

ARX-FLUTICASONE Nasal Spray

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ARX-FLUTICASONE?

ARX-FLUTICASONE contains the active ingredient Fluticasone furoate. ARX-FLUTICASONE is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing, and watery, itchy or red eyes.

For more information, see Section [1. Why am I using ARX-FLUTICASONE?](#) in the full CMI.

2. What should I know before I use ARX-FLUTICASONE?

Do not use if you have ever had an allergic reaction to ARX-FLUTICASONE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ARX-FLUTICASONE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARX-FLUTICASONE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ARX-FLUTICASONE?

- **Adults and adolescents 12 years and older** - The usual starting dose is 2 sprays in each nostril once a day (55 micrograms fluticasone furoate). Once symptoms are controlled you may be able to decrease your dose to 1 spray in each nostril once a day.
- **Children (2 to 11 years):** The usual starting dose is 1 spray in each nostril once a day (27.5 micrograms fluticasone furoate).

More instructions can be found in Section [4. How do I use ARX-FLUTICASONE?](#) in the full CMI.

5. What should I know while using ARX-FLUTICASONE?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using ARX-FLUTICASONE.• Tell your doctor, if you are taking any other medicines.• Tell your doctor if you become pregnant or are trying to become pregnant.• Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.• Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.
Things you should not do	<ul style="list-style-type: none">• Do not stop using ARX-FLUTICASONE or change the dose without first checking with your doctor.• Do not use ARX-FLUTICASONE in or near the eyes.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.• Do not use ARX-FLUTICASONE to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ARX-FLUTICASONE affects you.• ARX-FLUTICASONE is unlikely to affect your ability to drive or use machinery.
Looking after your medicine	<ul style="list-style-type: none">• Store your ARX-FLUTICASONE below 30°C, protected from direct sunlight. Always keep the cap on.• Do not freeze.

For more information, see Section [5. What should I know while using ARX-FLUTICASONE?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. ARX-FLUTICASONE can cause allergic reactions which may be severe. **If you develop symptoms of an allergic reaction, call your doctor straight away or go straight to the Emergency Department at your nearest hospital.**

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ARX-FLUTICASONE

Active ingredient(s): Fluticasone furoate

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARX-FLUTICASONE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ARX-FLUTICASONE.**

Where to find information in this leaflet:

- [1. Why am I using ARX-FLUTICASONE?](#)
- [2. What should I know before I use ARX-FLUTICASONE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ARX-FLUTICASONE?](#)
- [5. What should I know while using ARX-FLUTICASONE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ARX-FLUTICASONE?

ARX-FLUTICASONE contains the active ingredient **fluticasone furoate**. ARX-FLUTICASONE belongs to a group of medicines known as corticosteroids, frequently called 'steroids'. ARX-FLUTICASONE works to decrease inflammation caused by allergy (rhinitis).

ARX-FLUTICASONE is used to treat symptoms of allergic rhinitis including stuffy, runny or itchy nose, sneezing, and watery, itchy or red eyes. The effects are usually felt within the first day, although some people will not feel the effects until several days after first taking it.

Your doctor may have prescribed ARX-FLUTICASONE for another reason.

ARX-FLUTICASONE is not addictive.

2. What should I know before I use ARX-FLUTICASONE?

Warnings

Do not use ARX-FLUTICASONE if:

- you are allergic to fluticasone furoate, or any of the ingredients listed at the end of this leaflet.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if:

- you have any other medical conditions
- you are allergic to foods, dyes, or any other medicine.
- you take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ARX-FLUTICASONE and affect how it works.

For example, medicines like ketoconazole, used to treat fungal infection, and ritonavir used to treat HIV infection, may affect how ARX-FLUTICASONE works. If you are taking these medicines, consult your doctor or pharmacist who will advise on what you should do.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARX-FLUTICASONE.

4. How do I use ARX-FLUTICASONE?

How much to take

Adults and adolescents 12 years and older:

- The usual starting dose is 2 sprays in each nostril once a day (55 micrograms fluticasone furoate).
- Once symptoms are controlled you may be able to decrease your dose to 1 spray in each nostril once a day.

