1. What Alvesco is and what it is used for:

Alvesco is used to relieve and prevent asthma symptoms. It helps reduce airway irritation and swelling caused by asthma attacks, making breathing easier.

2. How to use Alvesco:

Always use this medicine exactly as your doctor has told you. You should read the leaflet carefully and make sure you understand how to use your inhaler. Ask your doctor or pharmacist if you have any questions.

3. Take special care with Alvesco:

Before beginning treatment with this medicine, tell your doctor if you:

- have allergies (hypersensitive) to ciclesonide or any of the other ingredients of this medicine.
- are allergic to any ingredients of this medicinal product (see section 2).

4. Possibility of interaction:

There is no interaction between Alvesco and food and drink.

5. What you need to know before you use Alvesco:

- If you have liver or kidney disorders.
- If you have any other medical conditions.
- If you know you have allergies to any of the ingredients.

6. Contents of the pack and other information:

Alvesco Inhaler comes in a pack containing a canister with the inhaler, with or without an inhaler holder. The canister contains a plastic cup under the tablet chamber.

7. Driving and using machines:

This medicine and its ingredients have no or negligible effects on the ability to drive or use machines.

8. How much Alvesco should I take each day:

Your doctor will decide on your further treatment. You should not exceed the recommended dose as stated above.

9. Possible side effects:

If you get serious symptoms such as nausea (feeling sick), vomiting or diarrhea, please tell your doctor. There is no interaction between Alvesco and food and drink.

10. Pregnancy, breast feeding:

This medicine is not suitable for use in an acute attack of asthma.

11. Children below 12 years of age:

This medicine is not recommended for children below the age of 12 because of a lack of information about its possible effects.

12. Patients with liver or kidney disorders:

There is no need to adjust the dose of ciclesonide if you have liver or kidney disorders.

13. Other medicines and Alvesco:

If you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

14. Using this medicine with food and drink:

There is no interaction between Alvesco and food and drink.

15. Pregnancy, breast-feeding and fertility:

Tell your doctor if you are pregnant, want to become pregnant or are breast-feeding.

16. What happens if you take too much Alvesco:

If you accidentally take more than the recommended dose, please refer to your doctor, pharmacist or nurse.

17. Stop use of Alvesco:

If you suddenly stop using this medicine, speak to your doctor as soon as possible.

18. Adverse reactions:

These may intensify the action of Alvesco so that the probability of side effects cannot be completely ruled out.

19. Long-term use:

Your doctor will discuss with you the risks resulting from the long-term use of Alvesco.

20. Overdose:

If you have taken too much Alvesco, speak to your doctor, pharmacist or nurse immediately.

21. What happens if you forget to take a dose:

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose. In this case, do not double the dose.

22. What happens if you stop using Alvesco:

If you stop using this medicine, you may experience an asthma attack. It is important to consult your doctor.

23. Special storage instructions:

Store below 25°C.

24. Disposal of unused medicine:

Do not flush any unused Alvesco down the toilet or the sink. Do not dispose of this product into the environment.

25. Quality assurance:

The manufacturer confirms that Alvesco meets all the requirements of the European Pharmacopoeia (EP) and the British Pharmacopoeia (BP).}

This medicine is not suitable for use in an acute attack of asthma. This process may sometimes reveal minor allergies such as rhinitis (swelling, itching, and redness of the nose).
If you find it difficult to use the inhaler, your doctor may recommend the use of a spacer. The spacer that fits the Alvesco inhaler is called AerO Chamber Plus™. If you use the Aero Chamber Plus™ device, please follow the instructions provided with it. Your doctor or pharmacist will be able to advise you about the device.

If you use more Alvesco than you should
It is important that you take your dose as advised by your doctor. You should not increase or decrease your dose without seeking medical advice. There is no specific treatment necessary if you have used too much Alvesco but you should inform your doctor. If high doses are used over long periods, a certain degree of reduction in adrenal function cannot be ruled out and control of the adrenal function may be necessary.

