

ARNUITY 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?

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

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 is one inhalation once a day. 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	<ul style="list-style-type: none">• Remind any Healthcare Professional (HCP) you visit that you are using ARNUITY ELLIPTA.• Contact your doctor if you are concerned about any side effects.• Tell your doctor immediately, if you become or intent to become pregnant while using ARNUITY ELLIPTA.• 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 (such as VENTOLIN/salbutamol) more than usual.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dosage without checking with your doctor.• Do not take any other medicines to help you breathe without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how ARNUITY ELLIPTA affects you.
Looking after your medicine	<ul style="list-style-type: none">• Do not open the foil lid until you are ready to use the inhaler for the first time. Once ARNUITY ELLIPTA has been removed from the tray you may store it for a maximum period of one month or when the counter reads "0", whichever comes first.• Store it in a cool dry place (below 30°C) away from moisture, heat, or sunlight.• If you store it in the refrigerator, allow the inhaler to return to room temperature at least 1 hour before you use it.

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

6. Are there any side effects?

Less serious side effects include headache, infection of the nose sinuses or throat, influenza, pain and irritation in the back of the mouth and throat, pressure or pain in the cheeks and forehead, itchy, runny or blocked nose, cough, hoarseness, bronchitis, back pain, oral thrush, weakening of the bones, rounded face or slowing of growth in children and adolescents. Serious side effects include allergic reaction, blurred vision or eye pain, cataracts, or immediate breathing difficulties and wheezing.

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.

ARNUITY ELLIPTA

Active ingredient: fluticasone furoate 50, 100 or 200 micrograms per inhalation

Consumer Medicine Information (CMI)

This leaflet provides important information about using ARNUITY ELLIPTA. **You should also speak to your Healthcare Professional (HCP) if you would like further information or if you have any concerns or questions about using ARNUITY 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?

ARNUITY ELLIPTA contains the active ingredient fluticasone furoate. Fluticasone furoate belongs to a group of medicines called inhaled corticosteroids, often simply called steroids.

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

Asthma is a condition affecting the lungs. Symptoms of asthma include shortness of breath, wheezing, chest tightness and cough. Two main causes of asthma symptoms are bronchoconstriction (tightening of the muscle surrounding the airways) and inflammation (swelling and irritation of the airways).

Inhaled 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. Inhaled corticosteroids also help prevent attacks of asthma.

When ARNUITY ELLIPTA is used regularly, it can help to control your breathing difficulties.

ARNUITY ELLIPTA should not be used 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/salbutamol).

Your doctor may have prescribed ARNUITY ELLIPTA for another reason.

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 prescription.

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

Warnings

Do not use ARNUITY ELLIPTA if:

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

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

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 any medicines for any other condition.

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.

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.

ARNUITY ELLIPTA is not usually recommended for use during pregnancy. Your doctor will weigh up the benefits to you against the potential risks to your baby when considering the use of ARNUITY ELLIPTA during your pregnancy.

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

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 Healthcare Professional (HCP) 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 ARNUITY ELLIPTA and affect how it works or make it more likely that you will have side effects.

These medicines include:

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

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

Check with your Healthcare Professional (HCP) if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ARNUITY ELLIPTA.

4. How do I use ARNUITY ELLIPTA?

How much to use:

Always use ARNUITY ELLIPTA exactly as your doctor has told you to. Check with your Healthcare Professional (HCP) if you are not sure.

Adults and adolescents (aged 12 years and over):

- The dose for asthma is one inhalation of ARNUITY ELLIPTA 100 micrograms once daily OR one inhalation of ARNUITY ELLIPTA 200 micrograms once daily, at the same time each day.
- Your doctor will decide which strength of ARNUITY ELLIPTA is required to treat your asthma.
- If you have liver disease, your doctor may decide that the maximum dose you should use is one inhalation of ARNUITY ELLIPTA 100 micrograms once daily, at the same time each day.