Children (2 to 11 years):

- The usual starting dose is 1 spray in each nostril once a day (27.5 micrograms fluticasone furoate).
- If symptoms are severe, your doctor may increase the dose to 2 sprays in each nostril once a day until symptoms are under control. It may then be possible for the dose to be reduced to 1 spray in each nostril once a day.

Follow the instructions provided and use ARX-FLUTICASONE until your doctor tells you to stop.

When to take ARX-FLUTICASONE

- See the instruction leaflet inside the pack for information on how to use ARX-FLUTICASONE.
- Shake well before use.
- ARX-FLUTICASONE is sprayed into the nose as a fine mist. It has virtually no taste.
- ARX-FLUTICASONE is not for use in the eyes.
- Use ARX-FLUTICASONE once a day and at the same time each day. This will treat your symptoms throughout the day and night.

If you forget to use ARX-FLUTICASONE

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, use the product as soon as you remember, then go back to using the product as you would normally.

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

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

How long to use it for

Your doctor will tell you how long to use ARX-FLUTICASONES.

Do not stop using ARX-FLUTICASONES, or change the dose without first checking with your doctor.

If you use too much ARX-FLUTICASONES

If you think that you or anyone else have used too much ARX-FLUTICASONES, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ARX-FLUTICASONES?

Things you should do

- Tell your doctor or pharmacist that you are using ARX-FLUTICASONES if you are about to be started on any new medicines.
- Tell your doctor if you become pregnant or are trying to become pregnant.
- Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed.
- Tell your doctor if you experience a change in your vision.
- Use ARX-FLUTICASONES only in your nose.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Call your doctor straight away if you experience:

- **Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.**

Remind any doctor, dentist or pharmacist you visit that you are using ARX-FLUTICASONES.

Things you should not do

- **Do not use ARX-FLUTICASONES in or near the eyes.**
- **Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**
- **Do not use ARX-FLUTICASONES to treat any other complaints unless your doctor says to.**

Use in children

ARX-FLUTICASONES is not recommended for use in children below 2 years of age.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARX-FLUTICASONES affects you.

ARX-FLUTICASONES is unlikely to affect your ability to drive or use machinery.

Looking after your medicine

Store your ARX-FLUTICASONES below 25°C.

Protect from direct sunlight.

Do not refrigerate or freeze.

Discard 2 months after opening

Do not store, or any other medicine, in a bathroom or near a sink.

Do not leave ARX-FLUTICASONES in the car or on window sills.

Always keep the cap on.

Keep ARX-FLUTICASONES in its pack until it is time to use it. Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• nose bleeds.• nasal ulceration - which may cause irritation or discomfort in your nose. You may also get streaks of blood when you blow your nose.• headache.• Pain, burning, irritation, soreness or dryness in the inside of the nose.• Slowing of growth in children has also been observed, however the frequency of this occurring cannot be estimated from the available data.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergic Reaction: <ul style="list-style-type: none">• wheezing• swelling of the lips/mouth• difficulty in breathing• hay fever• lumpy rash ("hives")• fainting	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of

Serious side effects	What to do
	these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ARX-FLUTICASONE contains

Active ingredient (main ingredient)	fluticasone furoate
Other ingredients (inactive ingredients)	glucose anhydrous, dispersible cellulose, polysorbate 80, benzalkonium chloride, disodium edetate, and purified water.
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What ARX-FLUTICASONE looks like

ARX-FLUTICASONE nasal spray is a white suspension contained in an amber glass bottle, fitted with a pump.

The bottle contains 120 sprays.

Each spray delivers approximately 27.5 micrograms fluticasone furoate.

AUST R 448527

Who distributes FLUTICASONE-

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St
Cremorne VIC 3121

Sponsor:

Helix Pharmaceuticals Pty.Ltd

C/E-EGA Corporate Advisers Pty Ltd
Level 12, 468 St Kilda Rd
Melbourne VIC 3004
Australia

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