

AXCEL MOMETASONE 0.05% W/W NASAL SPRAY

Mometasone Furoate Monohydrate (0.05%w/w)

What is in this leaflet

1. What Axcel Mometasone 0.05% Nasal Spray Is Used For.
2. How Axcel Mometasone 0.05% Nasal Spray Works.
3. Before You Use Axcel Mometasone 0.05% Nasal Spray.
4. How to Take Axcel Mometasone 0.05% Nasal Spray.
5. While You Are Using It.
6. Side Effects.
7. Storage and Disposal of Axcel Mometasone 0.05% Nasal Spray.
8. Product Description.
9. Manufacturer and Product Registration Holder.
10. Date of revision.

What Axcel Mometasone 0.05% Nasal Spray is used for

Axcel Mometasone 0.05% Nasal Spray is used to treat the symptoms of seasonal (hay fever) or perennial rhinitis in adults and children 3 years of age and older. It also used to treat nasal polyps in patients 18 years and above.

How Axcel Mometasone 0.05% Nasal Spray works

Mometasone Furoate is a topical glucocorticosteroid with local anti-inflammatory properties at doses that are not systemically active.

Before you use Axcel Mometasone 0.05% Nasal Spray

-When you must not use it

Do not take Axcel Mometasone 0.05% Nasal Spray if:

- You are sensitive to Mometasone furoate or to any other component of this preparation.
- Severe nasal infection especially candidiasis.
- Hemorrhagic diathesis or with a history of recurrent nasal bleeding.

-Before you start to use it

Tell your doctor if:

- are pregnant or nursing baby.
- are allergic to Mometasone or other corticosteroid medicines.

-Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Mometasone 0.05% Nasal Spray:

- Loratadine

It may still be all right for you to take Axcel Mometasone 0.05% Nasal Spray and your doctor will be able to decide what is suitable for you.

How to use Axcel Mometasone 0.05% Nasal Spray

After initial priming of the Axcel Mometasone 0.05%w/w Nasal Spray (Usually 6 or 7 actuations, until a uniform spray is observed), each actuation delivers approximately 100mg of mometasone furoate suspension, containing mometasone furoate monohydrate equivalent to 50mcg mometasone furoate. If the spray pump has not been used for 14 days or longer, it should be reprimed before next use. Shake container well before each use.

-How much to use

Seasonal allergic or perennial rhinitis: Adults (including geriatric patients) and adolescents: The usual recommended dose for prophylaxis and treatment is two sprays (50mcg/spray) in each nostril once daily (total dose 200 mcg). Once symptoms are controlled, dose reduction to one spray in each nostril (total dose 100 mcg) may be effective for maintenance.

If symptoms are inadequately controlled, the dose may be increased to a maximum daily dose of four sprays in each nostril once daily (total dose 400mcg). Dose reduction is recommended following control of symptoms.

Clinically significant onset of action occurs as early as 12 hours after the first dose.

Children between the ages of 3 and 11 years: The usual recommended dose is one spray (50 mcg/spray) in each nostril once daily (total dose 100 mcg).

Administration to young children should be aided by an adult.

Nasal polyposis:

Adults (including geriatric patients) and adolescents 18 years of age and older: The usual recommended dose for polyposis is two sprays (50mcg/spray) in each nostril twice daily (total daily dose of 400 mcg). Once symptoms are

adequately controlled, dose reduction to two sprays in each nostril once daily (total daily dose 200 mcg) is recommended.

-When to use it

When you showed the symptoms of seasonal or perennial rhinitis or nasal polyposis.

-How long to use it

- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

-If you forget to use it

- Do not double up the dosage as Axcel Mometasone 0.05% Nasal Spray may give you unacceptable side effects.

-If you use too much (overdose)

- Overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage. It is advisable for you to contact and inform your doctor if you did take Axcel Mometasone 0.05% Nasal Spray too much.

While you are using it

-Things you must do

- Discuss with your doctor or pharmacist the dos' and don'ts' while taking this medicine.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Take the Axcel Mometasone 0.05% Nasal Spray according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

-Things you must not do

- Do not take your medicine more than the suggested frequency in a day.
- Do not over dosage the medicine during any single consumption.

-Things to be careful of

- Used with caution if you are with active or quiescent tuberculous

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infections of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections or ocular herpes simplex. Adrenal suppression may occur especially in infants and children.

- Patients who are transferred from long-term administration of systemically active corticosteroids to Axcel Mometasone 0.05%w/w Nasal Spray require careful attention.
- Treatment with higher than recommended doses may result in clinically significant adrenal suppression. If there is evidence for higher than recommended dose being used, then additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.
- Safety and efficacy of Axcel Mometasone 0.05%w/w Nasal Spray for the treatment of nasal polyposis in children and adolescents less than 18 years of age have not been studied.
- Patients receiving corticosteroids who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (e.g. chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs.

Side effects

Like all medicines, Axcel Mometasone 0.05% Nasal Spray 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:

Common side effects:

- Headache
- Epitaxis
- Frank bleeding
- Blood-tinged mucus
- Blood flecks
- Pharyngitis
- Nasal burning
- Nasal irritation
- Sneezing

Rare side effects:

- Immediate hypersensitivity reactions (eg. Bronchospasm, dyspnea)
- Anaphylaxis
- Angioedema
- Disturbances of taste and smell

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website np.ra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of Axcel Mometasone 0.05% Nasal Spray

-Storage

Keep Axcel Mometasone 0.05% Nasal Spray out of reach of children. Store below 30°C. Keep container well closed and protect from light.

-Disposal

Do not use Axcel Mometasone 0.05% Nasal Spray after the expiry date which is stated on the carton.

Product description

-What it looks like

Axcel Mometasone 0.05% Nasal Spray is white to off white suspension.

-Ingredients

- Active Ingredient (s):

Mometasone Furoate Monohydrate

- Inactive Ingredients:

Benzalkonium Chloride,
Microcrystalline Cellulose,
Carboxymethylcellulose Sodium,
Glycerine, Sodium Citrate, Citric
Acid Anhydrous, Polysorbate 80
and Purified Water

-MAL Number

MAL14025010AZ

Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd
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