

ARNUITY ELLIPTA

Fluticasone furoate 50, 100 or 200 micrograms per inhalation

Australian Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start using ARNUITY ELLIPTA.

This leaflet answers some common questions about ARNUITY ELLIPTA.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ARNUITY ELLIPTA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ARNUITY ELLIPTA is used for

ARNUITY ELLIPTA is used to treat asthma in patients 5 years and over.

To use ARNUITY ELLIPTA, you breathe it into your lungs through your mouth using the ELLIPTA inhaler.

Asthma is when the muscles surrounding the smaller airways become tight (bronchoconstriction), swollen and irritated (inflammation). Symptoms come and go and include shortness of breath, wheezing, chest tightness and cough.

ARNUITY ELLIPTA contains the active ingredient fluticasone furoate.

Fluticasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids. Corticosteroids are used to reduce inflammation. They reduce the swelling and irritation in the small air passages in the lungs and so ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is not addictive.

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

ARNUIITY ELLIPTA should not be used in children under the age of 5 years.

Before you use ARNUITY ELLIPTA

Your doctor has weighed any risks of you using ARNUITY ELLIPTA against the benefits they expect it will have for you. You can talk to your doctor about the risks and benefits of using this medicine.

When you must not use it

Don't use ARNUITY ELLIPTA:

- **to relieve a sudden attack of breathlessness or wheezing. If you get this sort of attack you must use a quick-acting inhaler (such as VENTOLIN).**
- **if you are allergic (hypersensitive) to lactose or milk protein**
- **if you are allergic (hypersensitive) to fluticasone furoate or any other ingredients of ARNUITY ELLIPTA (listed at the end of this leaflet).**

If you think either of these applies to you, don't use ARNUITY ELLIPTA until you have checked with your doctor.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

ARNUITY ELLIPTA contains lactose.

If you have been diagnosed with an intolerance to milk protein, talk to your doctor before you use ARNUITY ELLIPTA.

ARNUITY ELLIPTA is not usually recommended for use during pregnancy.

If you are pregnant, if you think you may be pregnant don't use ARNUITY ELLIPTA without asking your doctor.

Your doctor will consider the benefit to you and the risk to your baby of taking ARNUITY ELLIPTA while you are pregnant.

If you are breast-feeding, check with your doctor before you take ARNUITY ELLIPTA.

It is not known whether the ingredients of ARNUITY ELLIPTA can pass into breast milk.

Do not give this medicine to a child under the age of 5 years.

Safety and effectiveness in children younger than 5 years has not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Your doctor should give you a personal Action Plan to help manage your asthma. This plan will include what medicines to take regularly to control your asthma, as well as what "reliever" medicines to use when you have sudden attacks of breathlessness or wheezing.

Ask your doctor or pharmacist if you have any questions about your Action Plan.

Talk to your doctor before you use ARNUITY ELLIPTA if you:

- **have liver disease, as you may be more likely to have side effects, and your doctor may need to lower your dose. ARNUITY ELLIPTA is not recommended for use in children under 12 years of age with liver disease.**

- **are being or have ever been treated for tuberculosis (TB) or pneumonia**
- **have eye problems such as glaucoma or cataracts**
- **have weak bones (osteoporosis)**
- **have any long-standing or untreated infections or have recently been exposed to chickenpox or measles or been around anyone who has chickenpox or measles.**

Check with your doctor before you use ARNUITY ELLIPTA if you think any of these apply to you.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. This should include all of the medicines that you are using for your asthma.

Medicines which are similar to ARNUITY ELLIPTA should not be used together as an overdose may result.

Some medicines may affect how ARNUITY ELLIPTA works, or make it more likely that you'll have side effects. These include:

- ketoconazole, to treat fungal infections
- ritonavir, to treat viral infections.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you are currently on oral or injectable corticosteroids for asthma, please do not stop taking these medicines suddenly without talking to your doctor first.

How to use ARNUITY ELLIPTA

Follow all directions given to you by your doctor or pharmacist carefully.

If you do not understand the instructions in the user leaflet, ask your doctor or pharmacist for help.

How much to use

Always use ARNUITY ELLIPTA exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you're not sure.

- **Adults and adolescents (aged 12 years and over:**

The usual recommended dose of ARNUITY ELLIPTA for asthma is one inhalation of 100 micrograms of fluticasone furoate once daily at the same time each day.

If you have severe asthma, your doctor may decide that you should use one inhalation of the higher strength ARNUITY ELLIPTA inhaler (200 micrograms fluticasone furoate).

If you have liver disease, your doctor may decide that the maximum dose you should use is one inhalation of the 100 micrograms strength of the ARNUITY ELLIPTA inhaler, once daily at the same time each day.

- **Children (aged 5 to less than 12 years):**

The usual dose of ARNUITY ELLIPTA for asthma is one inhalation of 50 micrograms of fluticasone furoate once daily at the same time each day.

ARNUITY ELLIPTA is not recommended for children less than 5 years of age. ARNUITY ELLIPTA has not been tested in children in this age group.

Your doctor will assess your asthma at regular intervals to ensure that you are receiving the dose most suitable to the severity of your asthma.

How to use the inhaler

The full instructions for using ARNUITY ELLIPTA are given on a leaflet inside the pack.

ARNUITY ELLIPTA is ready to use straight away. No preparation or checks of the inhaler are required.

Do not open ARNUITY ELLIPTA until you are ready to take a dose.

After using ARNUITY ELLIPTA, you may clean the mouthpiece, using a dry tissue, before you close the cover. Do not immerse ARNUITY ELLIPTA in water.

When to use it

Use ARNUITY ELLIPTA regularly.

