE TABLETS

1. NAME OF THE MEDICINAL PRODUCT

Aerius 2.5 mg orodispersible tablets
desloratadine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each dose of orodispersible tablet contains 2.5 mg desloratadine.

3. LIST OF EXCIPIENTS

Contains mannitol and aspartame.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

5 orodispersible tablets
6 orodispersible tablets
10 orodispersible tablets
12 orodispersible tablets
15 orodispersible tablets
18 orodispersible tablets
20 orodispersible tablets
30 orodispersible tablets
50 orodispersible tablets
60 orodispersible tablets
90 orodispersible tablets
100 orodispersible tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/160/037	5 orodispersible tablets
EU/1/00/160/038	6 orodispersible tablets
EU/1/00/160/039	10 orodispersible tablets
EU/1/00/160/040	12 orodispersible tablets
EU/1/00/160/041	15 orodispersible tablets
EU/1/00/160/042	18 orodispersible tablets
EU/1/00/160/043	20 orodispersible tablets
EU/1/00/160/044	30 orodispersible tablets
EU/1/00/160/045	50 orodispersible tablets
EU/1/00/160/046	60 orodispersible tablets
EU/1/00/160/047	90 orodispersible tablets
EU/1/00/160/048	100 orodispersible tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Aerius 2.5 mg orodispersible tablet

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Aerius 2.5 mg orodispersible tablets
desloratadine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX OF 5, 6, 10, 12, 15, 18, 20, 30, 50, 60, 90, 100 ORODISPERSIBLE TABLETS

1. NAME OF THE MEDICINAL PRODUCT

Aerius 5 mg orodispersible tablets
desloratadine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each dose of orodispersible tablet contains 5 mg desloratadine.

3. LIST OF EXCIPIENTS

Contains mannitol and aspartame.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

5 orodispersible tablets
6 orodispersible tablets
10 orodispersible tablets
12 orodispersible tablets
15 orodispersible tablets
18 orodispersible tablets
20 orodispersible tablets
30 orodispersible tablets
50 orodispersible tablets
60 orodispersible tablets
90 orodispersible tablets
100 orodispersible tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/160/049	5 orodispersible tablets
EU/1/00/160/050	6 orodispersible tablets
EU/1/00/160/051	10 orodispersible tablets
EU/1/00/160/052	12 orodispersible tablets
EU/1/00/160/053	15 orodispersible tablets
EU/1/00/160/054	18 orodispersible tablets
EU/1/00/160/055	20 orodispersible tablets
EU/1/00/160/056	30 orodispersible tablets
EU/1/00/160/057	50 orodispersible tablets
EU/1/00/160/058	60 orodispersible tablets
EU/1/00/160/059	90 orodispersible tablets
EU/1/00/160/060	100 orodispersible tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Aerius 5 mg orodispersible tablet

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

1. NAME OF THE MEDICINAL PRODUCT

Aerius 5 mg orodispersible tablets
desloratadine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOTTLE OF 30 ML, 50 ML, 60 ML, 100 ML, 120 ML, 150 ML, 225 ML, 300 ML

1. NAME OF THE MEDICINAL PRODUCT

Aerius 0.5 mg/ml oral solution
desloratadine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each ml of oral solution contains 0.5 mg desloratadine.

3. LIST OF EXCIPIENTS

Contains propylene glycol and sorbitol.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

oral solution
30 ml with 1 spoon
50 ml with 1 spoon
60 ml with 1 spoon
100 ml with 1 spoon
120 ml with 1 spoon
150 ml with 1 spoon
150 ml with 1 oral syringe
225 ml with 1 spoon
300 ml with 1 spoon

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Do not freeze. Store in the original package.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/00/160/061	30 ml with 1 spoon
EU/1/00/160/062	50 ml with 1 spoon
EU/1/00/160/063	60 ml with 1 spoon
EU/1/00/160/064	100 ml with 1 spoon
EU/1/00/160/065	120 ml with 1 spoon
EU/1/00/160/066	150 ml with 1 spoon
EU/1/00/160/069	150 ml with 1 oral syringe
EU/1/00/160/067	225 ml with 1 spoon
EU/1/00/160/068	300 ml with 1 spoon

