

AXCEL OXYMETAZOLINE Consumer Medication Information Leaflet (RiMUP)

NASAL DROPS

Oxymetazoline HCl (0.025%/0.05% w/v)

WHAT IS IN THIS LEAFLET

1. What Axcel Oxymetazoline Nasal Drops is used for.
2. How Axcel Oxymetazoline Nasal Drops works.
3. Before you use Axcel Oxymetazoline Nasal Drops.
4. How to take Axcel Oxymetazoline Nasal Drops.
5. While you are using it.
6. Side effects.
7. Storage and disposal of Axcel Oxymetazoline Nasal Drops.
8. Product description.
9. Manufacturer and Product Registration Holder.
10. Date of revision.

WHAT AXCEL OXYMETAZOLINE NASAL DROPS IS USED FOR

Axcel Oxymetazoline Nasal Drops is used for relief of nasal congestion in acute colds, paranasal sinusitis (inflammation of the sinuses at the air spaces within the bones of the face) and otitis media (inflammation of the middle ear).

HOW AXCEL OXYMETAZOLINE NASAL DROPS WORKS

Oxymetazoline is a direct – acting sympathomimetic agent which has a vasoconstrictor effect on mucosal blood vessels. Sympathomimetic agent is widely used as nasal decongestants to provide symptomatic relief. They act by vasoconstriction and redistributing local blood flow to reduce oedema of the nasal mucosa (swelling of the mucous membrane) thus improving ventilation, drainage and nasal stuffiness.

BEFORE YOU USE AXCEL OXYMETAZOLINE NASAL DROPS

When you must not use it

Do not use Axcel Oxymetazoline Nasal Drops if:

- If you are allergic or hypersensitive to Oxymetazoline and Benzalkonium Chloride.

- If you have inflammation of the skin and rhinitis sicca (chronic form of dryness of the mucous membranes in the nose).
- Do not use Axcel Oxymetazoline Nasal Drops if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not use Axcel Oxymetazoline Nasal Drops if you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

Before you start to use it

Tell your doctor if:

- If you are receiving treatment with monoamine-oxidase inhibitors (MAOI's)
- If you are having heart disease, high blood pressure, thyroid disease, diabetes or difficulty in urination.
- If you are on pregnancy and breastfeeding.
- Should not be used in children younger than 1 year of age.

Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Oxymetazoline Nasal Drops:

- Antihypertensive (agent to lower blood pressure) therapy.
- Monoamine oxidase inhibitors (MAOI) (for the treatment of depression).

HOW TO USE AXCEL OXYMETAZOLINE NASAL DROPS

How much to use

Direction for use:

Axcel Oxymetazoline 0.025% Nasal Drops: Children above 1 year old.

Axcel Oxymetazoline 0.05% Nasal Drops: Adults and children above 6 years old.

Unless otherwise prescribed, instill 1-2 drops of Axcel Oxymetazoline Nasal Drops from the dropper into each nostril 2-3 times daily.

Application: Do not swallow.

When to use it

Your doctor will decide when it is appropriate for you to use Axcel Oxymetazoline Nasal Drops according to the type of condition you have.

How long to use it

Continue taking Axcel Oxymetazoline Nasal Drops for as long as doctor recommends.

The medicine should not be used more frequently than recommended. Unless, specifically prescribed by the doctor, should not be used for up to 4 weeks.

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Use the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not use a double dose to make up for the missed dose.

If you use too much (overdose)

Symptoms of overdose:

- Central nervous system depression leading to coma and marked reduction in body temperature, especially in infants
- Tachycardia (a faster than normal heart rate)
- Sleepiness
- Shock-like states

It is advisable for you to contact and inform your doctor if you did take Axcel Oxymetazoline Nasal Drops too much.

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 treating you that you are taking Axcel Oxymetazoline Nasal Drops.

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

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 Axcel Oxymetazoline Nasal Drops to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

- Avoid prolonged usage with high dosage.
- The usage is restricted to periods of not more than 7 consecutive days, or if necessary not longer than 4 weeks.
- Avoid using the product dispenser by more than one person as it may spread infection.
- If you are pregnant and breastfeeding.

SIDE EFFECTS

Like all medicines, Axcel Oxymetazoline Nasal Drops can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

- Local stinging or burning, sneezing and dryness of the mouth and throat.
- Prolonged or excessive use may cause rebound congestion and drug induced rhinitis (inflammation of the mucous membrane inside the nose).

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 AXCEL OXYMETAZOLINE NASAL DROPS

Storage

Keep Axcel Oxymetazoline Nasal Drops out of reach of children. Store below 30°C. Keep container well closed and protect from light.

Disposal

Do not use Axcel Oxymetazoline Nasal Drops after the expiry date which is stated on the carton. 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

Axcel Oxymetazoline Nasal Drops is a clear, colorless liquid.

Ingredients

Active Ingredient:
Oxymetazoline HCl

Inactive Ingredients:

Benzalkonium Chloride, EDTA, Dibasic Sodium Phosphate, Citric Acid, PVP K30, Sorbitol, Glycerin and Purified Water.

MAL Numbers

Axcel Oxymetazoline 0.025% Nasal Drops
MAL20040821A

Axcel Oxymetazoline 0.05% Nasal Drops
MAL20033489A

MANUFACTURER AND PRODUCT REGISTRATION HOLDER

KOTRA PHARMA (M) SDN BHD
No. 1, 2 & 3, Jalan TTC 12,
Cheng Industrial Estate,
75250 Melaka, Malaysia.

DATE OF REVISION

10/12/2014

SERIAL NUMBER

BPFK(R4/1)041214/00071