SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

LUXAT 10 mg film coated tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

Montelukast ..... 10 mg (as 10.4 mg montelukast sodium)

Excipients:

Lactose monohydrate (derived from cow's milk) ..... 84.3 mg

Croscarmellose sodium ..... 7 mg

See section 6.1 for excipients.

3. PHARMACEUTICAL FORM

Film coated tablet.

Yellow, homogeneous appearance, round tablets with a 'd' emblem on one side, film coated tablets.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

LUXAT is indicated for the treatment of persistent asthma in patients aged 15 years and older (prevention of daytime and nighttime symptoms, treatment of aspirin-sensitive asthma patients, and prevention of exercise-induced bronchoconstriction).

LUXAT is indicated for the relief of symptoms of seasonal allergic rhinitis and perennial allergic rhinitis (year-round) in patients aged 15 years and older.

4.2. Posology and method of administration

Dosage/frequency and duration of administration:

For adolescents and adults aged 15 years and older, the dose is one 10 mg tablet once daily.

Persistent asthma in patients aged 15 years and older

LUXAT should be taken once daily in the evening.

Allergic rhinitis

Seasonal allergic rhinitis and perennial allergic rhinitis in patients aged 15 years and older

LUXAT should be taken once daily for allergic rhinitis. The timing of administration can be personalized according to the patient's needs.

Asthma and allergic rhinitis in patients aged 15 years and older:

Patients with both asthma and allergic rhinitis should take only one 10 mg film coated tablet once daily in the evening.

Method of administration:
The therapeutic effect of LUXAT on asthma parameters begins within one day. LUXAT can be taken with or without food. Patients should be advised to continue taking LUXAT even after their asthma is under control, as well as during periods when their asthma worsens.

Additional information for specific populations
Renal impairment:
No dose adjustment is necessary in patients with renal impairment (see Section 5.2).

Hepatic impairment:
No dose adjustment is necessary in patients with mild to moderate hepatic impairment (see Section 5.2). There is no data available for patients with severe hepatic impairment.

Pediatric population:
The safety and efficacy of LUXAT in pediatric patients aged 6-14 years with asthma have been demonstrated in adequate, well-controlled studies. The safety and efficacy profiles in this age group are similar to those in adults.

The efficacy of LUXAT in the treatment of seasonal allergic rhinitis in pediatric patients aged 2-14 years and in the treatment of perennial allergic rhinitis in pediatric patients aged 6 months-14 years of age is supported by extrapolation from the efficacy demonstrated in patients aged 15 years and older with allergic rhinitis and the assumption that the disease course, pathophysiology, and effect of the drug in these populations are quite similar.

Geriatric population
Individuals aged 65 years and older constituted 3.5% of the total number of volunteers included in LUXAT clinical studies, and individuals aged 75 years and older constituted 0.4%. No overall differences in safety or efficacy were observed between these individuals and younger individuals, and other reported experiences did not identify differences in responses between elderly and younger patients. However, increased sensitivity in some elderly individuals cannot be ruled out.

Treatment with LUXAT in combination with other asthma treatments:
Inhaled corticosteroids: LUXAT therapy may be used as an adjunctive treatment when necessary in patients who do not achieve adequate clinical control with inhaled corticosteroids and/or short-acting β-agonists. The dose of the inhaled corticosteroid may be gradually reduced when necessary. However, steroids should never be abruptly discontinued when initiating treatment with LUXAT.

4.3. Contraindications
LUXAT is contraindicated in patients with hypersensitivity to the active substance of this product or to any of the excipients listed in Section 6.1.

4.4. Special warnings and precautions for use

Patients should be advised never to use oral montelukast for the treatment of acute asthma attacks and to keep their usual rescue medication readily available for this purpose.
A short-acting inhaled beta-agonist should be used during an acute attack. Patients should contact their doctor as soon as possible if they require more inhalations of short-acting beta-agonists than usual.

Montelukast should not be abruptly started in place of inhaled or oral corticosteroids.
There is no evidence to suggest that the dose of oral corticosteroids can be reduced when montelukast is administered concomitantly.

