

## 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 swelling and irritation in the lungs inflammation in the lungs. Only a very small dose is needed as it is inhaled straight to the lungs.

This has been prescribed by your doctor to treat either:

- Asthma in adults and adolescents over 16 years of age or
- Chronic Obstructive Pulmonary Disease (COPD) in adults only, when given with other medicines (long-acting beta agonist (such as salmeterol)) to open the airways.

You must use Arquist every day as directed by your doctor, even if there are no complaints. This makes sure that it works properly in controlling your asthma or COPD.

### 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

Talk to your doctor, pharmacist or nurse before using Arquist

- if you have ever been treated for tuberculosis (TB).
- If you have ever had thrush in your mouth
- 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 (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 a viral infection or stomach upset.
  - thinning of the bones
  - eyeproblems (cataract and glaucoma)
  - slowing of growth (mainly occurs in children and adolescents)
- Contact your doctor if you experience blurred vision or other visual disturbances.

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

**Children and adolescents:**

Arquist are recommended for asthma in adults and adolescents over 16 years of age and Chronic Obstructive Pulmonary Disease (COPD) in adults..

**Other medicines and Arquist**

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines. Remember to take this medicine with you if you have to go into hospital.

Tell your doctor if you are taking any of the following medicines, before you start using Arquist:

- 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)
  - medicines to treat infections (such as ketoconazole and erythromycin),

**Arquist with food and drink**

You can use Arquist at any time of day, with or without food.

**Pregnancy and, breast-feeding**

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**

There are no studies performed on the influence of this product on your ability to drive or operate machinery. However, it is unlikely that this product has a negative influence.

**3. How to use Arquist**

Always use this medicine exactly as your doctor has told you. Check with your doctor, nurse or pharmacist if you are not sure.

Arquist comes in two different strengths for oral inhalation use only. Your doctor will decide which strength you need.

**Using this medicine**

- If you are on higher doses (above 1,000 micrograms daily) you should take your Arquist via the Volumatic large-volume spacer device to help reduce side-effects in the mouth and throat. Your doctor, nurse or pharmacist will be able to advise you about this.
- Some people find it difficult to release a puff of medicine just after they start to breathe in. The Volumatic spacer device helps to overcome this problem. Your doctor, nurse or pharmacist will be able to advise you about this.

- **It may takes a few days to a few months for this medicine to work and it is very important that you use it regularly.**

## **Asthma**

### **Adults and Children over 16 years of age**

#### *Mild asthma*

- The usual starting dose is up to 250 micrograms twice a day.

#### *Moderate asthma*

- The usual starting dose is 250 to 500 micrograms twice a day.

#### *Severe asthma*

- The usual starting dose is 500 to 1000 micrograms twice a day.

## **Chronic Obstructive Pulmonary Disease (COPD)**

### **Adult**

- 500 micrograms twice daily.
- For the treatment of COPD Arquist is taken with another medicine called a long acting bronchodilator.

### **Use in children and adolescents**

Arquist are recommended for asthma in adults and adolescents over 16 years of age and Chronic Obstructive Pulmonary Disease (COPD) in adults only.

Your doctor may give you a Arquist 250 microgram if your dose is increased.

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.

Patients, who have been on high doses of steroids, including Arquist for a long time, must not stop taking their medicine suddenly without talking to their doctor. Suddenly stopping treatment can make you feel unwell and may cause symptoms such as vomiting, drowsiness, nausea, headache, and tiredness, loss of appetite, low blood sugar level and convulsions.

### **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 or COPD 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**

- 1 When using the inhaler for the first time, test it to ensure that it is working. 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 five days or more, release two puffs of medicine into the air.

### **Using 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 is 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.

Older children 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 be able to advise you.

#### **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**

- 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 told to do so by your doctor. Patients who have been on high doses of steroids for a long time, must not stop taking their medicine suddenly without talking to their 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.**

You may need urgent medical treatment.

