

Package leaflet: Information for the patient

Icsori 125 microgram per actuation pressurised inhalation, suspension Icsori 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 [Nationally to be completed] is and what it is used for
2. What you need to know before you use [Nationally to be completed]
3. How to use [Nationally to be completed]
4. Possible side effects
5. How to store [Nationally to be completed]
6. Contents of the pack and other information

1 What [Nationally to be completed] is and what it is used for

This medicine contains the active substance fluticasone propionate which belongs to a group of medicines called corticosteroids. [Nationally to be completed] 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.

[Nationally to be completed] will not help treat sudden asthma attacks where you feel breathless. A different medicine is used for treating sudden attacks.

2. What you need to know before you use [Nationally to be completed]

Do not use [Nationally to be completed]

- 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 [Nationally to be completed] immediately

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

Talk to your doctor, pharmacist or nurse before using [Nationally to be completed] if you have ever been treated for tuberculosis (TB).

- 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 [Nationally to be completed].

Other medicines and [Nationally to be completed]

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 ketoconazole, clarithromycin, telithromycin, ritonavir, cobicistat, atazanavir, indinavir, nelfinavir or saquinavir. These medicines may increase the effect of [Nationally to be completed] and your doctor may wish to monitor you carefully if you are taking these medicines.
- steroid tablets together with your [Nationally to be completed] 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.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using [Nationally to be completed].

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

[Nationally to be completed] is not likely to affect your ability to drive or use any tools or machines.

3. How to use [Nationally to be completed]

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

Using this medicine

- [Nationally to be completed] 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 16 years of age

The recommended dose is 50-500 micrograms twice daily.

Use in children

[Nationally to be completed] is not recommended for children below 16 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 [Nationally to be completed] 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

- 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 a puff into the air. If you have not used the inhaler for a week 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 [Nationally to be completed] 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 [Nationally to be completed]

- 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 [Nationally to be completed]

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 reaction (may affect up to 1 in 100 people) or severe allergic reactions (may affect up to 1 in 10,000 people) 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.
- 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)

- hoarseness of voice and throat irritation
- bruising
- Pneumonia (infection of the lung) in COPD patients

Tell your doctor if you have any of the following while taking [Nationally to be completed] they could be symptoms of a lung infection:

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

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 mainly occur in children)
- joint pain
- indigestion
- level of sugar (glucose) in your blood may increase
- using high doses of [Nationally to be completed] 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 children and adolescents (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)
- nosebleeding
- blurred vision

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 directly via the National reporting system listed in Appendix V*. [By reporting side effects you can help provide more information on the safety of this medicine.](#)

5. How to store [Nationally to be completed]

- Keep this medicine out of the sight and reach of children.
- Do not use [Nationally to be completed] 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. 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 [Nationally to be completed] 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 220 mcg fluticasone propionate respectively.
- This medicine contains fluorinated greenhouse gases.
Each inhaler contains 12.5 g HFC-134a (norflurane) corresponding to 0.018 tonne CO₂ equivalent (global warming potential GWP = 1430).

What [Nationally to be completed] 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:

1 or 2 (bundled package 2x1) canisters containing 120 metered doses.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

[Nationally to be completed]

Manufacturer

[Nationally to be completed]

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:

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

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

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