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Aerius

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE OF 30 ML, 50 ML, 60 ML, 100 ML, 120 ML, 150 ML, 225 ML, 300 ML

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Aerius 0.5 mg/ml oral solution
desloratadine

2. METHOD OF ADMINISTRATION

Oral use

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

30 ml
50 ml
60 ml
100 ml
120 ml
150 ml
225 ml
300 ml

6. LIST OF EXCIPIENTS

Contains propylene glycol and sorbitol.
See leaflet for further information.

7. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

8. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

9. SPECIAL STORAGE CONDITIONS

Do not freeze. Store in the original package.

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Aerius 5 mg film-coated tablets
desloratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. **See section 4.**

What is in this leaflet

1. What Aerius is and what it is used for

What Aerius is
Aerius contains desloratadine which is an antihistamine.

How Aerius works
Aerius is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

When Aerius should be used
Aerius relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults and adolescents 12 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Aerius is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. What you need to know before you take Aerius

Do not take Aerius
- if you are allergic to desloratadine, or any of the other ingredients of this medicine (listed in section 6) or to loratadine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Aerius:
- if you have poor kidney function.
- if you have medical or familial history of seizures.

Use in children and adolescents
Do not give this medicine to children less than 12 years of age.

Other medicines and Aerius
There are no known interactions of Aerius with other medicines.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Aerius with food, drink and alcohol
Aerius may be taken with or without a meal.
Use caution when taking Aerius with alcohol.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Taking Aerius is not recommended if you are pregnant or nursing a baby.
Fertility
There is no data available on male/female fertility.

Driving and using machines
At the recommended dose, this medicine is not expected to affect your ability to drive or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicinal product.

Aerius contains lactose
Aerius tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Aerius

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents 12 years of age and over
The recommended dose is one tablet once a day with water, with or without food.

This medicine is for oral use.
Swallow the tablet whole.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Aerius.
If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician will recommend you a treatment schedule that will depend on the evaluation of the history of your disease.
If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your physician may recommend you a longer term treatment.

For urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your physician.

If you take more Aerius than you should
Take Aerius only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Aerius than you were told to, tell your doctor, pharmacist or nurse immediately.

If you forget to take Aerius
If you forget to take your dose on time, take it as soon as possible and then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Aerius
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

During the marketing of Aerius, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.

In clinical studies in adults, side effects were about the same as with a dummy tablet. However, fatigue, dry mouth and headache were reported more often than with a dummy tablet. In adolescents, headache was the most commonly reported side effect.

In clinical studies with Aerius, the following side effects were reported as:

Common: the following may affect up to 1 in 10 people
- fatigue
- dry mouth
- headache

Adults
During the marketing of Aerius, the following side effects were reported as:

Very rare: the following may affect up to 1 in 10,000 people
- severe allergic reactions
- rash
- pounding or irregular heartbeat
- fast heartbeat
- stomach ache
- feeling sick (nausea)
- vomiting
- upset stomach
- diarrhoea
- dizziness
- drowsiness
- inability to sleep
- muscle pain
- hallucinations
- seizures
- restlessness with increased body movement
- liver inflammation
- abnormal liver function tests

Not known: frequency cannot be estimated from the available data
- unusual weakness
- yellowing of the skin and/or eyes
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium
- changes in the way the heart beats
- abnormal behaviour
- aggression
- weight increased, increased appetite

Children
Not known: frequency cannot be estimated from the available data
- slow heartbeat
- change in the way the heart beats

● abnormal behaviour ● aggression

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aerius

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Store in the original package.

Do not use this medicine if you notice any change in the appearance of the tablets.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Aerius contains

- The active substance is desloratadine 5 mg
- The other ingredients of the tablet are calcium hydrogen phosphate dihydrate, microcrystalline cellulose, maize starch, talc. Tablet coating contains film coat (containing lactose monohydrate, hypromellose, titanium dioxide, macrogol 400, indigotin (E132)), clear coat (containing hypromellose, macrogol 400), carnauba wax, white wax.

