ANNEX I

SCIENTIFIC CONCLUSIONS PRESENTED BY THE EMEA

SCIENTIFIC CONCLUSIONS

Orbax is licensed for the treatment of urinary tract infections for dogs in a number of Member States and the Applicant submitted an application for the extension of the indication to cover the treatment of skin and soft tissue infections at a different dose to that recommended for the original claim. The basis for the arbitration procedure was the concerns raised by Denmark and Spain, that the three fold increase in the dose of orbifloxacin recommended for the treatment of skin and soft tissue infections compared to the recommended dose for the treatment of urinary tract infections was not justified. The Applicant was requested to provide justification for the three-fold increase in the dose for the additional indication.

The CVMP considered the written response provided by the Applicant, the joint Rapporteur-Co-Rapporteur's assessment report on the response of the Applicant and the comments from CVMP members, including references to published literature in this field.

Taking into account

- that it is preferable to recommend a single dose (rather than a dose range) for treatment;
- the risk of antimicrobial resistance of a lower dose, in pathogens causing skin infections, as concentrations in skin are lower than in the urinary tract;
- that the recommended dose was confirmed to be effective in a clinical trial;

the CVMP agreed that the recommended dose of 7.5 mg/kg is sufficient to ensure appropriate treatment of skin infections in the dog. They also agreed that to use a lower dose than 7.5 mg/kg is not recommended due to the risk of resistance emerging and also a possible lack of efficacy.

Therefore, the CVMP has recommended the granting of the Marketing Authorisations for which the Summaries of Product Characteristics are set out in Annex III for Orbax.

ANNEX II

LIST OF THE PHARMACEUTICAL FORMS, STRENGTHS, ROUTES OF ADMINISTRATION, PACKAGING AND PACKAGE SIZES OF THE VETERINARY MEDICINAL PRODUCT IN THE MEMBER STATES

ANNEX II

Marketing Authorisation Holder (Name and address):

Reference Member State: **United Kingdom**

Schering-Plough Ltd
Schering-Plough House
Shire Park
Welwyn Garden City
Herts AL7 1TW
United Kingdom

Concerned Member States:

Austria Essex Tierarznei Ndl. der Essex Pharma GmbH Thomas-Dehler-Str. 27 81737 Munchen Germany	**Ireland** Schering-Plough Ltd Schering-Plough House Shire Park Welwyn Garden City Herts AL7 1TW United Kingdom
Belgium Schering-Plough NV/SA Rue de Stallesstraat 73 1180 Brussels Belgium	**Luxembourg** Schering-Plough NV/SA Rue de Stallesstraat 73 1180 Brussels Belgium
Denmark Schering-Plough A/S Hvedemarken 12 DK-3520 Farum Denmark	**Portugal** Schering-Plough II-Veterinaria,Lda Casal Colaride, Agualva 2735-Cacem Portugal
Finland Schering-Plough A/S Hvedemarken 12 DK-3520 Farum Denmark	**Spain** Schering-Plough SA Km 36, Carretera Nacional I 28750 San Agustin de Guadalix Madrid Espana
France Schering-Plough Veterinaire 92 rue Baudin 92300 Levallois-Perret France	**Sweden** Schering-Plough A/S Hvedemarken 12 DK-3520 Farum Denmark
Germany Essex Tierarznei Ndl. der Essex Pharma GmbH Thomas-Dehler-Str. 27 81737 Munchen Germany	**The Netherlands** Schering-Plough NV/SA Rue de Stallesstraat 73 1180 Brussels Belgium
Greece Schering-Plough S.A. 63, Agiou Dimitriou Str. 174 55 Alimos Athens Greece	

Presentations:

Invented Name	Strength	Pharmaceutical Form	Target Species	Route of administration	Packaging	Package-size
Orbax	6.25 mg	Tablet	Dog	Oral	Blister (PVC/Alu)	10
Orbax	6.25 mg	Tablet	Dog	Oral	Blister (PVC/Alu)	100
Orbax	25 mg	Tablet	Dog	Oral	Blister (PVC/Alu)	10
Orbax	25 mg	Tablet	Dog	Oral	Blister (PVC/Alu)	100
Orbax	75 mg	Tablet	Dog	Oral	Blister (PVC/Alu)	8
Orbax	75 mg	Tablet	Dog	Oral	Blister (PVC/Alu)	80

ANNEX III

SUMMARY OF PRODUCT CHARACTERISTICS
OF THE REFERENCE MEMBER STATE

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

ORBAX® 6.25 mg film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Orbifloxacin 6.25 mg per tablet
Film coating containing titanium dioxide (E171)

3. PHARMACEUTICAL FORM

Film-coated tablet

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterial for systemic use.
ATCvet code: QJ01MA95.

