

**PATIENT INFORMATION LEAFLET  
DES LorATADINE (DES-lor-A-ta-deen)  
TABLETS USP**

**Rx only**

Read the Patient Information that comes with desloratadine tablets before you start taking it and each time you get a refill. There may be new information. This leaflet is a summary of the information for patients. Your doctor or pharmacist can give you additional information. This leaflet does not take the place of talking to your doctor about your medical condition or treatment.

**What are desloratadine tablets?**

Desloratadine tablets are prescription medicine that contains the medicine desloratadine (an antihistamine).

Desloratadine tablets are used to help control the symptoms of:

- seasonal allergic rhinitis (sneezing, stuffy nose, runny nose and itching of the nose) in people 12 years of age and older.
- perennial allergic rhinitis (sneezing, stuffy nose, runny nose and itching of the nose) in people 12 years of age and older.

Desloratadine tablets are not for children younger than 12 years of age.

**Who should not take desloratadine tablets?**

Do not take desloratadine tablets if you:

- are allergic to desloratadine or any of the ingredients in desloratadine tablets. See the end of this leaflet for a complete list of ingredients.
- are allergic to loratadine (Alavert, Claritin).

Talk to your doctor before taking this medicine if you have any questions about whether or not to take this medicine.

**What should I tell my doctor before taking desloratadine tablets?**

Before you take desloratadine tablets, tell your doctor if you:

- have liver or kidney problems.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if desloratadine tablets

will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.

- are breast-feeding or plan to breast-feed. Desloratadine **can pass into your breast milk**. Talk to your doctor about the best way to feed your baby if you take desloratadine tablets.

**Tell your doctor about all the medicines you take,**

including prescription and non-prescription medicines, vitamins and herbal supplements. Desloratadine tablets may affect the way other medicines work, and other medicines may affect how desloratadine works. Especially tell your doctor if you take:

- ketoconazole (Nizoral)
- erythromycin (Ery-tab, Eryc, PCE)
- azithromycin (Zithromax, Zmax)
- antihistamines
- fluoxetine (Prozac)
- cimetidine (Tagamet)

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

**How should I take desloratadine tablets?**

- Take desloratadine tablets exactly as your doctor tells you to take it.
- Do not change your dose of desloratadine tablets or take more often than prescribed.
- Desloratadine tablets can be taken with or without food.
- If you take too much desloratadine tablets, call your doctor or get medical attention right away.

**What are the possible side effects of desloratadine tablets?**

Desloratadine tablets may cause serious side effects, including:

- Allergic reactions. Stop taking desloratadine tablets and call your doctor right away or get emergency help if you have any of these symptoms:
  - rash
  - itching
  - hives
  - swelling of your lips, tongue, face, and throat

**SAP Code: 6010002090  
263068 Desloratadine Tabs Med Guide(Bklt)-v1.pdf**

Issued For Final Production :-	
Issued For Re-Approval :-	
Issued For Approval :-	13-Nov-19 10:32:28
<b>TEMPLE Packaging Pvt. Ltd.</b>	
Tel:- 28476601, Email:- info@templepackaging.co.in	
Customer :-	LUPIN LTD.
Location :-	Goa
Product Name :-	MG DESLOERATIDINE TABS USP US R4
Product Code :-	263068
Version No. :-	01
Date :-	13-Nov-19
Artwork Status :-	FINAL
Open Size :-	200X140 MM
Folding Size :-	24PGS/BOOKLET
Substrate :-	60 GSM MAPLITHO PAPER
Cover Page :-	NA
Remark :-	NA
Printing Colours	



Note - This approval will be considered for final printing. Please recheck for corrections indicated earlier, in this proof also.			
Prepared by :	Checked by :	Q.A. Checked :	Approved by :
13-Nov-19	shaji		

CUSTOMER APPROVAL			
Checked By		Approved By	
Packaging Development	Production	Regulatory Affairs	Quality Assurance

- shortness of breath or trouble breathing

The most common side effects of desloratadine tablets in adults and children 12 years of age and older with allergic rhinitis include:

- sore throat
- dry mouth
- muscle pain
- tiredness
- sleepiness
- menstrual pain

Increased sleepiness or tiredness can happen if you take more desloratadine tablets than your doctor prescribed to you.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of desloratadine tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. **You may report side effects to Lupin Pharmaceuticals, Inc at 1-800-399-2561 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch)**

#### How should I store desloratadine tablets?

- Store at 25° C (77° F); excursions permitted to 15° to 30° C (59° to 86° F).
- **Desloratadine tablets** are sensitive to heat. Do not store above 30°C (86°F).
- Protect **desloratadine tablets** from moisture.

Keep **desloratadine tablets** and all medicines out of the reach of children.

#### General information about desloratadine tablets

Medicines are sometimes prescribed for purposes other than those listed in a patient information leaflet. Do not use desloratadine tablets for a condition for which it was not prescribed. Do not give desloratadine tablets to other people, even if they have the same condition you have. It may harm them.

This Patient Information leaflet summarizes the most important information about desloratadine tablets. If you would like more

information, talk with your doctor. You can ask your pharmacist or doctor for information about desloratadine tablets that is written for health professionals.

#### What are the ingredients in desloratadine tablets?

Active ingredient: desloratadine

**Inactive ingredients in desloratadine tablets:** anhydrous lactose, colloidal silicon dioxide, FD&C Blue#2/Indigo Carmine Aluminium Lake, hydrogenated vegetable oil, hypromellose, microcrystalline cellulose, polyethylene glycol, pregelatinised starch and titanium dioxide.

The brands listed are trademarks of their respective owners and are not trademarks of Lupin Pharmaceuticals, Inc. The makers of these brands are not affiliated with and do not endorse Lupin Pharmaceuticals, Inc. or its products.

Manufactured for:  
**Lupin Pharmaceuticals, Inc.**  
Baltimore, Maryland 21202  
United States

Manufactured by:  
**Lupin Limited**  
Goa 403 722  
INDIA

Revised: February 2020

ID#: 263068

**SAP Code: 6010002090**

**263068 Desloratadine Tabs Med Guide(Bklt)-v1.pdf**

Issued For Final Production :-	
Issued For Re-Approval :-	
Issued For Approval :-	13-Nov-19 10:32:28
<b>TEMPLE Packaging Pvt. Ltd.</b>	
Tel:- 28476601, Email:- <a href="mailto:info@templepackaging.co.in">info@templepackaging.co.in</a>	
Customer :-	LUPIN LTD.
Location :-	Goa
Product Name :-	MG DESLOERATIDINE TABS USP US R4
Product Code :-	263068
Version No. :-	01
Date :-	13-Nov-19
Artwork Status :-	FINAL
Open Size :-	200X140 MM
Folding Size :-	24PGS/BOOKLET
Substrate :-	60 GSM MAPLITHO PAPER
Cover Page :-	NA
Remark :-	NA
Printing Colours	

K

Note - This approval will be considered for final printing. Please recheck for corrections indicated earlier, in this proof also.				
Prepared by :	Checked by :	Q.A. Checked :	Approved by :	
13-Nov-19	shaji			
<b>CUSTOMER APPROVAL</b>				
Checked By		Approved By		
Packaging Development	Production	Regulatory Affairs	Quality Assurance	