Eosinophilic conditions
In rare cases, patients treated with anti-asthma agents such as montelukast may present with systemic eosinophilia; this condition may occasionally be accompanied by clinical features of vasculitis consistent with a disorder called Churg-Strauss syndrome, which is usually treated with systemic corticosteroid medications. Although not always, these events have generally been associated with the reduction or discontinuation of oral corticosteroid therapy. The possibility that leukotriene receptor antagonists are associated with the onset of Churg-Strauss syndrome cannot be ruled out or proven. Physicians should be alert for eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy in their patients. Patients who develop these symptoms should be reevaluated and their treatment regimens reviewed.

Montelukast therapy does not alter the need for aspirin-sensitive patients to avoid aspirin and other nonsteroidal anti-inflammatory drugs.

Neuropsychiatric events such as behavioral changes, depression, and suicidal tendencies have been reported in all age groups using montelukast (see Section 4.8).

If treatment is not discontinued, symptoms may become severe and persistent.

Therefore, if neuropsychiatric symptoms occur during treatment, treatment with montelukast should be discontinued.

Advise patients and/or caregivers to be alert to neuropsychiatric events and to inform their doctor if such changes in behavior occur.

Excipients:
Lactose: Patients with rare hereditary galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medication.

This medication contains less than 1 mmol of sodium (23 mg) per tablet, i.e. it is essentially 'sodium-free.'

4.5. Interaction with other medicinal products and other forms of interaction

Montelukast has been used in combination with other treatments routinely used in asthma prophylaxis and chronic asthma treatment. In drug interaction studies, the recommended clinical dose of montelukast did not cause clinically significant effects on the pharmacokinetic properties of the following drugs: theophylline, prednisone, prednisolone, oral contraceptives (ethinyl estradiol/norethindrone 35/1), terfenadine, digoxin, and warfarin.

The area under the plasma concentration curve (AUC) of montelukast was reduced by approximately 40% in patients receiving concomitant phenobarbital. Since montelukast is metabolized by CYP 3A4, 2C8, and 2C9, caution should be exercised when administering montelukast concomitantly with CYP 3A4, 2C8, and 2C9 inducers such as phenytoin, phenobarbital, and rifampicin, especially in children.

In vitro studies have shown that montelukast is a potent inhibitor of CYP 2C8. However, data from a clinical drug interaction study involving montelukast and rosiglitazone (a research substrate representing medicinal products primarily metabolized by CYP 2C8) showed that montelukast did not inhibit CYP 2C8 under *in vivo* conditions. Therefore, montelukast is not expected to significantly alter the metabolism of medicinal products metabolized by this enzyme (e.g., paclitaxel, rosiglitazone, and repaglinide).

In vitro studies have shown that montelukast is a substrate of CYP 2C8 and, to a lesser extent, 2C9 and 3A4. In a clinical drug-drug interaction study involving montelukast and gemfibrozil (both a CYP 2C8 and 2C9 inhibitor), gemfibrozil increased the systemic exposure of montelukast by 4.4-fold. No routine dose adjustment of montelukast is necessary when administered with gemfibrozil or other potent CYP 2C8 inhibitors; however, physicians should be aware of the potential for increased adverse reactions.

Based on *in vitro* data, clinically significant drug interactions are not expected with other known CYP 2C8 inhibitors (e.g., trimethoprim). Furthermore, co-administration of montelukast with itraconazole alone did not result in a significant increase in systemic exposure to montelukast.

Additional information on special populations:

No interaction studies have been conducted in special populations.

Pediatric population:

LUXAT is not indicated in the pediatric population (under 15 years of age); no interaction studies have been conducted in this population.

4.6. Pregnancy and lactation

General recommendation

Pregnancy category B.

Women of childbearing potential/Birth control (Contraception)
There is insufficient data on the effects on reproductive capacity in women of childbearing potential.

Limited data on exposure during pregnancy (montelukast) do not indicate that LUXAT has adverse effects on pregnancy or the health of the fetus/newborn child. No significant epidemiological data have been obtained to date.

Animal studies have not shown any direct or indirect harmful effects on pregnancy/embryonic/fetal development/birth or postnatal development (see Section 5.3.).

Caution should be exercised when administering to pregnant women.

Pregnancy
Animal studies have not shown any harmful effects related to pregnancy/embryonic/fetal development (see Section 5.3).

