

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dasselta 5 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 5 mg desloratadine.

Excipient with known effect:

Each film-coated tablet contains 16.15 mg lactose (as monohydrate).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Light blue, round, film-coated tablets with beveled edges (diameter: 6.5 mm, thickness: 2.3–3.5 mm).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Dasselta 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 Dasselta 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 Dasselta 5 mg film-coated tablets in children below the age of 12 years have not been established.

Method of administration

Oral use.

The tablet 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, Dasselta 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 (see section 4.8), 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.

Dasselta contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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 desloratadine 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 desloratadine 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 desloratadine 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

Desloratadine 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 desloratadine 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 ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1,000$ to $< 1/100$), rare ($\geq 1/10,000$ 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 desloratadine
Metabolism and nutritional disorders	Not known	Increased appetite
Psychiatric disorders	Very rare Not known	Hallucinations Abnormal behaviour, aggression, depressed mood
Nervous system disorders	Common Very rare	Headache Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Eye disorders	Not known	Eye dryness
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.

A retrospective observational safety study indicated an increased incidence of new-onset seizure in patients 0 to 19 years of age when receiving desloratadine compared with periods not receiving desloratadine. Among children 0-4 years old, the adjusted absolute increase was 37.5 (95% Confidence Interval (CI) 10.5-64.5) per 100,000 person years (PY) with a background rate of new onset seizure of 80.3 per 100,000 PY. Among patients 5-19 years of age, the adjusted absolute increase was 11.3 (95% CI 2.3-20.2) per 100,000 PY with a background rate of 36.4 per 100,000 PY. (See section 4.4.)

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: Other antihistamines for systemic use, ATC code: R06AX27

Mechanism of action

Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H₁-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H₁-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. Desloratadine 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, desloratadine was effective in relieving symptoms such as sneezing, nasal discharge and itching, as well as ocular itching, tearing and redness, and itching of palate. Desloratadine effectively controlled symptoms for 24 hours.

Paediatric population

The efficacy of desloratadine 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.

Desloratadine 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, desloratadine 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 nonresponsive 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 desloratadine 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 can not 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:

Microcrystalline cellulose (E460)
Hypromellose (E464)
Hydrochloric acid (E507) (for pH adjustment)
Sodium hydroxide (E524) (for pH adjustment)
Maize starch
Lactose monohydrate
Talc (E553b)

Film coating:

Hypromellose (E464)
Macrogol
Lactose monohydrate
Titanium dioxide (E171)
Indigo carmine (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years

Shelf life after first opening of the tablet container: 3 months.

6.4 Special precautions for storage

Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Blister (OPA/Alu/PVC//Alu): 7, 10, 20, 30, 50, 90 and 100 film-coated tablets, in a box.

Tablet container (HDPE, volume 60 ml), PP closure with desiccant: 250 film-coated tablets, in a box.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

8. MARKETING AUTHORISATION NUMBER(S)

7 film-coated tablets: EU/1/11/739/001

10 film-coated tablets: EU/1/11/739/002

20 film-coated tablets: EU/1/11/739/003

30 film-coated tablets: EU/1/11/739/004

50 film-coated tablets: EU/1/11/739/005

90 film-coated tablets: EU/1/11/739/006

100 film-coated tablets: EU/1/11/739/007

250 film-coated tablets: EU/1/11/739/008

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28 November 2011

Date of latest renewal: 16 August 2016

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. MANUFACTURER(S) 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. MANUFACTURER(S) RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer(s) responsible for batch release

KRKA, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

TAD Pharma GmbH
Heinz-Lohmann-Straße 5
27472 Cuxhaven
Germany

The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

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 (PSURs)**

The requirements for submission of PSURs for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates 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)**

Not applicable.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

BOX

1. NAME OF THE MEDICINAL PRODUCT

Dasselta 5 mg film-coated tablets
desloratadine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 5 mg desloratadine.

3. LIST OF EXCIPIENTS

Excipient: lactose monohydrate.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

film-coated tablet

for blister:

7 film-coated tablets
10 film-coated tablets
20 film-coated tablets
30 film-coated tablets
50 film-coated tablets
90 film-coated tablets
100 film-coated tablets

for tablet container:

250 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral 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

for tablet container:

Shelf life after first opening of the tablet container: 3 months.

