ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Desloratadine ratiopharm 5 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg desloratadine.

Excipient(s) with known effect:
Each tablet contains 14.25 mg lactose (as monohydrate).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

Round, biconvex, blue film-coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Desloratadine ratiopharm is indicated in adults for the relief of symptoms associated with:
- allergic rhinitis (see section 5.1)
- chronic idiopathic urticaria as initially diagnosed by a physician (see section 5.1)

4.2 Posology and method of administration

Posology

The recommended dose is one tablet once a day.

Duration of treatment

The duration of treatment depends on the type, duration and course of symptoms.
If symptoms persist for more than 7 days or deteriorate, patients should seek medical advice in order to minimise the risk of masking an underlying disease.

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.

For chronic idiopathic urticaria the symptoms may persist more than 6 weeks it is characterised by recurrent episodes and continued treatment may be necessary.

Paediatric population
Desloratadine ratiopharm is not recommended for use in children and adolescents below 18 years of age.
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 Desloratadine ratiopharm 5 mg film-coated tablets in children below the age of 12 years have not been established.
Currently available data are described in sections 4.8 and 5.1 but no recommendation on a posology can be made.

Method of administration

Oral use.
The tablet can be taken with or without food.

4.3 Contraindications

Hypersensitivity to the active substance, to loratadine or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Chronic idiopathic urticaria

Chronic idiopathic urticarial should initially be diagnosed by a physician.
In case of symptom that indicate angioedema, the patient needs to seek medical help immediately.

Hepatic impairment

In the case of severe hepatic impairment, desloratadine should be used with caution, as hepatitis and jaundice are possible adverse reactions (see section 4.8).

Renal impairment

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

Seizures

Desloratadine should be administered with caution in patients with medical or familial history of seizures, and mainly young children, 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.

Excipients

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

Sodium
This medicinal product 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).

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. Breast-feeding women shall seek medical advice before using desloratadine.

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 %).

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 (≥ 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) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reactions seen with desloratadine
Metabolism and nutrition disorders	Not known	Increased appetite
Psychiatric disorders	Very rare Not known	Hallucinations Abnormal behaviour, aggression
Nervous system disorders	Common Very rare	Headache Dizziness, somnolence, insomnia, psychomotor hyperactivity, seizures
Cardiac disorders	Very rare Not known	Tachycardia, palpitations QT prolongation

System Organ Class	Frequency	Adverse reactions seen with desloratadine
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

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 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: antihistamines – H_1 antagonist, ATC code: R06A X27

Mechanism of action

Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H_1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H_1-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 aetiology, 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 non-responsive 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 cannot 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:
Poloxamer type 188
Citric acid monohydrate
Microcrystalline cellulose
Maize starch
Croscarmellose sodium
Lactose monohydrate
Talc

Film-coating:
Polyvinyl alcohol (part. hydrolysed)
Titanium dioxide (E171)
Macrogol/PEG 3350
Talc
Indigo carmine aluminium lake (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 30 °C.
Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

PVC/PVdC/aluminium blister:
Pack sizes of 7, 10, 14, 15, 20 and 30 film-coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

ratiopharm GmbH
Graf-Arco-Straße 3
89079 Ulm
Germany

8. MARKETING AUTHORISATION NUMBER(S)

EU/1/11/746/001 - Cartons of 7 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/002 - Cartons of 10 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/003 - Cartons of 14 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/004 - Cartons of 15 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/005 - Cartons of 20 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/006 - Cartons of 30 film-coated tablets in PVC/PVdC/aluminium blisters

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 January 2012
Date of latest renewal: 8 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. MANUFACTURERS 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. MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturers responsible for batch release

Merckle GmbH
Ludwig-Merckle-Straße 3
89143 Blaubeuren
Germany

TEVA Pharmaceutical Works Private Limited Company
Pallagi út 13
4042 Debrecen
Hungary

TEVA UK Ltd
Brampton Road, Hampden Park, Eastbourne
East Sussex, BN22 9AG
United Kingdom

Pharmachemie B.V.
Swensweg 5,
2031 GA Haarlem
The Netherlands

Teva Czech Industries s.r.o
Ostravska 29, c.p. 305,
74770 Opava-Komarov
Czech Republic

Teva Operations Poland Sp. Z o.o.
ul. Mogilska 80
31-546 Krakow
Poland

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 not 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)**

The marketing authorisation holder (MAH) shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the European Medicines Agency;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OUTER CARTON

1. NAME OF THE MEDICINAL PRODUCT

Desloratadine ratiopharm 5 mg film-coated tablets
desloratadine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each film-coated tablet contains 5 mg desloratadine.

3. LIST OF EXCIPIENTS

Contains lactose. Read the package leaflet before use.

4. PHARMACEUTICAL FORM AND CONTENTS

7 film-coated tablets
10 film-coated tablets
14 film-coated tablets
15 film-coated tablets
20 film-coated tablets
30 film-coated tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Swallow the tablet whole with water.
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

9. SPECIAL STORAGE CONDITIONS

Do not store above 30 °C.

