

AVOTYNE 10MG TABLET

Loratadine 10mg



Read all of this leaflet carefully before you start taking this medicine.

Avotyne 10mg Tablet is referred to as only "Avotyne" in this leaflet.

What is in this leaflet:

- What Avotyne is used for
- How Avotyne works
- Before you use Avotyne
- How to use Avotyne
- While you are using Avotyne
- Side effect
- Storage and disposal of Avotyne
- Product description
- Manufacturer
- Product Registration Holder
- Date of revision
- Serial Number

What Avotyne is used for:

The name of your medicine is Avotyne 10 mg Tablet (called „Avotyne“ in this leaflet). Avotyne contains a medicine called loratadine.

Avotyne is used for the symptomatic treatment of allergic inflammation of the nasal airways, prolonged itchy rash and allergic skin disorders.

How Avotyne works:

AVOTYNE belongs to a group of medicines called tricyclic antihistamine with selective peripheral H1-receptor antagonistic activity. It is a long-acting non-sedating antihistamine, but without any significant sedative or anticholinergic properties.

Before you use Avotyne:**When you must not use it.**

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to loratadine or any of the other ingredients of Avotyne (listed in Section 6 below).
- You are pregnant or breast feeding.
- You are below 6 years old.
- You have liver problems
- You have lactose intolerance, as this medicine contains lactose
- You are operating heavy machineries or intend to drive

Before you start to use it.

Check with your doctor or pharmacist before taking this medicine:

- If you are pregnant or planning to become pregnant.
- If you are breast feeding. You should choose to bottle feed your baby or not take Avotyne.
- If you consume high volume of alcohol
- If you have liver problems

Taking other medicines.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

Potential interaction may occur with all known inhibitors of CYP3A4 or CYP2D6 resulting in elevated levels of loratadine, which may cause an increase in adverse events.

How to take Avotyne:**How much to use:**

Adults and children over 12 years of age: 10mg once daily (one tablet once daily).

Children 2 to 12 years of age are dosed by weight:

Bodyweight more than 30kg: 10mg once daily (one tablet once daily).

Bodyweight less than 30kg: 5mg once daily (half tablet once daily).

The above dose may be decreased or increased by your doctor, if needed.

Hence, always take AVOTYNE as directed by your doctor.

When to use it.

AVOTYNE can be taken with or without food.

How long to use it.

The time period for taking AVOTYNE depends on your doctor's instruction.

If you forget to use it.

If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at your regular time.

If you take too much (overdose).

If you take too much AVOTYNE, call your doctor or Poison Control Center, or go to the nearest hospital emergency room right away.

While you are using Avotyne:**Things you must do.**

- Swallow the tablets whole with a glass of water
- Take your dose at same time of the day
- Never take 2 doses in 1 day unless instructed by your doctor.
- Keep taking Avotyne until the treatment is finished, even if you feel better.

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

Things you must not do.

Do not stop your medication without consulting your doctor.

Things to be careful of.

- If you have liver problems the dose might be lowered. You may have more frequent blood tests to see how your liver is working.
- Pregnancy and breast-feeding: ask your doctor or pharmacist for advice before taking any medicine if you think you might be or if you are pregnant or if you are breastfeeding.
- Inform your doctor if you have lactose intolerance as this medicine contains lactose.
- Although there is no reports of impairment in driving ability, avoid driving while taking this medicine.

Side effect:

The most frequent adverse reactions reported were somnolence, headache, increased appetite, nervousness, fatigue and insomnia. Other adverse reactions reported very rarely are as below:

- Serious allergic reactions (anaphylaxis)
- Dizziness

- Increase in heart rate and palpitation
- Nausea
- Dry mouth
- Inflammation of stomach lining (gastritis)
- Abnormal liver function
- Rash
- Loss of hair (alopecia)
- Fatigue

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Avotyne:**Storage.**

- Keep out of the reach and sight of children.
- Do not use Avotyne after the expiry date refers to the last day on the carton. The expiry date refers to the last day of that month.
- Store in the original pack in a dry place at or below 30°C.
- Do not use Avotyne if the tablets are chipped or there are other visible signs of deterioration.

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.**

The tablet is a white oval-shaped tablet, one side with score, the other side with "CCP" mark.

Ingredients in AVOTYNE

Active ingredients: Loratadine

Inactive ingredients: Lactose, base granule and magnesium stearate.

MAL No.: MAL13115129ACZ

Manufacturer:

China Chemical & Pharmaceutical Co. Ltd., No. 182-1, Keng Tze Kou, Hsinfong Shiang, Hsinchu County 304, Taiwan R.O.C.

Product Registration Holder:

Abio Marketing Sdn Bhd, No. 2, Jalan SS 13/5, 47500 Subang Jaya, Selangor, Malaysia

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