Orbifloxacin is a synthetic broad spectrum antibacterial agent from the class of fluoroquinolone carboxylic acid derivatives.

Orbifloxacin is bactericidal with activity against mainly Gram-negative bacteria but also against some Gram-positive bacteria. The mode of action of the fluoroquinolones is through interference with the bacterial enzyme DNA gyrase which is needed for the synthesis of bacterial DNA. Orbifloxacin has been shown to be active against most strains of the following organisms.

Escherichia coli
Proteus mirabilis
Staphylococcus intermedius
Staphylococcus aureus
Pasteurella multocida
Enterobacter agglomerans
Klebsiella pneumoniae

Bacterial resistance to the fluoroquinolones may occur through alterations in bacterial cell wall permeability, activation of an efflux pump or alteration in the 4-quinolone molecule's binding site via mutation of DNA gyrase or topoisomerase IV. Resistance to one fluoroquinolone frequently results in resistance to all (cross-resistance). Some mutations that can confer resistance to the fluoroquinolones can also confer resistance to other classes of antibiotics such as the cephalosporins and tetracyclines.

4.2 Pharmacokinetic properties

The oral bioavailability of orbifloxacin in dogs is approximately 100%. Maximum plasma concentrations of 2.3 and 6.8 μg/ml are achieved within two hours following administration at 2.5 and 7.5 mg/kg, respectively. The plasma elimination half life is approximately 6 hours. The accumulation between doses given at 24 hour intervals is negligible. Approximately 50% of an orally administered dose is excreted in the urine as unchanged drug. After a 2.5 mg/kg dose, urine concentrations of

orbifloxacin are approximately 100 μg/ml for approximately 12 hours after dosing. By 24 hours, urine concentrations of orbifloxacin are approximately 40 μg/ml. Following once daily multiple dosing at 7.5 mg/kg, skin concentrations of orbifloxacin in diseased skin exceed concentrations in plasma.

5. CLINICAL PARTICULARS

5.1 Target species

Dog

5.2 Indications for use

Treatment of uncomplicated bacterial cystitis due to susceptible strains of E coli and Proteus mirabilis, and treatment of skin and associated soft tissue infections (wounds and abscesses), associated with bacteria susceptible to orbifloxacin.

5.3 Contraindications

Orbax® Tablets are contraindicated in juvenile dogs during the rapid growth phase (up to 8 months of age in small and medium sized breeds, up to 12 months in large and up to 18 months of age in giant breeds).

As no specific studies have been carried out in breeding dogs, Orbax® tablets should not be used in dogs intended for breeding.

Concurrent use of fluoroquinolones with oral cyclosporin is contraindicated.

5.4 Undesirable Side effects

Mild side effects such as vomiting, soft faeces or diarrhoea may occasionally occur in some animals.

5.5 Special Precautions for use

In field trials with orbifloxacin, canine pyoderma was not clinically evaluated; consequently, dogs with this skin condition should be excluded from therapy.

Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions which have responded poorly to other classes of antimicrobials.

Use of fluoroquinolones such as orbifloxacin should be based on susceptibility testing and take into account official and local antimicrobial policies.

5.6 Use during pregnancy and lactation

As no specific studies have been conducted in pregnant dogs, it is not recommended to administer Orbax® tablets to dogs during pregnancy and lactation.

5.7 Interactions with other medicaments

Concurrent administration with metal cations such as those contained in antacids made with magnesium hydroxide or aluminium hydroxide, or multivitamins containing iron or zinc, has been reported to dramatically decrease the bioavailability of fluoroquinolones.

The dosage of theophylline should be reduced when used concurrently with fluoroquinolones.

