ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE MEDICINAL PRODUCT

Dasselta 5 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg desloratadine.

Excipient:
- lactose: 16.15 mg/tablet

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.
Light blue, round, film-coated tablets with beveled edges.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Dasselta is indicated 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

Adults and adolescents (12 years of age and over): one tablet once a day, with or without a meal for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticaria (see section 5.1).

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.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients or to loratadine.

4.4 Special warnings and precautions for use

Efficacy and safety of Dasselta tablets in children under 12 years of age have not been established.

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

Dasselta contains lactose. 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).

In a clinical pharmacology trial desloratadine taken concomitantly with alcohol did not potentiate the performance impairing effects of alcohol (see section 5.1).

4.6 Pregnancy and lactation

Desloratadine was not teratogenic in animal studies. The safe use of the medicinal product during pregnancy has not been established. The use of desloratadine during pregnancy is therefore not recommended.

Desloratadine is excreted into breast milk, therefore the use of desloratadine is not recommended in breastfeeding women.

4.7 Effects on ability to drive and use machines

In clinical trials that assessed the driving ability, no impairment occurred in patients receiving desloratadine. However, patients should be informed that very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

4.8 Undesirable effects

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 events reported in excess of placebo were fatigue (1.2 %), dry mouth (0.8 %) and headache (0.6 %). 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.

Other undesirable effects reported very rarely during the post-marketing period are listed in the following table.

<table>
<thead>
<tr>
<th>Psychiatric disorders</th>
<th>Hallucinations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nervous system disorders</td>
<td>Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td>Tachycardia, palpitations</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Abdominal pain, nausea, vomiting, dyspepsia, diarrhoea</td>
</tr>
<tr>
<td>Hepatobiliary disorders</td>
<td>Elevations of liver enzymes, increased bilirubin, hepatitis</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>Myalgia</td>
</tr>
<tr>
<td>General disorders</td>
<td>Hypersensitivity reactions (such as anaphylaxis, angioedema, dyspnoea, pruritus, rash, and urticaria)</td>
</tr>
</tbody>
</table>

4.9 Overdose

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

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

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antihistamines for systemic use, ATC code: R06AX27

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.

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. 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

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.

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.

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.

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.

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 with desloratadine reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, and toxicity to reproduction. 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)
Hypermellose (E464)
Hydrochloric acid (E507)
Sodium hydroxide (E524)
Maize starch
Lactose monohydrate
Talc (E553b)

Film-coating
Hypermellose (E464)
Macrogol
Lactose monohydrate
Titanium dioxide (E171)
Indigo carmine (E132)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years.

After first opening of the tablet container, the medicinal product should be used within 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

Blisters (OPA/Al/PVC/Al): 7, 10, 20, 30, 50, 90 and 100 film-coated tablets, in a box.
Tablet container (HDPE), 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)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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
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

Pharmacovigilance system
The MAH must ensure that the system of pharmacovigilance presented in Module 1.8.1. of the Marketing Authorisation is in place and functioning before and whilst the medicinal product is on the market.

Risk Management Plan
Not applicable.

PSURs
The PSUR submission schedule should follow the PSUR submission schedule for the reference medicinal product.

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

Not applicable.

• OBLIGATION TO CONDUCT POST-AUTHORISATION MEASURES

Not applicable.
ANNEX III

LABELLING AND PACKAGE LEAFLET
A. LABELLING
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

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

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 REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE
**for tablet container:**
After first opening of the tablet container, the product should be used within 3 months.

### 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)

EU/0/00/000/000

### 13. BATCH NUMBER

Lot

### 14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

### 15. INSTRUCTIONS ON USE

### 16. INFORMATION IN BRAILLE

Dasselta 5 mg
<table>
<thead>
<tr>
<th>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</th>
</tr>
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<tbody>
<tr>
<td>BLISTER</td>
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</table>

<table>
<thead>
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<th>1. NAME OF THE MEDICINAL PRODUCT</th>
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<tr>
<td>Dasselta 5 mg film-coated tablets</td>
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<tr>
<td>Desloratadine</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>2. NAME OF THE MARKETING AUTHORISATION HOLDER</th>
</tr>
</thead>
<tbody>
<tr>
<td>KRKA</td>
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</table>

<table>
<thead>
<tr>
<th>3. EXPIRY DATE</th>
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<td>EXP</td>
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<tr>
<th>4. BATCH NUMBER</th>
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<td>Lot</td>
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<tr>
<th>5. OTHER</th>
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</table>
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING
TABLET CONTAINER/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
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 REACH AND SIGHT OF CHILDREN
Keep out of the reach and sight of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE
EXP
After first opening of the tablet container, the product should be used within 3 months.