It is very important that you use ARNUITY ELLIPTA every day, as instructed by your doctor. This will help to keep you free of symptoms throughout the day and night.

If you feel you are getting breathless or wheezy more often than normal, or if you are using your quick-acting inhaler more than usual, see your doctor.

How long to use it

Don't stop ARNUITY ELLIPTA without medical advice.

Use ARNUITY ELLIPTA for as long as your doctor recommends. It will only be effective as long as you are using it. Don't stop unless your doctor advises you to, even if you feel better.

If you forget to take it

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

Don't take an extra dose to make up for a missed dose.

If you are not sure what to do, ask your doctor or pharmacist.

If you become wheezy or breathless, or develop any other symptoms of an asthma attack, use your quick-acting inhaler (e.g. VENTOLIN), then seek medical advice.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

In Australia, immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, if you think that you or anyone else may have taken too much ARNUITY ELLIPTA. Do this even if there are no signs of discomfort or poisoning.

If you accidentally take a larger dose of ARNUITY ELLIPTA than your doctor has instructed, you may notice that your heart is beating faster than usual, you feel shaky or have a headache.

If you have used larger doses than instructed for a long period of time, it is particularly important that you ask your doctor or pharmacist for advice. This is because larger doses of ARNUITY ELLIPTA may reduce the amount of steroid hormones produced naturally by your body.

While you are using ARNUITY ELLIPTA

Things you must do

If you have an Action Plan for your asthma that you have agreed with your doctor, follow it closely at all times.

Contact your doctor if you experience a change in your vision.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ARNUITY ELLIPTA.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take ARNUITY ELLIPTA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Do not take any other medicines for your breathing problems without checking with your doctor.

Things to be careful of

This medicine is not expected to affect your ability to drive a car or operate machinery. It is prudent to be careful with driving or operating machinery until you know how ARNUITY ELLIPTA affects you.

Side effects

Like all medicines, ARNUITY ELLIPTA can cause side effects, although not everybody gets them. To reduce the chance of side effects, your doctor will prescribe the lowest effective dose of ARNUITY ELLIPTA to control your asthma.

If your breathing or wheezing gets worse straight after using ARNUITY ELLIPTA, stop using it and get medical help immediately.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Very Common side effects

These may affect more than 1 in 10 people:

- headache
- runny nose.

Common side effects

These may affect up to 1 in 10 people:

- sore, raised patches in the mouth or throat caused by a fungal infection (candidiasis). Rinsing your mouth out with water immediately after using ARNUITY ELLIPTA may help stop this side effect developing.

You must tell your doctor if you have any of the following symptoms while taking ARNUITY ELLIPTA:

- inflammation of the lungs (bronchitis)
- infection of the nose sinuses or throat
- flu (influenza)
- pain and irritation in the back of the mouth and throat
- inflammation of the sinuses
- itchy, runny or blocked nose
- cough

- high temperature (fever)
- back pain.

If you think you are having an allergic reaction to ARNUITY ELLIPTA, stop using this medicine and tell your doctor immediately or go to the accident and emergency department at your nearest hospital. Symptoms of an allergic reaction usually include some or all of the following:

- wheezing
- swelling of the lips/mouth, tongue or throat
- difficulty in breathing
- hay fever
- lumpy rash ("hives")
- fainting.

It is possible that some people particularly those taking higher doses of ARNUITY ELLIPTA for a long time, may rarely suffer from the following side effects:

- Rounded face
- Loss of bone density
- Eye problems (e.g. cataract, glaucoma)

- **Slowing of growth in children and adolescents. It is unclear what, if any, difference this makes to a child's final height.**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

After using ARNUITY ELLIPTA

Storage

Do not use ARNUITY ELLIPTA after the expiry date shown on the pack.

Store in the original package container in order to protect from moisture and do not open the foil lid until ready to inhale for the first time.

Safely throw away ARNUITY ELLIPTA one month after you open the foil tray or when the counter reads "0", whichever comes first. Write the date the inhaler should be discarded on the label in the space provided. The date should be added as soon as the inhaler has been removed from the tray.

Keep your inhaler in a cool dry place where the temperature stays below 30°C.

If you store in a refrigerator, allow the inhaler to return to room temperature for at least an hour before use.

Do not store ARNUITY ELLIPTA or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ARNUITY ELLIPTA is inhaled through the mouth using the ELLIPTA device. The active substance is in a blister in powder form inside the device. There are either 14 or 30 blisters on the strip, and so each device contains either 14 or 30 doses depending on which pack size you have been given.

The ELLIPTA device itself is a plastic inhaler with a light grey body, a pale orange mouthpiece cover and a dose counter. It is packaged in a foil laminate tray with a peelable foil lid. The tray contains a desiccant sachet, to reduce the moisture in the packaging. Once you have opened the lid of

the tray, throw the desiccant away - do not open, eat or inhale it.

Ingredients

The active ingredient in ARNUITY ELLIPTA is fluticasone furoate.

Each dose contains 50, 100 or 200 micrograms of the active ingredient fluticasone furoate. The amount depends on which strength of ARNUITY ELLIPTA you have been given.

ARNUITY ELLIPTA also contains the inactive ingredient lactose monohydrate.

Supplier

ARNUITY ELLIPTA is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford Victoria 3067

Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from

patient information groups and books, for example in public libraries.

The information provided applies only to ARNUITY ELLIPTA.

ARNUITY ELLIPTA 50 micrograms: AUST R 300141

ARNUITY ELLIPTA 100 micrograms: AUST R 231095

ARNUITY ELLIPTA 200 micrograms: AUST R 231103

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