Data from prospective and retrospective cohort studies evaluating the use of montelukast in pregnant women have shown no drug-related risk of major birth defects. Current studies have methodological limitations, including small sample sizes, retrospective data collection in some cases, and inconsistent comparison groups.

LUXAT may be used during pregnancy only if deemed absolutely necessary.

Lactation
Studies in rats have shown that montelukast is excreted in milk (see Section 5.3). It is unknown whether montelukast or its metabolites are excreted in human milk.

LUXAT should only be used during lactation if it is deemed absolutely necessary.

Reproductive ability/Fertility
In animal studies, montelukast did not affect fertility or reproductive performance at systemic exposures 24 times higher than the clinical systemic exposure. In a female fertility study in rats, a slight decrease in pup weight was observed at a dose of 200 mg/kg/day (more than 69 times the clinical systemic exposure). In studies in rabbits, the incidence of incomplete ossification was higher at systemic exposures >24 times the clinical systemic exposure seen at the clinical dose compared to concurrent control animals. No abnormalities were seen in rats. Montelukast has been shown to cross the placental barrier and to be excreted in milk in animals.

There is insufficient data on the reproductive capacity of LUXAT in humans.

4.7. Effects on the ability to drive and use machines

LUXAT has no or negligible effects on the ability to drive and use machines. However, individuals have reported drowsiness or dizziness.

4.8. Undesirable effects

In clinical studies, montelukast has been evaluated as follows:

- 10 mg film coated tablets in approximately 4000 adolescent and adult asthmatic patients aged 15 years and older
- 10 mg film coated tablets in approximately 400 adolescents and adults with seasonal allergic rhinitis aged 15 years and older
- 5 mg chewable tablets in 1,750 pediatric asthma patients aged 6–14 years

In clinical studies of patients **aged 15 years and older (two 12-week studies, n=795)** with asthma treated with montelukast, the following drug-related adverse reactions were reported at a higher rate than with placebo and were common (≥1/100, <1/10):

Nervous system disorders:
Common: Headache

Gastrointestinal disorders:
Common: Abdominal pain

In clinical studies conducted in asthmatic patients **aged 6-14 years** treated with montelukast **(one 8-week study n=201, two 56-week studies n=615)**, the following adverse reactions were reported at a higher rate than with placebo and were considered drug-related and common (≥1/100, <1/10):

Nervous system disorders:
Common: Headache

The safety profile has not changed in adults treated for up to 2 years and in pediatric patients aged 6-14 years treated for up to 6 months in long-term asthma treatment in a specific number of patients in clinical studies.

Post-marketing experience

Adverse reactions reported during post-marketing use are listed according to System Organ Class and specific Adverse Event Term. Frequency categories are calculated based on relevant clinical studies. Frequency category: For each Adverse Event Term, it is defined as the incidence reported in the clinical studies database: 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).

Infections and infestations:
Very common: Upper respiratory tract infection†

Blood and lymphatic system disorders:
Rare: Increased tendency to bleed
Very rare: Thrombocytopenia

Immune system disorders:
Uncommon: Hypersensitivity reactions including anaphylaxis
Very rare: Hepatic eosinophilic infiltration

Psychiatric disorders:
Uncommon: Dream abnormalities including nightmares, insomnia, sleepwalking, agitation including anxiety, aggressive behavior or hostility, depression, psychomotor hyperactivity (including irritability, restlessness, tremor)
Rare: Attention deficit, memory impairment, tics
Very rare: Hallucinations, disorientation, suicidal thoughts and behavior (suicidal tendencies), obsessive-compulsive symptoms, dysphagia

Neurological disorders:
Uncommon: Dizziness, lightheadedness, paresthesia/hypoesthesia, seizures

Cardiac disorders:
Rare: Palpitations

Respiratory, thoracic disorders, and mediastinal disorders:
Uncommon: Epistaxis
Very rare: Churg-Strauss Syndrome (CSS) (see Section 4.4), pulmonary eosinophilia

Gastrointestinal disorders:
Common: Diarrhea‡, nausea‡, vomiting‡
Uncommon: Dry mouth, dyspepsia

Hepatobiliary disorders:
Common: Elevated serum transaminase (ALT, AST) levels
Very rare: Hepatitis (including cholestatic, hepatocellular, and mixed-type liver damage)