What Aerius looks like and contents of the pack

Aerius 5 mg film-coated tablets are packed in blisters in packs of 1, 2, 3, 5, 7, 10, 14, 15, 20, 21, 30, 50, 90 or 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Waarderweg 39
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Manufacturer: SP Labo N.V., Industriepark 30, B-2220 Heist-op-den-Berg, Belgium.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency website http://www.ema.europa.eu.

Package leaflet: Information for the patient

Aerius 2.5 mg orodispersible tablets
desloratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. **See section 4.**

What is in this leaflet

1. What Aerius orodispersible tablet is and what it is used for

What Aerius is
Aerius contains desloratadine which is an antihistamine.

How Aerius works
Aerius orodispersible tablet is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

When Aerius should be used
Aerius orodispersible tablet relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults, adolescents and children 6 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Aerius orodispersible tablet is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. What you need to know before you take Aerius orodispersible tablet

Do not take Aerius orodispersible tablet
- if you are allergic to desloratadine, or any of the other ingredients of this medicine (listed in section 6) or to loratadine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Aerius:
- if you have poor kidney function.
- if you have medical or familial history of seizures.

Use in children and adolescents
Do not give this medicine to children less than 6 years of age.

Other medicines and Aerius
There are no known interactions of Aerius with other medicines.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Aerius orodispersible tablet with food, drink and alcohol
Aerius orodispersible tablet does not need to be taken with water or liquid. Additionally, Aerius orodispersible tablet may be taken with or without a meal. Use caution when taking Aerius with alcohol.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Taking Aerius is not recommended if you are pregnant or nursing a baby.
Fertility
There is no data available on male/female fertility.

Driving and using machines
At the recommended dose, this medicine is not expected to affect your ability to drive or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicinal product.

Aerius orodispersible tablet contains aspartame
This product contains aspartame. Aspartame is a source of phenylalanine, which may be harmful for people with phenylketonuria.

3. How to take Aerius orodispersible tablet

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents 12 years of age and over
The recommended dose is two tablets once a day with or without food.

This medicine is for oral use.
Before using, carefully peel open the blister and remove the dose of orodispersible tablet without crushing it. Place it in your mouth and it will disperse immediately. Water or other liquid is not needed to swallow the dose. Take the dose immediately after removal from the blister.

Children from 6 to 11 years of age
The recommended dose is one tablet once a day with or without food.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Aerius orodispersible tablets.
If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician will recommend you a treatment schedule that will depend on the evaluation of the history of your disease.
If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your physician may recommend you a longer term treatment.

For urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your physician.

If you take more Aerius orodispersible tablet than you should
Take Aerius orodispersible tablet only as prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Aerius orodispersible tablet than you were told to, tell your doctor, pharmacist or nurse immediately.

If you forget to take Aerius orodispersible tablet
If you forget to take your dose on time, take it as soon as possible and then go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Aerius orodispersible tablet
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

During the marketing of Aerius, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.

In clinical studies in adults, side effects were about the same as with a dummy tablet. However, fatigue, dry mouth and headache were reported more often than with a dummy tablet. In adolescents, headache was the most commonly reported side effect.

In clinical studies with Aerius, the following side effects were reported as:

Common: the following may affect up to 1 in 10 people
- fatigue
- dry mouth
- headache

Adults
During the marketing of Aerius, the following side effects were reported as:

Very rare: the following may affect up to 1 in 10,000 people
- severe allergic reactions
- fast heartbeat
- vomiting
- dizziness
- muscle pain
- restlessness with increased body movement
- rash
- stomach ache
- upset stomach
- drowsiness
- hallucinations
- liver inflammation
- pounding or irregular heartbeat
- feeling sick (nausea)
- diarrhoea
- inability to sleep
- seizures
- abnormal liver function tests

Not known: frequency cannot be estimated from the available data
- unusual weakness
- yellowing of the skin and/or eyes
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium
- changes in the way the heart beats
- abnormal behaviour
- aggression
- weight increased, increased appetite

Children
Not known: frequency cannot be estimated from the available data
- slow heartbeat
- change in the way the heart beats
- abnormal behaviour
- aggression

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aerius orodispersible tablet

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package.

