

Package leaflet: Information for the patient

Arquist 125 microgram per actuation pressurised inhalation, suspension

Arquist 250 microgram per actuation pressurised inhalation, suspension

fluticasone propionate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Arquist is and what it is used for
2. What you need to know before you use Arquist
3. How to use Arquist
4. Possible side effects
5. How to store Arquist
6. Contents of the pack and other information

1. What Arquist is and what it is used for

This medicine contains the active substance fluticasone propionate which belongs to a group of medicines called corticosteroids. Arquist works by reducing inflammation in the lungs. This helps to prevent asthma attacks in people who need regular treatment. It takes 4-7 days for this medicine to work and it is very important that you use it regularly also when you do not have symptoms.

Arquist is used for the regular treatment of asthma in adult and adolescents over 12 years of age.

2. What you need to know before you use Arquist

Do not use Arquist

- if you are allergic to fluticasone propionate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Stop using Arquist immediately

- if you experience difficulty in breathing with immediate increase in wheezing just after taking a dose of this medicine.

In this case, immediately use a short-acting bronchodilator inhaler.

Talk to your doctor, pharmacist or nurse before using Arquist

- if you have ever been treated for tuberculosis (TB), viral, bacterial or fungal infections;
- if you have a history of diabetes mellitus (because fluticasone may increase your blood sugar level);
- if you have used high doses of this medicine for a long period of time and notice any of the following.
 - weight gain and a rounded (moon shaped) face (these could be signs of Cushing's Syndrome);
 - vague symptoms such as tummy ache, sickness, diarrhoea, headache or drowsiness (adrenal suppression, acute adrenal crisis). This is more likely during an infection such as viral infection or stomach upset;

- thinning of the bones;
- eyeproblems (cataract and glaucoma);
- slowing of growth (mainly occurs in children and adolescents).

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before using Arquist.

Contact your doctor if you experience blurred vision or other visual disturbances.

Do not use Arquist to relieve acute symptoms of asthma or a sudden asthma attacks. In this case you must use a short-acting bronchodilator i. e. short-acting inhaled beta-2- agonist.

Children

Arquist is not intended for children below 12 years of age.

Other medicines and Arquist

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. In particular tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat different types of infections such as ritonavir, ketoconazole, clarithromycin, telithromycin, atazanavir, indinavir, nelfinavir or saquinavir;
- steroid tablets together with your Arquist inhaler or if you have just finished taking steroid tablets. You should carry a steroid warning card as there is a possibility of impaired adrenal function, especially during stressful circumstances (such as a serious accident or if you have surgery) and your doctor may decide to give you extra steroid medicines during such a time.
- some medicines may increase the effects of Arquist and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Arquist.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Arquist is not likely to affect your ability to drive or use any tools or machines.

3. How to use Arquist

Arquist comes in two different strengths for oral inhalation use only. Your doctor will decide which strength you need. Always use Arquist exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Using this medicine

- Arquist may be used with the Volumatic spacer device by patients who find it difficult to release a puff (actuation) of medicine just after they start to breathe in.
- The starting dose needs to be appropriate considering the severity of the disease. Your doctor will work with you to decrease your dose to the lowest dose that effectively controls your asthma.

Adults and adolescent patients over 12 years of age

The recommended dose is 125 micrograms to 500 micrograms twice daily.

Use in children

Arquist is not intended for children below 12 years of age.

If you are using high doses of an inhaled steroid for a long time you may sometimes need extra steroids, for example during stressful circumstances such as a road traffic accident or before an operation. Your doctor may decide to give you extra steroid medicines during this time.

Instructions for use

Your doctor, nurse or pharmacist should show you how to use your inhaler. They should check how you use it from time to time. Not using the Arquist properly or as prescribed, may mean that the medicine will not help your asthma as it should.

The medicine is contained in a pressurised canister in a plastic casing with a mouthpiece. To prevent your inhaler from blocking, it is important to clean it at least once a week.

Testing your inhaler

When you use the inhaler for the first time, you should test if it works properly.

- 1 Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.
- 2 To make sure that it works, shake the inhaler well, point the mouthpiece away from you and press the canister to release four puffs into the air. If you have not used the inhaler for a week or more, release two puffs of medicine into the air.

How to use your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

- 1 You should either stand up or sit upright when using your inhaler.
- 2 Remove the mouthpiece cover. Check inside and outside to make sure that the mouthpiece is clean and free of objects (figure A).



- 3 Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed (figure B).



- 4 Hold the inhaler upright with your thumb on the base, below the mouthpiece. Breathe out for as long as is comfortable (figure C). Do not breathe in again yet.



- 5 Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite (figure D).



- 6 Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Do this while still breathing in steadily and deeply (figure D).
- 7 Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as comfortable (figure E).