Skin and subcutaneous tissue disorders:
Common: Rash‡
Uncommon: Bruising, urticaria, pruritus
Rare: Angioedema
Very rare: Erythema nodosum, erythema multiforme

Musculoskeletal disorders and connective tissue and bone diseases:

Uncommon: Arthralgia, myalgia including muscle cramps

Renal and urinary tract disorders:
Uncommon: Enuresis in children

General disorders and administration site conditions:
Common: Fever‡
Uncommon: Asthenia/fatigue, malaise, edema

†This adverse event, reported very commonly in patients receiving montelukast, was also reported very commonly in patients receiving placebo in clinical trials.
‡This adverse event, commonly reported in patients receiving montelukast, was also commonly reported in patients receiving placebo in clinical trials.
§Frequency category: Rare

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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 in accordance with local requirements.

4.9. Overdose
In chronic asthma studies, montelukast has been administered to adult patients at doses up to 200 mg daily for 22 weeks and in short-term studies at doses up to 900 mg daily for approximately 1 week, with no clinically significant adverse events reported.

Post-marketing experience and clinical studies with montelukast have reported cases of acute overdose. These reports include doses as high as 1000 mg in adults and children (approximately 61 mg/kg in a 42-month-old child). The observed clinical and laboratory findings are consistent with the safety profile in adult and pediatric patients. The majority of overdose reports had no adverse events.

Symptoms:
The most common adverse events are consistent with the safety profile of montelukast and include abdominal pain, drowsiness, thirst, headache, vomiting, and psychomotor hyperactivity.

Treatment:
There is no specific information regarding the treatment of montelukast overdose.
There is no information on whether montelukast can be removed by peritoneal dialysis or hemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Leukotriene receptor antagonists
ATC code: R03DC03

Cysteinyl leukotrienes (LTC_4, LTD_4, LTE_4) are potent inflammatory eicosanoids released from various cells, including mast cells and eosinophils. These important pro-asthmatic mediators bind to cysteinyl leukotriene (CysLT) receptors. The CysLT type-1 ($CysLT_1$) receptor is found in the human respiratory tract (smooth muscle cells and macrophages in the respiratory tract) and other pro-inflammatory cells (eosinophils and certain myeloid progenitor cells). CysLTs are implicated in the pathophysiology of asthma and allergic rhinitis. The effects mediated by leukotrienes in asthma include bronchoconstriction, mucous secretion, vascular permeability, and eosinophil accumulation. In allergic rhinitis, CysLTs are released from the nasal mucosa in both early and late phase reactions after allergen exposure and are associated with allergic rhinitis symptoms.

Intranasal administration of CysLTs has been shown to increase airway resistance and nasal congestion symptoms.

Pharmacodynamic effects
Montelukast is an orally active compound that binds with high affinity and selectivity to the $CysLT_1$receptor. In clinical studies, montelukast at low doses such as 5 mg inhibits bronchoconstriction caused by inhaled LTD_4. Bronchodilation has been observed within 2 hours after oral administration. The bronchodilator effect caused by a β-agonist is additive to that caused by montelukast. Montelukast treatment inhibited both early and late-phase bronchoconstriction caused by antigen challenge. Compared to placebo, montelukast reduced peripheral blood eosinophils in both adult and pediatric patients. In a separate study, montelukast treatment reduced eosinophils in the airways (measured in sputum) and peripheral blood while improving clinical asthma control.

Clinical efficacy and safety
In studies in adults, once-daily 10 mg montelukast compared with placebo resulted in a significant improvement in morning FEV_1 (change of 10.4% vs. 2.7% from baseline) and morning peak expiratory flow rate (change of 24.5 L/min vs. 3.3 L/min from baselinevs. 3.3 L/min change from baseline) and a significant decrease in total β-agonist use (change from baseline of -26.1% vs. -4.6%). Improvements in patient-reported daytime and nighttime asthma symptom scores were significantly greater than with placebo.