Do not use this medicine if you notice any change in the appearance of Aerius orodispersible tablet.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Aerius orodispersible tablet contains

- The active substance is desloratadine 2.5 mg
- The other ingredients are microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, magnesium stearate, butylated methacrylate copolymer, crospovidone, sodium hydrogen carbonate, citric acid, colloidal silicon dioxide, ferric oxide, mannitol, aspartame (E951) and flavour Tutti-Frutti.

What Aerius orodispersible tablet looks like and contents of the pack

Aerius 2.5 mg orodispersible tablet is light red, speckled, and round with “K” branded on one side.
Aerius orodispersible tablet is packed in unit dose blisters in packs of
5, 6, 10, 12, 15, 18, 20, 30, 50, 60, 90 and 100 doses of orodispersible tablet. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Waarderweg 39
2031 BN Haarlem
The Netherlands

Manufacturer: SP Labo N.V., Industriepark 30, B-2220 Heist-op-den-Berg, Belgium.

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency website http://www.ema.europa.eu.

Package leaflet: Information for the patient

Aerius 5 mg orodispersible tablets
desloratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. **See section 4.**

What is in this leaflet

1. What Aerius orodispersible tablet is and what it is used for

What Aerius is
Aerius contains desloratadine which is an antihistamine.

How Aerius works
Aerius orodispersible tablet is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

When Aerius should be used
Aerius orodispersible tablet relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults and adolescents 12 years of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Aerius orodispersible tablet is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. What you need to know before you take Aerius orodispersible tablet

Do not take Aerius orodispersible tablet
- if you are allergic to desloratadine, or any of the other ingredients of this medicine (listed in section 6) or to loratadine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Aerius:
- if you have poor kidney function.
- if you have medical or familial history of seizures.

Use in children and adolescents
Do not give this medicine to children less than 12 years of age.

Other medicines and Aerius
There are no known interactions of Aerius with other medicines.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Aerius orodispersible tablet with food, drink and alcohol
Aerius orodispersible tablet does not need to be taken with water or liquid. Additionally, Aerius orodispersible tablet may be taken with or without a meal. Use caution when taking Aerius with alcohol.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Taking Aerius is not recommended if you are pregnant or nursing a baby.
Fertility
There is no data available on male/female fertility.

Driving and using machines
At the recommended dose, this medicine is not expected to affect your ability to drive or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicinal product.

Aerius orodispersible tablet contains aspartame
This product contains aspartame. Aspartame is a source of phenylalanine, which may be harmful for people with phenylketonuria.

3. How to take Aerius orodispersible tablet

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and adolescents 12 years of age and over
The recommended dose is one tablet once a day with or without food.

This medicine is for oral use.
Before using, carefully peel open the blister and remove the dose of orodispersible tablet without crushing it. Place it in your mouth and it will disperse immediately. Water or other liquid is not needed to swallow the dose. Take the dose immediately after removal from the blister.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Aerius orodispersible tablets.
If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician will recommend you a treatment schedule that will depend on the evaluation of the history of your disease.
If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your physician may recommend you a longer term treatment.

For urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your physician.

If you take more Aerius orodispersible tablet than you should
Take Aerius orodispersible tablet only as prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Aerius orodispersible tablet than you were told to, tell your doctor, pharmacist or nurse immediately.

If you forget to take Aerius orodispersible tablet
If you forget to take your dose on time, take it as soon as possible and then go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Aerius orodispersible tablet
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them.

During the marketing of Aerius, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.

In clinical studies in adults, side effects were about the same as with a dummy tablet. However, fatigue, dry mouth and headache were reported more often than with a dummy tablet. In adolescents, headache was the most commonly reported side effect.

