

ARNUIITY ELLIPTA

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 ARNUITY ELLIPTA?

ARNUIITY ELLIPTA contains the active ingredient fluticasone furoate. ARNUITY ELLIPTA is used to treat asthma in patients 5 years and over.

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

2. What should I know before I use ARNUITY ELLIPTA?

Do not use if you have ever had an allergic reaction to ARNUITY ELLIPTA or to lactose or milk protein 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 ARNUITY ELLIPTA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ARNUITY ELLIPTA 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 ARNUITY ELLIPTA?

- The usual dose of ARNUITY ELLIPTA for asthma is as prescribed by the doctor.
- Use ARNUITY ELLIPTA at the same time each day.

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

5. What should I know while using ARNUITY ELLIPTA?

Things you should do

- Remind any doctor, dentist, pharmacist or nurse you visit that you are using ARNUITY ELLIPTA.
- Tell your doctor immediately if you become pregnant or intend to become pregnant whilst using ARNUITY ELLIPTA.

| | |
|------------------------------------|---|
| | <ul style="list-style-type: none"> • Tell your doctor 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. |
| Things you should not do | <ul style="list-style-type: none"> • Do not stop using this medicine suddenly or lower the dosage without checking with your doctor. • Do not take any other medicines to help you breathe without first checking with your doctor. |
| Driving or using machines | <ul style="list-style-type: none"> • Be careful before you drive or use any machines or tools until you know how ARNUITY ELLIPTA affects you. |
| Looking after your medicine | <ul style="list-style-type: none"> • Store it in a cool dry place (below 30°C) away from moisture, heat or sunlight. • 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.

- If you store it in the refrigerator allow the inhaler to return to room temperature at least 1 hour before you use it.
- Safely throw away ARNUITY ELLIPTA one month after you open the foil tray or when the counter reads "0", whichever comes first.

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

6. Are there any side effects?

Side effects that have been reported include headache, runny nose, 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 or blocked nose, cough, high temperature (fever), back pain.

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.

ARNUIITY ELLIPTA

Active ingredient: *fluticasone furoate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARNUITY ELLIPTA. 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 **ARNUIITY ELLIPTA**.

Where to find information in this leaflet:

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

1. Why am I using ARNUITY ELLIPTA ?

ARNUIITY ELLIPTA contains the active ingredient fluticasone furoate.

ARNUIITY ELLIPTA 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.

ARNUIITY 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.

2. What should I know before I use ARNUITY ELLIPTA?

Warnings

Do not 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).

- always check the ingredients to make sure you can use this medicine.

Some symptoms of an allergic reaction may 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

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 quick acting 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.

Check with your doctor 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.
- have been diagnosed with an intolerance to milk protein
- take medications for any other conditions

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.

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

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

Children

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.

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 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.

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

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.

4. How do I use ARNUITY ELLIPTA?

How much to use:

- 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.

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.
- 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.

Children (aged 5 to less than 12 years):

- The usual recommended dose of ARNUITY ELLIPTA for asthma is one inhalation of 50 micrograms of fluticasone furoate once daily.
- 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.
- ARNUITY ELLIPTA is not recommended for use in children under 12 years of age with liver disease.

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.

When to use ARNUITY ELLIPTA

- ARNUITY ELLIPTA should be used regularly at the same time each 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 such as Ventolin more than usual, see your doctor.

How to use ARNUITY ELLIPTA

- Full instructions for using ARNUITY ELLIPTA are present in the leaflet in the pack.
- Do not open ARNUITY ELLIPTA until you are ready to take a dose.
- ARNUITY ELLIPTA is ready to use straight away. No preparation or checks of the inhaler is required.
- After using ARNUITY ELLIPTA you may clean the mouthpiece, using a dry tissue before closing the cover. Do not immerse ARNUITY ELLIPTA in water.
- Do not open ARNUITY ELLIPTA until you are ready to take a dose.

How long to use ARNUITY ELLIPTA

- 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 use ARNUITY ELLIPTA

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 it as soon as you remember, then go back to using it as you normally would.

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

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

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

If you use too much ARNUITY ELLIPTA

If you think that you have used too much ARNUITY ELLIPTA, 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.

If you 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.

5. What should I know while using ARNUITY ELLIPTA?

Things you should do

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

Call your doctor straight away if you:

- Experience a change in vision
- If you become pregnant while taking ARNUITY ELLIPTA

Remind any doctor, dentist, pharmacist or nurse you visit that you are using ARNUITY ELLIPTA

Things you should not do

- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.

- 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 take any other medicines for your breathing problems without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ARNUITY ELLIPTA affects you.

Looking after your medicine

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. 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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.

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.

To reduce the chance of side effects, your doctor will prescribe the lowest effective dose of ARNUITY ELLIPTA to control your asthma.

Less serious side effects

| Less serious side effects | What to do |
|--|--|
| Infections: <ul style="list-style-type: none">infection of the nose sinuses or throat | Speak to your doctor if you have any of these less serious side effects and they worry you. |

| Less serious side effects | What to do |
|---|-------------------|
| <ul style="list-style-type: none"> ● inflammation of the sinuses ● flu (influenza) ● high temperature (fever) ● 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 ● inflammation of the lungs (bronchitis) <p>Respiratory disorders:</p> <ul style="list-style-type: none"> ● cough ● pain and irritation in the back of the mouth and throat ● itchy, runny or blocked nose ● hoarseness <p>Pain:</p> <ul style="list-style-type: none"> ● headache ● back pain | |

Serious side effects

| Serious side effects | What to do |
|--|---|
| <p data-bbox="204 432 596 477">Allergic reaction:</p> <p data-bbox="204 512 735 846">If you have any of the following symptoms after using ARNUITY ELLIPTA, stop using this medicine and tell your doctor immediately.</p> <ul data-bbox="204 887 783 1597" style="list-style-type: none"><li data-bbox="204 887 660 987">● skin rash (hives) or redness<li data-bbox="204 1010 683 1173">● swelling, sometimes of the face or mouth (angioedema)<li data-bbox="204 1196 751 1359">● becoming very wheezy, coughing or having difficulty in breathing<li data-bbox="204 1382 783 1597">● suddenly feeling weak or light headed (may lead to collapse or loss of consciousness) <p data-bbox="204 1619 676 1720">Immediate breathing difficulties:</p> <ul data-bbox="204 1760 759 2031" style="list-style-type: none"><li data-bbox="204 1760 759 2031">● If your breathing or wheezing gets worse straight after using ARNUITY ELLIPTA, stop using it | <p data-bbox="810 432 1374 819">Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|---|-------------------|
| immediately, and tell your doctor as soon as possible. | |

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.

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 disorders
- eye problem (e.g. cataract, glaucoma)
- slowing of growth in children and adolescents. It is unclear what, if any, differences this makes to a child's final height.

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 ARNUITY ELLIPTA contains

| | |
|---|--|
| Active ingredient (main ingredient) | fluticasone furoate (50, 100 or 200 micrograms). The amount depends on which strength of ARNUITY ELLIPTA you have been given. |
| Other ingredients (inactive ingredients) | lactose monohydrate |
| Potential allergens | lactose monohydrate |

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

What ARNUITY ELLIPTA 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.

ARNUITY ELLIPTA 50 micrograms: AUST R 300141

ARNUITY ELLIPTA 100 micrograms: AUST R 231095

ARNUITY ELLIPTA 200 micrograms: AUST R 231103

Who distributes ARNUITY ELLIPTA

GlaxoSmithKline Australia Pty Ltd

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