9. SPECIAL STORAGE CONDITIONS
Store in the original package in order to protect from moisture.
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>10.</td>
<td>SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE</td>
</tr>
<tr>
<td>11.</td>
<td>NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER</td>
</tr>
<tr>
<td></td>
<td>KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia</td>
</tr>
<tr>
<td>12.</td>
<td>MARKETING AUTHORISATION NUMBER(S)</td>
</tr>
<tr>
<td>13.</td>
<td>BATCH NUMBER</td>
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<td>14.</td>
<td>GENERAL CLASSIFICATION FOR SUPPLY</td>
</tr>
<tr>
<td>15.</td>
<td>INSTRUCTIONS ON USE</td>
</tr>
<tr>
<td>16.</td>
<td>INFORMATION IN BRAILLE</td>
</tr>
</tbody>
</table>
B. PACKAGE LEAFLET
Dasselta 5 mg film-coated tablets
Desloratadine

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What Dasselta is and what it is used for
2. Before you take Dasselta
3. How to take Dasselta
4. Possible side effects
5. How to store Dasselta
6. Further information

1. WHAT DASSELTA IS AND WHAT IT IS USED FOR

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

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). 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.

Dasselta is indicated for adults and adolescents (12 years of age and older).

2. BEFORE YOU TAKE DASSELTA

Do not take Dasselta
- if you are allergic (hypersensitive) to desloratadine, to any of the other ingredients of Dasselta or to loratadine.

Take special care with Dasselta
- if you have poor kidney function.

If this applies to you, or if you are not sure, please check with your doctor before taking Dasselta.

Children
Dasselta should not be used in children under 12 years old.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
There are no known interactions of Dasselta with other medicines.

**Taking Dasselta with food and drink**
Dasselta may be taken with or without a meal.

**Pregnancy and breast-feeding**
Ask your doctor or pharmacist for advice before taking any medicine during pregnancy and breastfeeding.

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

**Driving and using machines**
At the recommended dose, Dasselta is not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

**Important information about some of the ingredients of Dasselta**
Dasselta contains 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 DASSELTA**

Adults and adolescents (12 years of age and older): take one tablet once a day. Swallow the tablet whole with water, with or without food.

Regarding the duration of treatment, your doctor will determine the type of allergic disease 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 problems are expected with accidental overdose. However, if you take more Dasselta than you were told to, contact your doctor or pharmacist.

**If you forget to take Dasselta**
If you forget to take your dose on time, take it as soon as possible, 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, Dasselta 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 (in less than 1 user in 10,000). Seek immediate medical care if this occurs.

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

Very rare side effects reported during the marketing:
- rash,
- palpitations,
- rapid heartbeat,
- stomach pain,
- nausea (feeling sick),
- vomiting,
- upset stomach,
- diarrhoea,
- dizziness,
- drowsiness,
- inability to sleep,
- muscle pain,
- hallucinations,
- seizures,
- restlessness with increased body movement,
- liver inflammation,
- abnormal liver function tests.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DASSELTA

Keep out of the reach and sight of children.

Do not use Dasselta 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.

After first opening of the tablet container, the product should be used within 3 months.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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), sodium hydroxide (E524), maize starch, lactose monohydrate and talc (E553b).
- The other ingredients in the film-coating are: hypromellose (E464), macrogol, lactose monohydrate, 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.
Dasselta is available in carton boxes of 7, 10, 20, 30, 50, 90 and 100 film-coated tablets in blisters and in plastic 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

**Manufacturers**
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:

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KRKA, d.d., Novo mesto
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**Luxembourg/Luxemburg**
KRKA, d.d., Novo mesto
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**България**
Представительство на KRKA в България
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KRKA Magyarország Kereskedelmi Kft.
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KRKA Sverige AB
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**Portugal**
KRKA Farmacêutica, Unipessoal Lda.
Tel: + 351 (0)21 46 43 650

**France**
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**Ísland**
KRKA Sverige AB

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Detailed information on this medicine is available on the European Medicines Agency web site: