

Ibicar S

(Salbutamol 100 mcg/actuation and Beclometasone 50 mcg/actuation Pressurised Inhalation)

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What Ibicar S is used for?

Ibicar S Inhaler contains Salbutamol and Beclometasone dipropionate. Salbutamol, this belongs to a group of medicines called fast acting bronchodilators and Beclometasone dipropionate which is one of a group of medicines known as corticosteroids. It is used for treatment of reversible airways obstruction.

How Ibicar S works

- Salbutamol works as bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out. They help to relieve chest tightness, wheezing and cough.
- Beclometasone dipropionate works deep in your lungs to make breathing easier by reducing the inflammation, swelling and irritation in the airways. It needs to be taken regularly every day, even if you have no symptoms.

Before you use Ibicar S

- When you must not use it

Do not use Ibicar S Inhaler if you:

- Are allergic to actives or any of the other ingredients
- Are suffering from a sudden attack of breathlessness. It will not help. Use a quick-acting 'reliever' inhaler for this purpose and carry it with you at all times.

- Before you start to use it

You should use properly the inhaler to ensure that the drug reaches the target area within the lungs. You have to use Ibicar S regularly, every day, for optimum benefit.

You have to inform to your doctor for regular reassessment so that your continued corticosteroid therapy has been reviewed.

Talk to your doctor before you start to use this medicine if:

- You are steroid-dependent, so that they may start therapy with Beclomethasone dipropionate.
- You are suffering from tuberculosis (TB) now or have suffered from it in the past
- You are allergic to other similar inhalers
- You must avoid alcohol for any reason
- Your asthma seems to be getting worse. Perhaps you are more wheezy and short of breath than usual, your 'reliever' inhaler seems to be less effective, you require more puffs from your reliever inhaler than usual, or you do not seem to be getting better. Your doctor may need to increase the dose of your steroid inhaler or give you a course of steroid tablets, or change your treatment altogether. If you have an infection in your chest your doctor may prescribe a course of antibiotics.
- You may have adrenal suppression if you had treated prolonged with high doses of inhaled corticosteroids.
- You are suffering from thyrotoxicosis (Graves syndrome/autoimmune hyperthyroidism) you should be caution to use Salbutamol.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any medicines bought with a prescription.

How to use Ibicar S

- How much to use

Remember that it is important to take your medicine as your doctor has told you. The label should remind you how many puffs to take and how often.

Do not take more puffs than your doctor has told you to. In some circumstances, your doctor may prescribe more than the usual number of puffs. You should check with your doctor or pharmacist if you are not sure. The usual number of puffs to take is:

Adult: Two inhalations, three or four times daily, titrated to the lowest effective dose. The maximum dose is two inhalations four times a day.

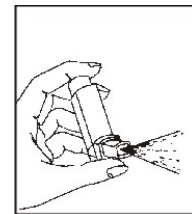
Children: One or two inhalations, two, three or four times daily. The maximum dose is two inhalations four times a day.

Elderly: There is no need to adjust the dose in elderly patients.

How to use the inhaler

Testing your inhaler:

If you are using the inhaler for the first time or if the inhaler has not been used for a minimum of two days, "test spray" the inhaler. Spray the inhaler 4 times into the air.(see pic no. 1)

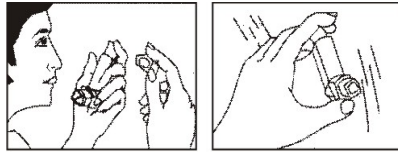


1

Remove the cap from the mouthpiece; the strap on the cap will stay attached to the actuator. If the strap is removed from the actuator, the mouthpiece should be inspected for the presence of foreign objects before each use. Make sure the canister is fully and firmly inserted into the actuator. (see pic no. 2)

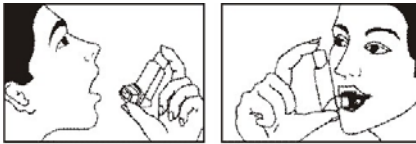
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2

Hold the inhaler upright with your thumb on the base. Place either one or two fingers on the top of the canister. Breathe out fully through your mouth expelling as much air from your lungs as possible. Thereafter, place the mouthpiece of the inhaler in your mouth between your teeth. (see pic no. 3).