If you forget to use Alvesco
If you have forgotten to use your Alvesco, just take your usual dose when it is next due. Do not take a double number of puffs to make up for the forgotten dose.

If you stop using Alvesco
Even if you feel better, you should not stop using your Alvesco inhaler. If you do, your asthma may be worse. You should continue to use your Alvesco inhaler unless your doctor tells you to stop.

4. Possible side effects
Like all medicines, Alvesco 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:
- severe allergic reactions such as swelling of lips, tongue and throat (may affect up to 1 in 1,000 patients treated)
- allergic reactions: skin rashes, redness, itching or eczema, swelling of the pharynx and larynx (may affect up to 1 in 100 patients treated)
- cough, or wheezing, which gets worse soon after taking an inhalation (may affect up to 1 in 100 patients treated)

The other side effects seen with Alvesco are usually mild. In most cases you can continue with your treatment. The side effects you may experience are:

Uncommon side effects (may affect up to 1 in 100 patients treated):
- hoarseness
- burning, inflammation, irritation of mouth or throat
- oral thrush (oral fungal infection)
- headache
- bad taste
- dryness of mouth or throat

Rare side effects (may affect up to 1 in 1,000 patients treated):
- sensation of heartbeat (palpitations)
- discomfort or pain in the abdomen
- high blood pressure

Frequency not known, but may also occur:
- sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable.
- These effects are more likely to occur in children

Alvesco may affect the normal production of corticosteroids in your body. This is usually seen in patients taking high doses over a long period of time. These rare side effects may include:
- reduced rate of growth in adolescents
- a thinning of the bones
- possible clouding of the lens of the eye (cataracts) causing blurred vision
- loss of vision caused by abnormally high pressure in the eye (glaucoma)
- moon-shaped face, weight gain in the upper body and thinning arms and legs (Cushingoid features or Cushing syndrome)

Adolescents who are receiving treatment for a long period of time will have their height checked regularly by their doctor. If your growth rate is slowed, your doctor will adjust your treatment if possible to the lowest dose at which effective control of asthma is maintained.

Corticosteroid tablets can lead to more side effects than a corticosteroid inhaler such as Alvesco. If you have been taking steroid tablets before or during the use of Alvesco, the risk of side effects from the tablets may continue for a period of time. Regular check-ups with your doctor will ensure that you are taking the right dose of Alvesco for you. Regular check-ups will also identify any side effects early on and reduce the chances of them worsening.

Please remember:
- if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor 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 directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Alvesco
Keep out of the sight and reach of children.

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

The container contains a pressurised liquid. Do not expose to temperatures higher than 50°C. The container should not be punctured, broken or burned even when apparently empty.

As with most inhaled medicines in pressurised containers, the healing effect of this medicinal product may become smaller when the container is cold. However, Alvesco delivers the same level of dose from minus 10°C to plus 40°C.

If your doctor decides to stop treatment or if the inhaler is empty, return it to your pharmacist for safe disposal. This is important as traces of medicine could remain in the container even if you have the impression that it might be empty.

If the inhaler fails to work properly or shows signs of any deterioration you should seek the advice of your pharmacist who will tell you what to do.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information
What Alvesco contains
- The active ingredient is ciclesonide.
- Each actuation (delivered dose from the mouthpiece) contains 160 micrograms of ciclesonide.
- The other ingredients are ethanol anhydrous and norflurane (HFA-134a).

What Alvesco looks like and contents of the pack
Alvesco consists of a clear and colourless pressurised inhalation solution in an aluminium container sealed with a metering valve contained in an orange plastic inhaler in moulded plastic with a red/orange cap, covering the mouthpiece.
Alvesco delivers through a mouthpiece an accurately measured dose of ciclesonide in the form of a spray.

Pack sizes:
Inhaler with 120 puffs.

Depending on the number of puffs per day your physician has recommended you to use:
- the inhaler with 120 puffs has enough medication for two to four months.

Manufacturer and Product Licence Holder
Manufactured by Star Pharmaceuticals Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, HA1 1XD.
Repackaged by Servipharm Ltd.

This leaflet was revised on 05.09.17[5]
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