Date of opening: _____

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

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**

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

12. MARKETING AUTHORISATION NUMBER(S)

7 film-coated tablets: EU/1/11/739/001
10 film-coated tablets: EU/1/11/739/002
20 film-coated tablets: EU/1/11/739/003
30 film-coated tablets: EU/1/11/739/004
50 film-coated tablets: EU/1/11/739/005
90 film-coated tablets: EU/1/11/739/006
100 film-coated tablets: EU/1/11/739/007
250 film-coated tablets: EU/1/11/739/008

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY**15. INSTRUCTIONS ON USE****16. INFORMATION IN BRAILLE**

Dasselta 5 mg

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

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Dasselta 5 mg film-coated tablets
desloratadine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

KRKA

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

LABEL

1. NAME OF THE MEDICINAL PRODUCT

Dasselta 5 mg film-coated tablets
desloratadine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 5 mg desloratadine.

3. LIST OF EXCIPIENTS

Excipient: lactose monohydrate.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

film-coated tablet

250 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral 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

Shelf life after first opening of the tablet container: 3 months.
Date of opening: _____

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture.

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

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

12. MARKETING AUTHORISATION NUMBER(S)

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Dasselta 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Dasselta is and what it is used for
2. What you need to know before you take Dasselta
3. How to take Dasselta
4. Possible side effects
5. How to store Dasselta
6. Contents of the pack and other information

1. What Dasselta is and what it is used for

What Dasselta is

Dasselta contains desloratadine which is an antihistamine.

How Dasselta works

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

When Dasselta should be used

Dasselta 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.

Dasselta 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 Dasselta

Do not take Dasselta

- if you are allergic to desloratadine, to any of the other ingredients of this medicine (listed in section 6) or to loratadine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dasselta:

- if you have poor kidney function.
- if you have medical or familial history of seizures.

Children and adolescents

Do not give this medicine to children less than 12 years of age.

Other medicines and Dasselta

There are no known interactions of Dasselta with other medicines.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Dasselta with food, drink and alcohol

Dasselta may be taken with or without a meal.

Use caution when taking Dasselta 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.

If you are pregnant or nursing a baby, taking Dasselta is not recommended.

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.

Dasselta contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Dasselta

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 doctor will determine the type of allergic rhinitis you are suffering from and will determine for how long you should take Dasselta.

If your allergic rhinitis is intermittent (presence of symptoms for less than 4 days per week or for less than 4 weeks), your doctor 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 doctor 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 doctor.

If you take more Dasselta than you should

Take Dasselta only as it is prescribed for you. No serious side effects are expected with accidental

overdose. However, if you take more Dasselta than you were told to, tell your doctor or pharmacist immediately.

If you forget to take Dasselta

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 tablet.

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

4. Possible side effects

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

During the marketing of desloratadine, 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 desloratadine, 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 desloratadine-containing products, 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,
- depressed mood,
- dry eyes.

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 or pharmacist. 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 Dasselta

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 packaging after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture.

Shelf life after first opening of the tablet container: 3 months.

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 protect the environment.

6. Contents of the pack and other information

What Dasselta contains

- The active substance is desloratadine. Each film-coated tablet contains 5 mg desloratadine.
- The other ingredients in the tablet core are: microcrystalline cellulose (E460), hypromellose (E464), hydrochloric acid (E507) (for pH adjustment), sodium hydroxide (E524) (for pH adjustment), maize starch, lactose monohydrate (see section 2 under »Dasselta contains lactose and sodium«.) and talc (E553b).
- The other ingredients in the film-coating are: hypromellose (E464), macrogol, lactose monohydrate (see section 2 under »Dasselta contains lactose and sodium«.), titanium dioxide (E171) and indigo carmine (E132).

What Dasselta looks like and contents of the pack

Light blue, round, film-coated tablets with beveled edges (diameter: 6.5 mm, thickness: 2.3–3.5 mm).

