AXCEL OXYMETAZOLINE NASAL SPRAY

Oxymetazoline Hydrochloride (0.025% w/v, 0.05% w/v)

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What Axcel Oxymetazoline Nasal Spray is used for

Axcel Oxymetazoline Nasal Spray is used for symptomatic relief of nasal and nasopharyngeal congestion.

How Axcel Oxymetazoline Nasal Spray works

Oxymetazoline is a direct – acting sympathomimetic agent which has a narrowing of the blood vessel effect. They act by redistributing local blood flow to reduce swelling of the nasal lining thus improving ventilation, drainage and nasal stuffiness.

Before you use Axcel Oxymetazoline Nasal Spray

-When you must not use it

Do not use Axcel Oxymetazoline Nasal Spray if:

- You are allergic or hypersensitive to any component of this medication.
- You are pregnant, trying to get pregnant or think you may be pregnant.
- You are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it

Tell your doctor if:

 You are having heart disease, high blood pressure, thyroid disease, diabetes or difficulty in urination.

-Taking other medicines

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

• Tricyclic antidepressant, maprotiline or monoamine oxidase inhibitors (MAOI).

It may still be all right for you to use Axcel Oxymetazoline Nasal Spray and your doctor will be able to decide what is suitable for you.

How to use Axcel Oxymetazoline Nasal Spray

-How much to use

Direction for use:

2-3 sprays into each nostril twice a day, morning and evening.

With the head upright, place the spray nozzle into the nostril without completely occluding the nostril. During each use, you should bend your head slightly forward and press the pump spray quickly and firmly to spray the recommended number of sprays in each nostril. Wipe nozzle clean after use.

For children 2 to 6 years of age, Axcel Oxymetazoline Nasal Spray 0.025% is used.

For adult and children 6 years and above, Axcel Oxymetazoline Nasal Spray 0.05% is used.

-When to use it

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

-How long to use it

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

-If you forget to use it

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

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)

 Overdosage may cause central nervous system depression, leading to coma and marked reduction in body temperature, especially in infants.

It is advisable for you to contact and inform your doctor if you did use Axcel Oxymetazoline Nasal Spray 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 Spray.
- 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 or pharmacist.
- Do not give Axcel Oxymetazoline Nasal Spray to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

- Do not exceed the recommended dosage.
- Avoid prolonged usage and avoid excess use.
- The usage is restricted to periods of not more than 3 consecutive days.
- Avoid using the product dispenser by more than one person may spread infection.

Side effects

Like all medicines, Axcel Oxymetazoline Nasal Spray can cause side effects although not everybody gets them. You are

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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 medicine induced rhinitis (inflammation of the lining 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 npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and disposal of Axcel Oxymetazoline Nasal Spray

-Storage

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

Disposal

Do not use Axcel Oxymetazoline Nasal Spray 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 Spray is a colorless liquid.

-Ingredients

- Active Ingredient: Oxymetazoline Hydrochloride
- Inactive Ingredients:

 Benzalkonium Chloride,
 Disodium Edetate, Disodium
 Hydrogen Phosphate Anhydrous,
 Citric Acid Anhydrous, Sorbitol,
 Glycerin, Sodium Hydroxide and
 Purified water.

-MAL Numbers

Axcel Oxymetazoline 0.025% Nasal Spray MAL09032006AZ

Axcel Oxymetazoline 0.05% Nasal Spray MAL09032007AZ

Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd No. 1, 2 & 3, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka, Malaysia.

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15/02/2018

Serial number

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