- allergic reactions (may affect up to 1 in 100 people) - the signs include skin rashes, redness, itching or wheals like nettle rash or hives
- severe allergic reactions (may affect up to 1 in 10,000 people) the signs include 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
- 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)

- candidiasis (certain fungal infections) with sore creamy-yellow spots (thrush) in the mouth and throat

##### **Common** (may affect up to 1 in 10 people)

- sore tongue or throat
- hoarseness of voice
- Problems with your mouth and throat can be reduced by doing certain things straight after inhaling your dose. These are rinsing your mouth or gargling with water and spitting it out. The thrush in mouth and throat can be treated with anti-fungal therapy while continuing with Fluticasone. Tell your doctor if you have these problems with your mouth or throat, but do not stop treatment unless you are told to
- The following side effects have also been reported in patients with Chronic Obstructive Pulmonary Disease (COPD):
  - Pneumonia (infection of the lung) in COPD patients (common side effect)

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
- Bruising.

**Rare (may affect up to 1 in 1,000 people)**

- thrush (candidiasis) in the oesophagus

**Very rare (may affect up to 1 in 10,000 people)**

- sleeping problems or feeling worried, over-excited and irritable. These effects are more likely to occur in children)
- indigestion
- joint pain
- level of sugar (glucose) in your blood may increase
- the way steroids are produced by your body may be affected when using Fluticasone(adrenal suppression). This is more likely to happen if you use high doses for a long period of time (e.g. 400 micrograms daily in children). This can cause:
  - young people to grow more slowly.
  - something called ‘Cushing’s syndrome’. This happens when you have too much steroid in your body and it can cause thinning of your bones and eye problems (such as cataracts and glaucoma which is high pressure in the eye).

Your doctor will help stop this happen<sup>ing</sup> 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
- nosebleed
- Blurred vision

These effects are more likely to occur in children.

**Talk to your doctor as soon as possible if:**

- after 7 days of using Arquist your shortness of breath or wheezing does not get better, or gets worse.
- you or your child is on high doses of inhaled steroid and become unwell with vague symptoms such as tummy ache, sickness, diarrhoea, headache or drowsiness. This can happen during an infection such as a viral infection or stomach upset. It is important that your steroid is not stopped suddenly as this could make your asthma worse and could also cause problems with the body’s hormones.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

Reporting of side effects:

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

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: [www.hpra.ie](http://www.hpra.ie)

e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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 this medicine 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 laminated aluminium pouch should not be opened until the patient is ready to use the inhaler. Arquist should be used within 3 months once the foil pouch is opened.

Do not store above 30° C.

Do not refrigerate or 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 canister contains a pressurised liquid. Do not expose to temperatures higher than 50°C. Do not pierce the canister.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any 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 mcg or 227 mcg fluticasone propionate respectively.
- The other ingredient is norflurane (HFA 134a).

### **What Arquist looks like and contents of the pack**

Arquist is a white homogeneous suspension, filled in an aluminum container fitted with a suitable metering valve and a plastic actuator. Grey coloured body with yellow cap.

Pack sizes:

1 or 2 canisters. Each canister contains 120 metered actuations of either 125 or 250 micrograms of fluticasone propionate.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Cipla Europe NV  
De Keyserlei 58-60,  
Box-19, 2018 Antwerp,  
Belgium

#### **Manufacturer**

S&D Pharma CZ, spol. s r.o.,  
Theodor 28,  
273 08 Pchery, (Pharmos a.s. facility),  
Czech Republic

Cipla (EU) Limited  
Dixcart House, Addlestone Road,  
Bourne Business Park,  
Addlestone, Surrey, KT15 2LE,  
United Kingdom

Cipla Europe NV  
De Keyserlei 58-60,  
Box-19, 2018 Antwerp,  
Belgium

**This leaflet is available in large print upon request.**

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

Belgium	FR: Arquist 125 microgrammes/dose, suspension pour inhalation en flacon pressurisé NL: Arquist 125/250 microgram/dosis aërosol, suspensie DE: Arquist 125 Mikrogramm/Dosis Druckgasinhalation, Suspension
Bulgaria	Аркуист 125/250 микрограма на впръскване, суспензия под налягане за инхалация
Greece	Arquist 125/250 μικρογραμμάρια ανά ενεργοποίηση,

	εναιώρημα για εισπνοή υπό πίεση
Croatia	Arquist 125/250 mikrograma/ dozi, stlačeni inhalat, suspenzija
Ireland	Arquist 125/250 microgram per actuation Pressurized inhalation, suspension
Poland	Efletua
Romania	Arquist 125/250 micrograme suspensie de inhalat presurizatã
Slovak Republic	Arquist 125/250 mikrogramov v jednej dávke inhalačnej suspenzie v tlakovom obale

**This leaflet was last revised in 10/2018**