Dasselta is available in carton boxes of 7, 10, 20, 30, 50, 90 and 100 film-coated tablets in blisters and in tablet container of 250 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

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

België/Belgique/Belgien

KRKA Belgium, SA.

Tél/Tel: + 32 (0) 487 50 73 62

Lietuva

UAB KRKA Lietuva

Tel: + 370 5 236 27 40

България

КРКА България ЕООД

Тел.: + 359 (02) 962 34 50

Luxembourg/Luxemburg

KRKA Belgium, SA.

Tél/Tel: + 32 (0) 487 50 73 62 (BE)

Česká republika

KRKA ČR, s.r.o.

Tel: + 420 (0) 221 115 150

Magyarország

KRKA Magyarország Kereskedelmi Kft.

Tel.: + 36 (1) 355 8490

Danmark

KRKA Sverige AB

Tlf: + 46 (0)8 643 67 66 (SE)

Malta

E. J. Busuttil Ltd.

Tel: + 356 21 445 885

Deutschland

TAD Pharma GmbH

Tel: + 49 (0) 4721 606-0

Nederland

KRKA Belgium, SA.

Tel: + 32 (0) 487 50 73 62 (BE)

Eesti

KRKA, d.d., Novo mesto Eesti filiaal

Tel: + 372 (0) 6 671 658

Norge

KRKA Sverige AB

Tlf: + 46 (0)8 643 67 66 (SE)

Ελλάδα

KRKA ΕΛΛΑΣ ΕΠΕ

Τηλ: + 30 2100101613

Österreich

KRKA Pharma GmbH, Wien

Tel: + 43 (0)1 66 24 300

España

KRKA Farmacéutica, S.L.

Tel: + 34 911 61 03 80

Polska

KRKA-POLSKA Sp. z o.o.

Tel.: + 48 (0)22 573 7500

France

KRKA France Eurl

Tél: + 33 (0)1 57 40 82 25

Portugal

KRKA Farmacêutica, Sociedade Unipessoal Lda.

Tel: + 351 (0)21 46 43 650

Hrvatska

KRKA - FARMA d.o.o.

Tel: + 385 1 6312 100

România

KRKA Romania S.R.L., Bucharest

Tel: + 4 021 310 66 05

Ireland

KRKA Pharma Dublin, Ltd.

Tel: + 353 1 413 3710

Slovenija

KRKA, d.d., Novo mesto

Tel: + 386 (0) 1 47 51 100

Ísland

LYFIS ehf.

Sími: + 354 534 3500

Slovenská republika

KRKA Slovensko, s.r.o.

Tel: + 421 (0) 2 571 04 501

Italia

KRKA Farmaceutici Milano S.r.l.
Tel: + 39 02 3300 8841

Κύπρος

KI.PA. (PHARMACAL) LIMITED
Τηλ: + 357 24 651 882

Latvija

KRKA Latvija SIA
Tel: + 371 6 733 86 10

Suomi/Finland

KRKA Finland Oy
Puh/Tel: + 358 20 754 5330

Sverige

KRKA Sverige AB
Tel: + 46 (0)8 643 67 66 (SE)

United Kingdom (Northern Ireland)

KRKA Pharma Dublin, Ltd.
Tel: + 353 1 413 3710

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Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

ANNEX IV

**SCIENTIFIC CONCLUSIONS AND GROUNDS FOR THE VARIATION TO THE TERMS
OF THE MARKETING AUTHORISATION(S)**

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for desloratadine, the scientific conclusions of the CHMP are as follows:

In view of available data from the literature including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between desloratadine and depressed mood is at least a reasonable possibility. The PRAC concluded that the product information of products containing desloratadine should be amended accordingly.

As described in the literature and signal section of some MAHs, WHO identified a potential safety signal of dry eyes for desloratadine during the reporting period. Based on the anticholinergic properties of desloratadine and strengthened by the reports with a short time to onset and both de- and rechallenges described, the PRAC considers that “eye dryness” should be considered for inclusion in the product labels and patient leaflets.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for desloratadine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing desloratadine is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.