In clinical studies with Aerius, the following side effects were reported as:

Common: the following may affect up to 1 in 10 people
- fatigue
- dry mouth
- headache

Adults
During the marketing of Aerius, the following side effects were reported as:

Very rare: the following may affect up to 1 in 10,000 people
- severe allergic reactions
- rash
- pounding or irregular heartbeat
- fast heartbeat
- stomach ache
- feeling sick (nausea)
- vomiting
- upset stomach
- diarrhoea
- dizziness
- drowsiness
- inability to sleep
- muscle pain
- hallucinations
- seizures
- restlessness with increased body movement
- liver inflammation
- abnormal liver function tests

Not known: frequency cannot be estimated from the available data
- unusual weakness
- yellowing of the skin and/or eyes
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium
- changes in the way the heart beats
- abnormal behaviour
- aggression
- weight increased, increased appetite

Children
Not known: frequency cannot be estimated from the available data
- slow heartbeat
- change in the way the heart beats

● abnormal behaviour ● aggression

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aerius orodispersible tablet

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store in the original package.

Do not use this medicine if you notice any change in the appearance of Aerius orodispersible tablet.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Aerius orodispersible tablet contains

- The active substance is desloratadine 5 mg
- The other ingredients are microcrystalline cellulose, pregelatinized starch, sodium starch glycolate, magnesium stearate, butylated methacrylate copolymer, crospovidone, sodium hydrogen carbonate, citric acid, colloidal silicon dioxide, ferric oxide, mannitol, aspartame (E951) and flavour Tutti-Frutti.

What Aerius orodispersible tablet looks like and contents of the pack

Aerius 5 mg orodispersible tablet is light red, speckled, and round with “A” branded on one side.
Aerius orodispersible tablet is packed in unit dose blisters in packs of
5, 6, 10, 12, 15, 18, 20, 30, 50, 60, 90 and 100 doses of orodispersible tablet.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Detailed information on this medicine is available on the European Medicines Agency website http://www.ema.europa.eu.

Package leaflet: Information for the patient

Aerius 0.5 mg/ml oral solution
desloratadine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. **See section 4.**

What is in this leaflet

1. What Aerius oral solution is and what it is used for

What Aerius is
Aerius contains desloratadine which is an antihistamine.

How Aerius works
Aerius oral solution is an antiallergy medicine that does not make you drowsy. It helps control your allergic reaction and its symptoms.

When Aerius should be used
Aerius oral solution relieves symptoms associated with allergic rhinitis (inflammation of the nasal passages caused by an allergy, for example, hay fever or allergy to dust mites) in adults, adolescents and children 1 year of age and older. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Aerius oral solution is also used to relieve the symptoms associated with urticaria (a skin condition caused by an allergy). These symptoms include itching and hives.

Relief of these symptoms lasts a full day and helps you to resume your normal daily activities and sleep.

2. What you need to know before you take Aerius oral solution

Do not take Aerius oral solution
- if you are allergic to desloratadine, or to any of the other ingredients of this medicine (listed in section 6) or to loratadine.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Aerius:
- if you have poor kidney function.
- if you have medical or familial history of seizures.

Use in children and adolescents
Do not give this medicine to children less than 1 year of age.

Other medicines and Aerius
There are no known interactions of Aerius with other medicines.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Aerius oral solution with food, drink and alcohol
Aerius may be taken with or without a meal.
Use caution when taking Aerius with alcohol.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Taking Aerius oral solution is not recommended if you are pregnant or nursing a baby.
Fertility
There is no data available on male/female fertility.

Driving and using machines
At the recommended dose, this medicine is not expected to affect your ability to drive or use machines. Although most people do not experience drowsiness, it is recommended not to engage in activities requiring mental alertness, such as driving a car or operating machinery until you have established your own response to the medicinal product.

Aerius oral solution contains sorbitol
Aerius oral solution contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Aerius oral solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Children
Children 1 through 5 years of age:
The recommended dose is 2.5 ml (½ of a 5 ml spoonful) of oral solution once a day.