Cimetidine has been shown to interfere with the metabolism of fluoroquinolones and should be used with care when used concurrently.

Concurrent administration of fluoroquinolones may increase the action of oral anticoagulants.

5.8 Dosage and Method of administration

Dose:
The recommended dose of Orbax® Tablets is 2.5 mg/kg bodyweight for treatment of bacterial cystitis and 7.5 mg/kg bodyweight for treatment of skin and associated soft tissue infections, administered once daily.

To ensure a correct dosage, body weight should be accurately determined to avoid underdosing.

Administration:
Orbax® Tablets should be administered for 10 consecutive days for treatment of bacterial cystitis, and skin and associated soft tissue infections. If no improvement is seen within 5 days of starting therapy, the diagnosis should be re-evaluated and a different course of therapy considered.

Dosing Chart for ORBAX® 6.25 mg Tablets (2.5 mg/kg once daily)

	Weight of Dog (kg)								
	2.5	5	10	15	20	25	30	45	60
# of 6.25 mg tablets	1	2							

Dosing Chart for ORBAX® 6.25 mg Tablets (7.5 mg/kg once daily)

	Weight of Dog (kg)								
	2.5	5	10	15	20	25	30	45	60
# of 6.25 mg tablets	3								

5.9 Overdosage

In tolerance studies in dogs, using up to 5 times the maximum recommended dosage of 7.5mg/kg, the product is well tolerated. In dogs that receive an overdose greater than 22.5 mg/kg, salivation, soft and/or mucoid faeces and vomiting may be observed. Symptomatic therapy is recommended.

5.10 Special warnings for target species

Fluoroquinolones have been shown to induce erosion of the articular cartilage in juvenile animals, the dog being particularly sensitive. The potential effects of orbifloxacin on the retina of the dog have not been studied.

5.11 Withdrawal periods

Not applicable.

5.12 Special Safety Precautions to be taken by the person administering the product:

None

6. PHARMACEUTICAL DATA

6.1 Incompatibilities

Not applicable.

6.2 Shelf-Life

2 years.

6.3 Special storage precautions

No special precautions for storage are required

6.4 Nature and content of container

The 6.25 mg strength is a round, biconvex, white, film-coated tablet.

The tablets are packaged in PVDC blister with aluminium foil lidding

6.25 mg tablet carton contains;
10 cards of 10 tablets (100 tablets)
1 card of 10 tablets (10 tablets)

6.5 Name or style and permanent address or registered place of the business of the holder of the authorisation to place the product on the market

Schering-Plough Limited
Schering-Plough House
Shire Park
Welwyn Garden City
Hertfordshire
AL7 1TW
United Kingdom

6.6 Special Precautions for disposal of unused product or waste materials, if any

Any unused product or waste material should be disposed of in accordance with national requirements.

7. FURTHER INFORMATION

7.1 Marketing authorisation Number

7.2 Legal category

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

ORBAX® 25 mg film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Orbifloxacin 25 mg per tablet
Film coating containing titanium dioxide (E171)

3. PHARMACEUTICAL FORM

Film-coated tablet

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterial for systemic use.
ATCvet code: QJ01MA95.

Orbifloxacin is a synthetic broad spectrum antibacterial agent from the class of fluoroquinolone carboxylic acid derivatives.

Orbifloxacin is bactericidal with activity against mainly Gram-negative bacteria but also against some Gram-positive bacteria. The mode of action of the fluoroquinolones is through interference with the bacterial enzyme DNA gyrase which is needed for the synthesis of bacterial DNA. Orbifloxacin has been shown to be active against most strains of the following organisms.

Escherichia coli
Proteus mirabilis
Staphylococcus intermedius
Staphylococcus aureus
Pasteurella multocida
Enterobacter agglomerans
Klebsiella pneumoniae

Bacterial resistance to the fluoroquinolones may occur through alterations in bacterial cell wall permeability, activation of an efflux pump or alteration in the 4-quinolone molecule's binding site via mutation of DNA gyrase or topoisomerase IV. Resistance to one fluoroquinolone frequently results in resistance to all (cross-resistance). Some mutations that can confer resistance to the fluoroquinolones can also confer resistance to other classes of antibiotics such as the cephalosporins and tetracyclines.