Children (aged 5 to less than 12 years):

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

When to use ARNUITY ELLIPTA

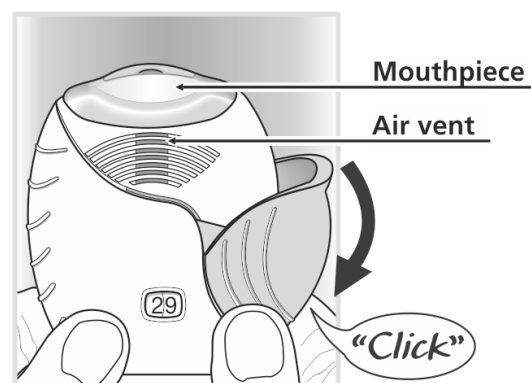
- Use ARNUITY ELLIPTA once daily, at the same time each day. It is very important that you use ARNUITY ELLIPTA every day, as instructed by your Healthcare Professional (HCP). This will help to keep you free of symptoms throughout the day and night.
- Use ARNUITY ELLIPTA for as long as your HCP recommends. It will only be effective as long as you are using it. Do not stop unless your HCP advises you to, even if you feel better.

How to use ARNUITY ELLIPTA

- To use ARNUITY ELLIPTA, you breathe it into your lungs through your mouth using the Ellipta inhaler.
- The full instructions for using ARNUITY ELLIPTA are present 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 inhale a dose of medicine.

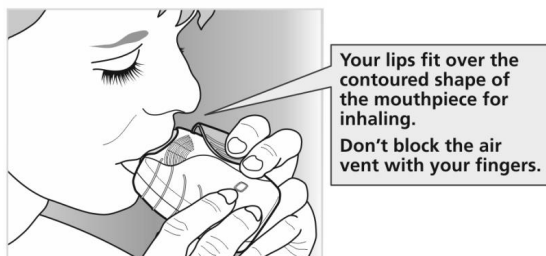
Step 1: Prepare a dose

- Wait to open the cover until you are ready to take your dose. Slide the cover down until you hear a "click".
- If the dose counter does not count down as you hear the "click", the inhaler will not deliver the medicine. Take it back to your pharmacist for advice.
- Do not shake the inhaler at any time.



Step 2: Inhale your medication

- While holding the inhaler away from your mouth, breathe out as far as is comfortable.
- Do not breathe out into the inhaler.
- Put the mouthpiece between your lips and close your lips firmly around it.
- Do not block the air vent with your fingers.

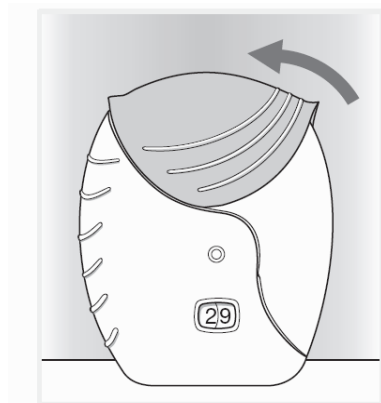


- Take one long, steady, deep breath in. Hold this breath for about 3-4 seconds or as long as is comfortable.
- Remove the inhaler from your mouth.
- Breathe out slowly and gently away from the mouthpiece.
- You may not be able to taste or feel the medicine, even when you are using the inhaler correctly.

After using ARNUITY ELLIPTA, you may clean the mouthpiece using a dry tissue, before you close the cover.

Step 3: Close the inhaler and rinse your mouth

- Slide the cover upwards as far as it will go, to cover the mouthpiece.



- Rinse your mouth out with water without swallowing after you have used the inhaler if possible. This will make it less likely that you will develop a sore mouth or throat as side effects.

If you forget to use ARNUITY ELLIPTA

ARNUIITY ELLIPTA should be used regularly at the same time each day.

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 normally would.