Children 6 through 11 years of age:
The recommended dose is 5 ml (one 5 ml spoonful) of oral solution once a day.

Adults and adolescents 12 years of age and over
The recommended dose is 10 ml (two 5 ml spoonfuls) of oral solution once a day.

In case an oral measuring syringe is provided with the bottle of oral solution, you can alternatively use it to take the appropriate amount of oral solution.

This medicine is for oral use.

Swallow the dose of oral solution and then drink some water. You can take this medicine with or without food.

Regarding the duration of treatment, your physician will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Aerius oral solution.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your physician will recommend you a treatment schedule that will depend on the evaluation of the history of your disease.
If your allergic rhinitis is persistent (presence of symptoms for 4 days or more per week and for more than 4 weeks), your physician may recommend you a longer term treatment.

For urticaria, the duration of treatment may be variable from patient to patient and therefore you should follow the instructions of your physician.

If you take more Aerius oral solution than you should
Take Aerius oral solution only as it is prescribed for you. No serious problems are expected with accidental overdose. However, if you take more Aerius oral solution than you were told to, tell your doctor, pharmacist or nurse immediately.

If you forget to take Aerius oral solution
If you forget to take your dose on time, take it as soon as possible and then go back to your regular dosing schedule. Do not take a double dose to make up for a forgotten dose.

If you stop taking Aerius oral solution
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

During the marketing of Aerius, cases of severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling) have been reported very rarely. If you notice any of these serious side effects, stop taking the medicine and seek urgent medical advice straight away.

In clinical studies in most children and adults, side effects with Aerius were about the same as with a dummy solution or tablet. However, common side effects in children less than 2 years of age were diarrhoea, fever and insomnia while in adults, fatigue, dry mouth and headache were reported more often than with a dummy tablet.

In clinical studies with Aerius, the following side effects were reported as:

Children
Common in children less than 2 years of age: the following may affect up to 1 in 10 children
- diarrhoea
- fever
- insomnia

Adults
Common: the following may affect up to 1 in 10 people
- fatigue
- dry mouth
- headache

During the marketing of Aerius, the following side effects were reported as:

Adults
Very rare: the following may affect up to 1 in 10,000 people
- severe allergic reactions
- rash
- pounding or irregular heartbeat
- fast heartbeat
- stomach ache
- feeling sick (nausea)
- vomiting
- upset stomach
- diarrhoea

- dizziness
- drowsiness
- inability to sleep
- muscle pain
- hallucinations
- seizures
- restlessness with increased body movement
- liver inflammation
- abnormal liver function tests

Not known: frequency cannot be estimated from the available data
- unusual weakness
- yellowing of the skin and/or eyes
- increased sensitivity of the skin to the sun, even in case of hazy sun, and to UV light, for instance to UV lights of a solarium
- changes in the way the heart beats
- abnormal behaviour
- aggression
- weight increased, increased appetite

Children
Not known: frequency cannot be estimated from the available data
- slow heartbeat
- change in the way the heart beats
- abnormal behaviour
- aggression

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aerius oral solution

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month.

Do not freeze. Store in the original package.

Do not use this medicine if you notice any change in the appearance of the oral solution.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Aerius oral solution contains

- The active substance is desloratadine 0.5 mg/ml
- The other ingredients of the oral solution are sorbitol, propylene glycol, sucralose E 955, hypromellose 2910, sodium citrate dihydrate, natural and artificial flavour (bubblegum), citric acid anhydrous, disodium edetate and purified water.

What Aerius oral solution looks like and contents of the pack

Aerius oral solution is available in bottles of 30, 50, 60, 100, 120, 150, 225 and 300 ml, with a childproof cap. For all packages except the 150 ml bottle, a measuring spoon is provided, marked for doses of 2.5 ml and 5 ml. For the 150 ml package, a measuring spoon or an oral measuring syringe is provided, marked for doses of 2.5 ml and 5 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Merck Sharp & Dohme B.V.
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Manufacturer: SP Labo N.V., Industriepark 30, B-2220 Heist-op-den-Berg, Belgium.

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