NEW ZEALAND CONSUMER MEDICINE INFORMATION

LORA-TABS® ALLERGY & HAYFEVER

Loratadine tablets 10 mg

What is in this leaflet

Please read this leaflet carefully before you start taking LORA-TABS ALLERGY & HAYFEVER.

This leaflet answers some common questions about LORA-TABS ALLERGY & HAYFEVER.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking LORA-TABS ALLERGY & HAYFEVER against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What LORA-TABS ALLERGY & HAYFEVER is used for

LORA-TABS ALLERGY & HAYFEVER is used to relieve symptoms associated with allergic rhinitis (hayfever), such as sneezing, runny or itchy nose, and burning or itchy eyes.

LORA-TABS ALLERGY & HAYFEVER may also be used to relieve symptoms associated with a skin condition called urticaria; these symptoms include itching, redness and lumps on the skin called hives.

LORA-TABS ALLERGY & HAYFEVER contains the active ingredient loratadine. It belongs to a group of medicines called antihistamines.

Antihistamines help reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced by the body.

Your doctor or pharmacist may, however, have recommended this medicine for another reason.

Ask your doctor or pharmacist if you have any questions about why this medicine has been recommended for you.

LORA-TABS ALLERGY & HAYFEVER is only available from a pharmacy.

There is no evidence that LORA-TABS ALLERGY & HAYFEVER is addictive.

Before you take LORA-TABS ALLERGY & HAYFEVER

When you must not take it

Do not take LORA-TABS ALLERGY & HAYFEVER if you have an allergy to:

- any medicine containing loratadine.
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give this medicine to a child under the age of 2 years. Safety and effectiveness in children younger than 2 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- liver problems
- intolerance to some sugars

They may advise you not to take the medicine or to take a smaller amount.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking LORA-TABS ALLERGY & HAYFEVER.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking LORA-TABS ALLERGY & HAYFEVER.

Some medicines may interfere with LORA-TABS ALLERGY & HAYFEVER. These include:

- ketoconazole, a medicine used to treat fungal infections
- erythromycin, an antibiotic medicine used to treat a number of bacterial infections
- cimetidine, a medicine used to treat heartburn and stomach ulcers

These medicines may be affected by LORA-TABS ALLERGY & HAYFEVER or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take LORA-TABS ALLERGY & HAYFEVER

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

The usual dosage for adults and children over 12 years is one tablet daily.

The usual dosage for children 2 to 12 years of age, weighing over 30 kg is one tablet daily (10 mg).

The usual dosage for children 2 to 12 years of age, weighing less than 30 kg is half a tablet daily (5 mg). Do not give to children under 2 years of age.

How to take it

Swallow the tablet with a full glass of water.

The tablet may be halved if you have difficulty swallowing it whole.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor or pharmacist tells you. This medicine helps to control your condition, but does not cure it

If you forget to take it

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking LORA-TABS ALLERGY & HAYFEVER

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking LORA-TABS ALLERGY & HAYFEVER.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are scheduled to have skin tests for allergies, do not take LORA-TABS ALLERGY & HAYFEVER for 2 days (48 hours) before having the tests. It may interfere with the results for these tests.

Things you must not do

Do not take LORA-TABS ALLERGY & HAYFEVER to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how LORA-TABS ALLERGY & HAYFEVER affects you.

This medicine may cause drowsiness in some people. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

Children should be careful when riding bicycles or climbing trees.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much LORA-TABS ALLERGY & HAYFEVER. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include tiredness, fast or irregular heartbeat and headache.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LORA-TABS ALLERGY & HAYFEVER. This medicine helps most people with allergies, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness
- dizziness
- convulsion
- feeling sick
- stomach problems
- tiredness
- headache
- increased appetite
- increased weight
- difficulty sleeping
- nervousness
- dry mouth
- unusual hair loss or thinning

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- skin and eyes that appear yellowish
- dark urine colour
- abdominal pain

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- shortness of breath
- fast or irregular heartbeat
- skin rash

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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

After taking LORA-TABS ALLERGY & HAYFEVER

Storage

Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store LORA-TABS ALLERGY & HAYFEVER or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-anda half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description.

What it looks like

LORA-TABS ALLERGY & HAYFEVER tablets are white to offwhite coloured oval shaped biconvex uncoated tablets with breakline and 10 on one side and plain on the other side.

Ingredients

<u>Active ingredient:</u> LORA-TABS ALLERGY & HAYFEVER contains 10 mg of loratadine as the active ingredient.

Inactive ingredients: LORA-TABS ALLERGY & HAYFEVER also contains:

- lactose monohydrate
- maize starch
- colloidal anhydrous silica
- magnesium stearate
- sodium lauryl sulfate
- sodium starch glycolate
- purified water

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

LORA-TABS ALLERGY & HAYFEVER is supplied in New Zealand by:

Arrotex Pharmaceuticals (NZ) Limited c/o Quigg Partners Level 7, The Bayleys Building 36 Brandon Street Wellington 6011

Date of Preparation

05 November 2024 (Based on datasheet dated 05 November 2024).