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

ratiopharm GmbH
Graf-Arco-Straße 3
89079 Ulm
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/11/746/001 - Cartons of 7 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/002 - Cartons of 10 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/003 - Cartons of 14 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/004 - Cartons of 15 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/005 - Cartons of 20 film-coated tablets in PVC/PVdC/aluminium blisters
EU/1/11/746/006 - Cartons of 30 film-coated tablets in PVC/PVdC/aluminium blisters

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription

15. INSTRUCTIONS ON USE

For adults
For treatment of allergic rhinitis
For treatment of chronic idiopathic urticaria, initially diagnosed by a doctor

Talk to your doctor if you do not feel better or if you feel worse after 7 days.

Pregnancy and breastfeeding, please see package leaflet.

Take one tablet per day.

16. INFORMATION IN BRAILLE

Desloratadine ratiopharm 5 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

<Not applicable.>

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

<Not applicable.>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Desloratadine ratiopharm 5 mg film-coated tablets
desloratadine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

ratiopharm

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Desloratadine ratiopharm 5 mg film-coated tablets
desloratadine
For adults

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

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

1. What Desloratadine ratiopharm is and what it is used for

What Desloratadine ratiopharm is
Desloratadine ratiopharm contains desloratadine which is an antihistamine.

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

When Desloratadine ratiopharm should be used
Desloratadine ratiopharm 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. These symptoms include sneezing, runny or itchy nose, itchy palate, and itchy, red or watery eyes.

Desloratadine ratiopharm is also used to relieve the symptoms associated with chronic idiopathic urticaria (a skin condition with unknown cause), initially diagnosed by your doctor. 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.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days. If you notice difficulties in breathing or swelling of lips, tongue or throat you must talk to a doctor immediately.

2. What you need to know before you take Desloratadine ratiopharm

Do not take Desloratadine ratiopharm
- if you are allergic to desloratadine, loratadine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Desloratadine ratiopharm:
- if you have poor kidney function or severe liver disease.
- if you have medical or familial history of seizures.

If you suffer from chronic idiopathic urticaria, this should be diagnosed by your doctor before taking Desloratadine ratiopharm.

Use in children and adolescents
Do not give this medicine to adolescents and children below 18 years of age.

Other medicines and Desloratadine ratiopharm
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
There are no known interactions of Desloratadine ratiopharm with other medicines.

Desloratadine ratiopharm with food, drink and alcohol
Desloratadine ratiopharm may be taken with or without a meal.
Use caution when taking Desloratadine ratiopharm 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.
Taking Desloratadine ratiopharm is not recommended if you are pregnant.
Your doctor will decide if you should stop breast-feeding your baby or stop treatment with Desloratadine ratiopharm.
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.

Desloratadine ratiopharm 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 Desloratadine ratiopharm

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet once a day with water.

The tablet may be taken with or without food. Swallow the tablet whole.

The duration of treatment depends on the type, duration and course of your complaints. You must talk to a doctor if you do not feel better or if you feel worse after 7 days. If you notice difficulties in breathing or swelling of lips, tongue or throat you must talk to a doctor immediately.

If your symptoms of allergic rhinitis used to last for less than 4 days per week or for less than 4 weeks in the past, please use this medicine until your symptoms are resolved. You can start again to use this medicine, when the symptoms return.
If your allergic symptoms used to last for a longer period in the past (4 days or more per week and for more than 4 weeks), continued treatment during the allergen exposure period may be necessary.

For chronic idiopathic urticaria, a treatment for more than 6 weeks may be necessary, depending on your symptoms. If symptoms return after stopping the treatment, you can take this medicine again.

If you take more Desloratadine ratiopharm than you should
No serious problems are expected with accidental overdose. However, if you take more Desloratadine ratiopharm than you should, tell your doctor or pharmacist immediately.

If you forget to take Desloratadine ratiopharm
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 dose.

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.

The following side effects are very rare, but you must stop taking this medicine and seek urgent medical advice straight away if you notice them:
- severe allergic reactions (difficulty in breathing, wheezing, itching, hives and swelling)

Other side effects that may occur:

Common (may affect up to 1 in 10 people)
- fatigue
- dry mouth
- headache

Very rare (may affect up to 1 in 10,000 people)
- rash
- pounding or irregular heartbeat, fast heartbeat
- stomach ache, feeling sick (nausea), vomiting, upset stomach, diarrhoea
- dizziness, drowsiness, inability to sleep, seizures, restlessness with increased body movement
- muscle pain
- hallucinations
- 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
- slow heartbeat, changes in the way the heart beats
- abnormal behaviour, aggression
- weight increased, increased appetite

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 Desloratadine ratiopharm

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 carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.
Store in the original package in order to protect from moisture.
Do not use this medicine if you notice any change in the appearance of the tablets.

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 Desloratadine ratiopharm contains
- The active substance is desloratadine. Each film-coated tablet contains 5 mg desloratadine.
- The other ingredients are:
  Tablet core: poloxamer type 188, citric acid monohydrate, microcrystalline cellulose, maize starch, croscarmellose sodium, lactose monohydrate (see section 2 “Desloratadine ratiopharm contains lactose and sodium”), talc.
  Film-coating: polyvinyl alcohol (part. hydrolysed), titanium dioxide (E171), macrogol/PEG 3350, talc and indigo carmine aluminium lake (E132).

What Desloratadine ratiopharm looks like and contents of the pack
Round, biconvex, blue film-coated tablets.
Desloratadine ratiopharm 5 mg film-coated tablets are supplied in PVC/PVdC/aluminium blister packs of 7, 10, 14, 15, 20 and 30 film-coated tablets.
Not all pack sizes may be marketed.

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