4.2 Pharmacokinetic properties

The oral bioavailability of orbifloxacin in dogs is approximately 100%. Maximum plasma concentrations of 2.3 and 6.8 μg/ml are achieved within two hours following administration at 2.5 and 7.5 mg/kg, respectively. The plasma elimination half life is approximately 6 hours. The accumulation between doses given at 24 hour intervals is negligible. Approximately 50% of an orally administered dose is excreted in the urine as unchanged drug. After a 2.5 mg/kg dose, urine concentrations of

orbifloxacin are approximately 100 μg/ml for approximately 12 hours after dosing. By 24 hours, urine concentrations of orbifloxacin are approximately 40 μg/ml. Following once daily multiple dosing at 7.5 mg/kg, skin concentrations of orbifloxacin in diseased skin exceed concentrations in plasma.

5. CLINICAL PARTICULARS

5.1 Target species

Dog

5.2 Indications for use

Treatment of uncomplicated bacterial cystitis due to susceptible strains of E coli and Proteus mirabilis, and treatment of skin and associated soft tissue infections (wounds and abscesses), associated with bacteria susceptible to orbifloxacin.

5.3 Contraindications

Orbax® Tablets are contraindicated in juvenile dogs during the rapid growth phase (up to 8 months of age in small and medium sized breeds, up to 12 months in large and up to 18 months of age in giant breeds).

As no specific studies have been carried out in breeding dogs, Orbax® tablets should not be used in dogs intended for breeding.

Concurrent use of fluoroquinolones with oral cyclosporin is contraindicated.

5.4 Undesirable Side effects

Mild side effects such as vomiting, soft faeces or diarrhoea may occasionally occur in some animals.

5.5 Special Precautions for use

In field trials with orbifloxacin, canine pyoderma was not clinically evaluated; consequently, dogs with this skin condition should be excluded from therapy.

Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions which have responded poorly to other classes of antimicrobials.

Use of fluoroquinolones such as orbifloxacin should be based on susceptibility testing and take into account official and local antimicrobial policies.

5.6 Use during pregnancy and lactation

As no specific studies have been conducted in pregnant dogs, it is not recommended to administer Orbax® tablets to dogs during pregnancy and lactation.

5.7 Interactions with other medicaments

Concurrent administration with metal cations such as those contained in antacids made with magnesium hydroxide or aluminium hydroxide, or multivitamins containing iron or zinc, has been reported to dramatically decrease the bioavailability of fluoroquinolones.

The dosage of theophylline should be reduced when used concurrently with fluoroquinolones.

Cimetidine has been shown to interfere with the metabolism of fluoroquinolones and should be used with care when used concurrently.

Concurrent administration of fluoroquinolones may increase the action of oral anticoagulants.

5.8 Dosage and Method of administration

Dose:
The recommended dose of Orbax® Tablets is 2.5 mg/kg bodyweight for treatment of bacterial cystitis and 7.5 mg/kg bodyweight for treatment of skin and associated soft tissue infections, administered once daily.

To ensure a correct dosage, body weight should be accurately determined to avoid underdosing.

Administration:
Orbax® Tablets should be administered for 10 consecutive days for treatment of bacterial cystitis, and skin and associated soft tissue infections. If no improvement is seen within 5 days of starting therapy, the diagnosis should be re-evaluated and a different course of therapy considered.

Dosing Chart for ORBAX® 25 mg Tablets (2.5 mg/kg once daily)

	Weight of Dog (kg)								
	2.5	5	10	15	20	25	30	45	60
# of 25 mg tablets		½	1	1½	2	2½			

Dosing Chart for ORBAX® 25 mg Tablets (7.5 mg/kg once daily)

	Weight of Dog (kg)								
	2.5	5	10	15	20	25	30	45	60
# of 25 mg tablets		1½							

5.9 Overdosage

In tolerance studies in dogs, using up to 5 times the maximum recommended dosage of 7.5mg/kg, the product is well tolerated. In dogs that receive an overdose greater than 22.5 mg/kg, salivation, soft and/or mucoid faeces and vomiting may be observed. Symptomatic therapy is recommended.

5.10 Special warnings for target species

Fluoroquinolones have been shown to induce erosion of the articular cartilage in juvenile animals, the dog being particularly sensitive. The potential effects of orbifloxacin on the retina of the dog have not been studied.

5.11 Withdrawal periods

Not applicable.

5.12 Special Safety Precautions to be taken by the person administering the product:

None

6. PHARMACEUTICAL DATA

6.1 Incompatibilities

Not applicable.

6.2 Shelf-Life

2 years.

6.3 Special storage precautions

No special precautions for storage are required

6.4 Nature and content of container

The 25 mg strength tablet is modified capsule shaped with an EZ-break score on one side and the Schering-Plough “SP” logo engraved on each half of the other side.

The tablets are packaged in PVDC blister with aluminium foil lidding.

25 mg tablet carton contains;
10 cards of 10 dividable tablets (100 tablets)
1 card of 10 dividable tablets (10 tablets)

6.5 Name or style and permanent address or registered place of the business of the holder of the authorisation to place the product on the market

Schering-Plough Limited
Schering-Plough House
Shire Park
Welwyn Garden City
Hertfordshire AL7 1TW
United Kingdom

6.6 Special Precautions for disposal of unused product or waste materials, if any

Any unused product or waste material should be disposed of in accordance with national requirements.

7. FURTHER INFORMATION

7.1 Marketing authorisation Number

7.2 Legal category

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

ORBAX® 75 mg film-coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Orbifloxacin 75 mg per tablet
Film coating contains Titanium Dioxide (E171)

3. PHARMACEUTICAL FORM

Film-coated tablet

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterial for systemic use.
ATCvet code: QJ01MA95.

Orbifloxacin is a synthetic broad spectrum antibacterial agent from the class of fluoroquinolone carboxylic acid derivatives.

Orbifloxacin is bactericidal with activity against mainly Gram-negative bacteria but also against some Gram-positive bacteria. The mode of action of the fluoroquinolones is through interference with the bacterial enzyme DNA gyrase which is needed for the synthesis of bacterial DNA. Orbifloxacin has been shown to be active against most strains of the following organisms.

Escherichia coli
Proteus mirabilis
Staphylococcus intermedius
Staphylococcus aureus
Pasteurella multocida
Enterobacter agglomerans
Klebsiella pneumoniae

Bacterial resistance to the fluoroquinolones may occur through alterations in bacterial cell wall permeability, activation of an efflux pump or alteration in the 4-quinolone molecule's binding site via mutation of DNA gyrase or topoisomerase IV. Resistance to one fluoroquinolone frequently results in resistance to all (cross-resistance). Some mutations that can confer resistance to the fluoroquinolones can also confer resistance to other classes of antibiotics such as the cephalosporins and tetracyclines.

4.2 Pharmacokinetic properties

The oral bioavailability of orbifloxacin in dogs is approximately 100%. Maximum plasma concentrations of 2.3 and 6.8 μg/ml are achieved within two hours following administration at 2.5 and 7.5 mg/kg, respectively. The plasma elimination half life is approximately 6 hours. The accumulation between doses given at 24 hour intervals is negligible. Approximately 50% of an orally administered dose is excreted in the urine as unchanged drug. After a 2.5 mg/kg dose, urine concentrations of orbifloxacin are approximately 100 μg/ml for approximately 12 hours after dosing. By 24 hours, urine

concentrations of orbifloxacin are approximately 40 μg/ml. Following once daily multiple dosing at 7.5 mg/kg, skin concentrations of orbifloxacin in diseased skin exceed concentrations in plasma.

5. CLINICAL PARTICULARS

5.1 Target species

Dog

5.2 Indications for use

Treatment of uncomplicated bacterial cystitis due to susceptible strains of E coli and Proteus mirabilis, and treatment of skin and associated soft tissue infections (wounds and abscesses), associated with bacteria susceptible to orbifloxacin.

5.3 Contraindications

Orbax® Tablets are contraindicated in juvenile dogs during the rapid growth phase (up to 8 months of age in small and medium sized breeds, up to 12 months in large and up to 18 months of age in giant breeds).

As no specific studies have been carried out in breeding dogs, Orbax® tablets should not be used in dogs intended for breeding.

