

Dasselta Film-coated Tablets

Desloratadine (5 mg)

What is in this leaflet

1. What *Dasselta* is used for
2. How *Dasselta* works
3. Before you use *Dasselta*
4. How to use *Dasselta*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Dasselta* Product Description
8. Manufacturer and Product Registration Holder
9. Date of revision

What *Dasselta* is used for

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

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

How *Dasselta* works

Dasselta tablets are indicated for the rapid relief of symptoms associated with allergic rhinitis such as sneezing, nasal discharge, itching, congestion/stuffiness, as well as ocular itching, tearing and redness.

Dasselta tablets are also indicated for the relief of symptoms associated with chronic idiopathic urticaria such as the relief of itching and the size and number of hives.

Before you use *Dasselta*

When you must not use it

If you are allergic to desloratadine, to any of the other ingredients of this medicine (listed in Product Description) or to loratadine.

Pregnancy and lactation

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.

Before you start use it

If you have poor kidney, *Dasselta* should be used with caution. If this applies to you, or if you are not sure, please check with your doctor before taking *Dasselta*.

Use in children and adolescents

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

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription.

There are no known interactions of *Dasselta* with other medicines.

Caution is advised if alcohol is taken concomitantly with *Dasselta*.

How to use *Dasselta*

How much to use

Adults and adolescents (12 years of age and older): once *Dasselta* 5 mg film-coated tablets once daily regardless of mealtime for the relief of symptoms associated with allergic rhinitis (including intermittent and persistent allergic rhinitis) and urticarial.

When to use it

Swallow the tablet whole with water, with or without food.

How long to use it

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.

If you forget to use it

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 use too much (overdose)

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.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking *Dasselta*.

Tell your doctor immediately if you become pregnant while taking this medication.

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

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Dasselta* to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

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.

Side effects

Like all medicines, *Dasselta* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Dasselta Film-coated Tablets

Desloratadine (5 mg)

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of 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.

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

Common:

- fatigue
- dry mouth
- headache

Very rare:

- severe allergic reactions
- fast heartbeat
- vomiting
- dizziness
- muscle pain
- restlessness with increased body movement
- rash
- stomach ache
- upset stomach
- drowsiness
- hallucinations
- liver inflammation
- pounding or irregular heartbeat
- feeling sick (nausea)
- diarrhoea
- inability to sleep
- seizures
- abnormal liver function tests

Not known:

- 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

- yellowing of the skin and/or eyes (jaundice)
- change in the way the heart beats

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Dasselta

Storage

Keep out of the sight and reach of children.

Do not store above 30 °C.

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

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

Disposal

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.

Product Description

What it looks like

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

Blisters packs: 10 or 100 tablets in a folding box.

Not all pack sizes may be marketed.

Ingredients

Active ingredient

Each film-coated tablet contains 5 mg desloratadine.

Inactive ingredients

In the tablet core are: microcrystalline cellulose, hypromellose, hydrochloric acid, sodium hydroxide, maize starch, lactose monohydrate and talc.

In the film-coating are: hypromellose, macrogol, lactose monohydrate, titanium dioxide (E171) and indigo carmine (E132).

MAL number:

MAL0000000AZ

Manufacturer

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

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai, 5 ½ Miles off
Jalan Meru, Klang, Selangor,
MALAYSIA.

Date of revision

08/08/2017