- 8 If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.
- 9 Afterwards, rinse your mouth with water and spit it out. This is to avoid side effects related to your mouth or throat. You can also brush your teeth.
- 10 After using your inhaler always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

Practise in front of a mirror for the first few times. If you see 'mist' coming from the top of your inhaler or the sides of your mouth, you should start again.

Adolescents or people with weak hands may find it easier to hold the inhaler with both hands. Put the two forefingers on top of the inhaler and both thumbs on the bottom below the mouthpiece. Your doctor, nurse or pharmacist will advise you how to do this.

Cleaning your Inhaler

To prevent your inhaler from blocking, it is important to clean it at least once a week.

To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the metal canister from the plastic casing at any time.
- Wipe the inside and outside of the mouthpiece and the plastic casing with a **dry cloth or tissue**.
- Replace the mouthpiece cover.

Do not put the metal canister in water.

If you use more Arquist than you should

If you use more than you should, talk to your doctor as soon as possible.

It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. Do not increase or decrease your dose without seeking medical advice.

If you forget to use Arquist

- Take the next dose when it is due.
- Do not take a double dose to make up for the forgotten dose.

If you stop using Arquist

Do not stop treatment even if you feel better unless your doctor told you to do so. If you have been on high doses of steroids for a long time, you must not stop taking your medicine suddenly without talking to your doctor, as this could make your asthma worse. Suddenly stopping treatment can also make you feel unwell and may cause symptoms such as vomiting, drowsiness, nausea, headache, tiredness, loss of appetite, low blood sugar level and fitting (having convulsions).

If you have any further questions on the use of this medicine ask your doctor, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you notice any of the following serious side effects, stop using this medicine and talk to your doctor straight away.

- If you have an allergic reaction (rarely) or severe allergic reactions (very rarely). The signs include skin rashes, redness, itching or weals like nettle rash or hives and swelling of your face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed and collapse respectively;
- If your breathing or wheezing gets worse straight after using your inhaler.

Other side effects include:

Very common: may affect more than 1 in 10 people

- thrush in the mouth and throat

Common: may affect up to 1 in 10 people

- blood clot (hematoma);
- throat irritation and hoarseness of voice;
- pneumonia (infection of the lung) in COPD patients.

Tell your doctor if you have any of the following while taking Arquist they could be symptoms of a lung infection:

- fever or chills
- increased mucus production, change in mucus colour
- increased cough or increased breathing difficulties

Very rare: may affect up to 1 in 10,000 people

- sleeping problems or feeling worried, over-excited and irritable (these effects mainly occur in children);
- Joint pain
- indigestion
- level of sugar (glucose) in your blood may increase;
- using high doses of Arquist for a long period of time can cause : adrenal suppression, adrenal crisis, Cushing's syndrome, thinning of your bones, eye problems (such as cataracts and glaucoma which is high pressure in the eye) and slowing of growth in young people (see section 2 "Warnings and precautions").

Your doctor will help stop this happening by making sure you use the lowest dose of steroid which controls your symptoms.

Not known: frequency cannot be estimated from the available data

- depression;
- feeling restless or nervous (these effects mainly occur in children).
- Nose bleeding
- blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via <to be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Arquist

Keep this medicine out of the sight and reach of children.

Do not use Arquist after the expiry date, which is stated on the label and carton after 'EXP'. The expiry date refers to the last day of that month.

The canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister. Do not freeze. Protect from frost and direct sunlight.

If the inhaler gets very cold, take the metal canister out of the plastic case and warm it in your hands for a few minutes before use. Never use anything else to warm it up.

The metal canister is pressurised. Do not puncture, break or burn it even when apparently empty.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If you are told to stop taking this medicine, return the inhaler to your pharmacist to be thrown away in an appropriate manner.

6. Contents of the pack and other information

What Arquist contains

- The active substance is fluticasone propionate. One metered dose (ex-valve) contains 125 or 250 micrograms of fluticasone propionate respectively. This is equivalent to a delivered dose (ex-actuator) of 110 microgram or 227 microgram fluticasone propionate respectively.
- This medicine contains fluorinated greenhouse gases.
Each inhaler contains 12.5g of HFC-134a (norflurane) corresponding to 0.018 tonne CO₂ equivalent (global warming potential GWP = 1430).

What Arquist looks like and contents of the pack

- The [Nationally to be completed] is a white suspension inside a fluorocarbon polymer treated aluminium alloy canister, which is sealed with a metering valve, actuator and dust cap.
- Each canister contains 120 metered actuations of either 125 or 250 micrograms of fluticasone propionate.

Pack sizes:

Single pack - Each single pack contain a canister with 120 actuations.

Multipack - Bundle pack of 2 or 3 single packs.

Hospital pack - Bundle pack of 10 single packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Cipla Europe NV

De Keyserlei,
60C, Bus-1301,
Antwerpen 2018,
Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in 2025-01-13.