Concurrent use of fluoroquinolones with oral cyclosporin is contraindicated.

5.4 Undesirable Side effects

Mild side effects such as vomiting, soft faeces or diarrhoea may occasionally occur in some animals.

5.5 Special Precautions for use

In field trials with orbifloxacin, canine pyoderma was not clinically evaluated; consequently, dogs with this skin condition should be excluded from therapy.

Heavy reliance on a single class of antibiotic may result in the induction of resistance in a bacterial population. It is prudent to reserve the fluoroquinolones for the treatment of clinical conditions which have responded poorly to other classes of antimicrobials.

Use of fluoroquinolones such as orbifloxacin should be based on susceptibility testing and take into account official and local antimicrobial policies.

5.6 Use during pregnancy and lactation

As no specific studies have been conducted in pregnant dogs, it is not recommended to administer Orbax® tablets to dogs during pregnancy and lactation.

5.7 Interactions with other medicaments

Concurrent administration with metal cations such as those contained in antacids made with magnesium hydroxide or aluminium hydroxide, or multivitamins containing iron or zinc, has been reported to dramatically decrease the bioavailability of fluoroquinolones.

The dosage of theophylline should be reduced when used concurrently with fluoroquinolones.

Cimetidine has been shown to interfere with the metabolism of fluoroquinolones and should be used with care when used concurrently.

Concurrent administration of fluoroquinolones may increase the action of oral anticoagulants.

5.8 Dosage and Method of administration

Dose:
The recommended dose of Orbax® Tablets is 2.5 mg/kg bodyweight for treatment of bacterial cystitis and 7.5 mg/kg bodyweight for treatment of skin and associated soft tissue infections administered once daily.

To ensure a correct dosage, body weight should be accurately determined to avoid underdosing.

Administration:
Orbax® Tablets should be administered for 10 consecutive days for treatment of bacterial cystitis, and skin and associated soft tissue infections. If no improvement is seen within 5 days of starting therapy, the diagnosis should be re-evaluated and a different course of therapy considered.

Dosing Chart for ORBAX® 75 mg Tablets (2.5 mg/kg once daily)

	Weight of Dog (kg)								
	2.5	5	10	15	20	25	30	45	60
# of 75 mg tablets				½			1	1½	2

Dosing Chart for ORBAX® 75 mg Tablets (7.5 mg/kg once daily)

	Weight of Dog (kg)								
	2.5	5	10	15	20	25	30	45	60
# of 75 mg tablets			1	1½	2	2½	3		

5.9 Overdosage

In tolerance studies in dogs, using up to 5 times the maximum recommended dosage of 7.5mg/kg, the product is well tolerated. In dogs that receive an overdose greater than 22.5 mg/kg, salivation, soft and/or mucoid faeces and vomiting may be observed. Symptomatic therapy is recommended.

5.10 Special warnings for target species

Fluoroquinolones have been shown to induce erosion of the articular cartilage in juvenile animals, the dog being particularly sensitive. The potential effects of orbifloxacin on the retina of the dog have not been studied.

5.11 Withdrawal periods

Not applicable.

5.12 Special Safety Precautions to be taken by the person administering the product:

None

6. PHARMACEUTICAL DATA

6.1 Incompatibilities

Not applicable.

6.2 Shelf-Life

2 years.

6.3 Special storage precautions

No special precautions for storage are required

6.4 Nature and content of container

The 75mg strength tablet is modified capsule shaped with an EZ-break score on one side and the Schering-Plough “SP” logo engraved on each half of the other side.

The tablets are packaged in PVDC blister with aluminium foil lidding.

75 mg tablet carton contains:
10 cards of 8 dividable tablets (80 tablets)
1 card of 8 dividable tablets (8 tablets)

6.5 Name or style and permanent address or registered place of the business of the holder of the authorisation to place the product on the market

Schering-Plough Ltd
Schering-Plough House
Shire Park
Welwyn Garden City
Hertfordshire AL7 1TW
United Kingdom

6.6 Special Precautions for disposal of unused product or waste materials, if any

Any unused product or waste material should be disposed of in accordance with national requirements.

7. FURTHER INFORMATION

7.1 Marketing authorisation Number

7.2 Legal category