Studies in adults have demonstrated montelukast's ability to enhance the clinical effect of inhaled corticosteroids (percentage change from baseline for beclomethasone inhalation + montelukast versus beclomethasone alone, respectively: FEV_1: 5.43% to 1.04%; β-agonist use: -8.7% to 2.64%). Compared to inhaled beclomethasone (200 µg twice daily via inhaler), montelukast showed a faster initial response, but beclomethasone showed a higher mean treatment effect over the 12-week study (percentage change from baseline for beclomethasone

versus montelukast, respectively FEV_1 : 7.49% vs. 13.3%; β-agonist use: -28.28% vs. -43.89%). However, a high percentage of patients achieved similar clinical responses with montelukast compared to beclomethasone (e.g., 50% of patients treated with beclomethasone achieved an improvement in FEV_1 of approximately 11% or more from baseline, while 42% of patients treated with montelukast achieved the same response).

A clinical study evaluated montelukast for the seasonal symptomatic treatment of asthma in adults and adolescents aged 15 years and older with seasonal allergic rhinitis. In this study, montelukast 10 mg tablets taken once daily showed a statistically significant improvement in the Daily Rhinitis Symptoms score compared to placebo. The Daily Rhinitis Symptoms score is the average of the Daytime Nasal Symptoms score (average of nasal congestion, runny nose, sneezing, and nasal itching) and the Nighttime Symptoms score (average of waking up with nasal congestion, difficulty falling asleep, and nighttime awakenings). Global assessments of allergic rhinitis by patients and physicians were significantly improved compared to placebo. The evaluation of asthma efficacy was not a primary objective in this study.

In an 8-week study in pediatric patients aged 6 to 14 years, once-daily 5 mg montelukast significantly improved respiratory function (FEV_1 from baseline by 8.71% to 4.16%) and reduced "as-needed" β-agonist use (from baseline by -11.7% to +8.2%).

In a 12-week study in adults, a significant decrease in exercise-induced bronchoconstriction (EIB) was observed (maximum decrease in FEV_1 was 22.33% for montelukast and 32.4% for placebo; time to improvement to 5% of baseline FEV1 was 44.22 min versus 60.64 min). This effect was consistent throughout the 12-week study period. A short-term study in pediatric patients also showed a decrease in PEF (maximum decrease in$_{FEV1}$was 18.27% for montelukast versus 26.11%; time to recovery to 5% of baseline FEV1 was 17.76 min versus 27.98 min). The effect in both studies was demonstrated at the end of the once-daily dosing interval.

In aspirin-sensitive asthma patients receiving concomitant corticosteroid inhalation and/or oral corticosteroids, montelukast treatment resulted in a significant improvement in asthma control compared to placebo (FEV_1 change from baseline of 8.55% to 1.74%, total β-agonist use change from baseline of -27.78% to 2.09%).

5.2. Pharmacokinetic properties

General characteristics

Absorption

Montelukast is rapidly absorbed from the gastrointestinal tract after oral administration. After administration of a 10 mg film coated tablet to adults on an empty stomach, montelukast reaches a mean peak plasma c e concentration (C_{max}) in 3 hours (T_{max}). The mean oral bioavailability is 64%. Oral bioavailability and C_{max} are not affected by a standard meal.

Safety and efficacy have been demonstrated in clinical studies where the 10 mg film coated tablet was administered independently of food intake.
With the 5 mg chewable tablet, C_{max} is reached 2 hours after administration in adults when administered on an empty stomach. The average bioavailability is 73% and decreases to 63% with a standard meal.

Distribution
Montelukast binds to plasma proteins at a rate greater than 99%. The steady-state distribution volume of montelukast is 8-11 liters. Studies in rats with radioisotope-labeled montelukast indicate minimal crossing of the blood-brain barrier. Furthermore, concentrations of radioisotope-labeled material 24 hours after dosing are minimal in all other tissues.

Biotransformation
Montelukast is extensively metabolized. In studies with therapeutic doses, plasma concentrations of montelukast metabolites are too low to be measured in adults and pediatric patients at steady state.

Cytochrome P450 2C8 is the major enzyme in the metabolism of montelukast. Additionally, CYP 3A4 and 2C9 may contribute to a small extent; however, itraconazole, a CYP 3A4 inhibitor, has been shown not to alter the pharmacokinetic variables of montelukast in healthy volunteers receiving 10 mg of montelukast daily. Based on additional *in vitro* results obtained from human liver microsomes, therapeutic plasma concentrations of montelukast do not inhibit cytochromes P450 3A4, 2C9, 1A2, 2A6, 2C19, or 2D6. The contribution of metabolites to the therapeutic effect of montelukast is minimal.