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

- If you are not sure what to do, ask your Healthcare Professional (HCP).
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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

If you use too much ARNUITY ELLIPTA (overdose)

If you think that you have used too much ARNUITY ELLIPTA, you may need urgent medical attention. You may notice that your heart is beating faster than usual, you feel shaky or have a headache.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia), 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 have used larger doses than instructed for a long period of time, it is particularly important that you ask your Healthcare Professional (HCP) 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

- Remind any Healthcare Professional (HCP) you visit that you are using ARNUITY ELLIPTA, especially if you are about to be started on any new medicine.
- Use ARNUITY ELLIPTA for as long as your doctor recommends. It will only be effective as long as you are using it. Do not stop unless your doctor advises you to, even if you feel better.
- Check with your doctor if you are unsure about which medicines for asthma you should continue taking while being treated with ARNUITY ELLIPTA.
- Continue to use a quick-acting inhaler (e.g., VENTOLIN/salbutamol) during an acute episode.
- If you are about to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- Keep all of your doctor's appointments so that your progress can be checked.

Call your doctor straight away if you:

- experience blurred vision or other visual disturbances.
- become pregnant while using ARNUITY ELLIPTA
- feel that your breathing or wheezing gets worse straight after using ARNUITY ELLIPTA. Stop using it immediately.

Please see Section [6. Are there any side effects?](#) for more instances in which you should contact your doctor.

Things you should not do

- Do not stop using this medicine suddenly or change the dosage without medical advice.

- Do not use 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.
- If you are currently on oral or injectable corticosteroids, do not stop taking these suddenly without checking with your doctor.
- Do not take any other long-acting inhalers which contain corticosteroids.
- 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.

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

Action Plan

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

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.
- 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 where the temperature stays below 30°C.

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.

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

When to discard your medicine

Ask your pharmacist to 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.

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 or if the packaging is torn or shows signs of tampering.

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.

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

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

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
Nervous system disorders: <ul style="list-style-type: none"> • headache Infections: <ul style="list-style-type: none"> • infection of the nose sinuses or throat • flu (influenza) Respiratory, thoracic and mediastinal disorders: <ul style="list-style-type: none"> • pain and irritation in the back of the mouth and throat • feeling pressure or pain in the cheeks and forehead (may be a sign of inflammation of the sinuses known as sinusitis) • itchy, runny or blocked nose • cough • hoarseness • inflammation of the lungs (bronchitis) Musculoskeletal and connective tissue disorders: <ul style="list-style-type: none"> • back pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>
Less serious side effects that require medical intervention. Please consult your doctor if you experience any of the following: <ul style="list-style-type: none"> • sore, raised patches in the mouth or throat caused by a fungal infection (oral thrush) • you have been told that you have weakening of the bones, leading to risk of fractures • rounded face • slowing of growth in children and adolescents 	<p>Contact your doctor if you experience any of these less serious side effects.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reaction:</p> <ul style="list-style-type: none">• If you have any of the following symptoms after using ARNUITY ELLIPTA, stop using this medicine and tell your doctor immediately.• Symptoms of an allergic reaction usually include some or all of the following:<ul style="list-style-type: none">o shortness of breatho wheezing, coughing or difficulty breathingo swelling of the face, lips/mouth, tongue or throato rash, itching, redness or hives on the skino suddenly feeling weak or light-headed (may lead to collapse or loss of consciousness) <p>Eye disorders:</p> <ul style="list-style-type: none">• blurred vision or eye pain (possible signs of glaucoma)• cataracts <p>Immediate breathing difficulties and wheezing:</p> <ul style="list-style-type: none">• If your breathing or wheezing gets worse straight after using ARNUITY ELLIPTA, stop using it immediately, and tell your doctor as soon as possible.	<p>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>

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 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	Fluticasone furoate
Other ingredients	Lactose monohydrate (contains milk protein)
Potential allergens	Lactose or milk protein 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 give.

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

What ARNUITY ELLIPTA looks like

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 active substances are in separate blisters in powder form inside the device. There are either 14 or 30 blisters on each strip, and so each device contains either 14 or 30 doses depending on which pack size you have been given.

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

Level 4, 436 Johnston Street,

Abbotsford, Victoria, 3067

Phone: 1800 033 109

www.gsk.com.au

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