Elimination
The plasma clearance of montelukast is approximately 45 mL/min in healthy adults. After an oral dose of radioisotope-labeled montelukast, 86% of the radioactivity was detected in 5-day fecal samples and <0.2% in urine. When considered together with the oral bioavailability figures for montelukast, this indicates that montelukast and its metabolites are excreted almost exclusively via the bile.

Linearity/Nonlinearity
The pharmacokinetic data for montelukast are linear up to oral doses of 50 mg. During once-daily dosing with 10 mg montelukast, the parent drug accumulated minimally in plasma (approximately 14%).

Characteristic in patients
Elderly:
No dose adjustment is required in the elderly.

Hepatic impairment:

No dose adjustment is necessary in patients with mild to moderate hepatic impairment. There are no data on the pharmacokinetics of montelukast in patients with severe hepatic impairment (Child-Pugh score >9).

Renal impairment:
No studies have been conducted in patients with renal impairment. Since montelukast and its metabolites are excreted via the bile, no dose adjustment is expected to be necessary in patients with renal impairment.

When high doses of montelukast were administered (20 and 60 times the recommended adult dose), a decrease in plasma theophylline concentration was observed. This effect was not seen with the recommended once-daily 10 mg dose.

5.3. Preclinical safety data

In animal toxicity studies, small, transient changes in serum biochemistry, including ALT, glucose, phosphorus, and triglyceride levels, were observed. Toxicity findings in animals included increased salivation, gastrointestinal symptoms, soft stools, and ion imbalance. These events occurred at doses resulting in systemic exposure >17 times that seen at the clinical dose. Adverse effects in monkeys were seen at doses >150 mg/kg/day (systemic exposure >232 times that seen at the clinical dose). In animal studies, montelukast did not affect fertility or reproductive performance at systemic exposures more than 24 times the clinical systemic exposure. In a female fertility study in rats receiving 200 mg/kg daily (more than 69 times the clinical systemic exposure), a small decrease in pup body weight was observed. In studies in rabbits, insufficient bone development was observed at systemic exposures >24 times the clinical systemic exposure seen at the clinical dose compared to concurrently examined control animals. No abnormalities were observed in rats. Montelukast has been shown to cross the placenta and pass into breast milk in animals.

No deaths were observed after single oral administration of montelukast sodium doses up to 5000 mg/kg (maximum dose tested) in mice and rats (15,000 mg/m² in mice and 30,000 mg/m² in rats). This dose is equivalent to 25,000 times the recommended daily adult human dose (based on a 50 kg patient).

Montelukast doses up to 500 mg/kg/day (approximately >200 times the systemic exposure) in mice were not phototoxic in the UVA, UVB, or visible light spectrums.
Montelukast did not show mutagenicity or tumor formation in *in vitro* and *in vivo* tests in rodent species.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose monohydrate (derived from cow's milk)
Microcrystalline cellulose PH 101
Microcrystalline cellulose PH 102

Sodium croscarmellose
Hydroxypropyl cellulose
Magnesium stearate
Film coating:
Hydroxypropyl cellulose
Hypromellose
Titanium dioxide
D&C Yellow No. 10

6.2. Incompatibilities
None reported.

6.3. Shelf life
36 months

6.4. Special precautions for storage
Store at room temperature below 25°C. Protect from light and moisture.

6.5. Nature and contents of container
LUXAT 10 mg film coated tablets, in Alu/Alu blister packaging, containing 14 or 15 tablets per blister.
Each carton box contains 28 film coated tablets or 90 film coated tablets.

6.6. Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
DEVA Holding A.S.
Halkalı Merkez Mah. Basın Ekspres Cad.
No:1 34303 Küçükçekmece/İstanbul/TÜRKİYE
Tel: 0 212 692 92 92
Fax: 0 212 697 00 24

8 MARKETING AUTHORISATION NUMBER
207/12

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
Initial license date: 28/12/2005
License renewal date:

10. DATE OF REVISION OF THE TEXT