3

Close your lips around it (do not bite it) tilt your head slightly backwards. Start breathing in slowly through your mouth. As you breathe in steadily and deeply, press down the canister to release one dose. (see pic no. 4)



4

Remove the inhaler from your mouth and hold breath for 10 seconds or for as long as it is comfortable. Breathe out slowly. (see pic no. 5)

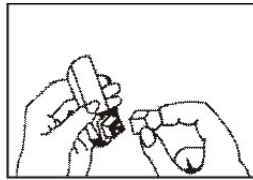


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Note:

Rinse your mouth or gargle with water after inhaling each dose. This is likely to reduce the soreness that may be caused by the drug. If another dose is required wait for at least one minute and repeat steps 2 through 5 for each inhalation prescribed by your Physician.

After use, replace the mouthpiece cover. (see pic no.6)



6

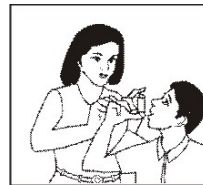
Practice in front of the mirror for the first few times. If you see 'mist' coming from top of the inhaler or sides of the mouth, this indicates failure of technique. Start again from Step 2. (see pic no. 7)



7

For Children:

Children should use the inhaler under adult supervision, as instructed by the Physician. (see pic no. 8)

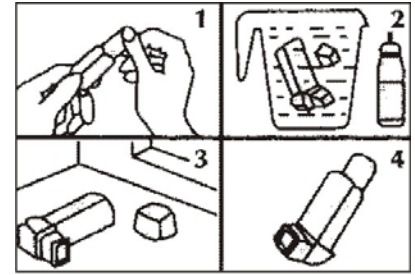


8

Cleansing:

Clean the inhaler at least once a day.

1. Gently pull the metal canister out of the plastic body of the inhaler. Remove the mouthpiece cover.
2. Rinse the plastic body and the mouthpiece cover in warm / running water.
3. Dry thoroughly. Avoid excess heat.
4. Replace the canister and the mouthpiece cover correctly.
5. Store the spacer by hygienically.
6. Discard the canister after using the labelled number of inhalation.



9

- When to use it

It needs to be taken regularly every day, even if you have no symptoms.

How long to use it

This inhaler must be used regularly, even when you feel well. You must not stop using your inhaler unless your doctor tells you to. Ask your doctor for a prescription for a replacement inhaler before this one is empty. If your doctor decided to stop treatment, return the inhaler to your doctor or pharmacist for safe disposal.

If you forget to use it

If you forget to use this inhaler at your usual time, take your recommended number of puffs as soon as you remember unless it is nearly time for the next dose. DO NOT take a double dose to make up for a forgotten dose. Then continue to use your inhaler regularly at the correct time, as prescribed by your doctor.

If you use too much (overdose)

It is important that you take your dose as stated on the pharmacist's label, or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice. If you accidentally take more puffs than recommended, please tell your doctor.

While you are using it

Things you must do

- Your doctor may prescribe this inhaler to replace steroid tablets, which may mean that for a short time you may have to take both medicines. It is important to follow your

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doctor's advice. Whilst you are reducing the number of steroid tablets that you may take you may feel generally unwell even though you can breathe as well as normal or better. If you have other allergies, you may find that stopping your steroid tablets makes them worse. If this happens keep using your inhaler and tell your doctor.

- If you have been treated for a long time with high dose of inhaled steroid, you may require a course of steroid tablets or possibly a steroid injection in times of stress. Your doctor will decide if you need any extra treatment and will also advise you as to how long you need to take the course of steroid tablets and how you should reduce these as you get better.
- If you think your usual treatment is not working, for example your symptoms are not getting better, or are getting worse, or you need to use more puffs from your reliever inhaler, please tell your doctor. Your asthma may be getting worse.
- Visit your doctor regularly for a review of your condition.

- Things you must not do

- This inhaler must be used regularly, even when you feel well. You must not stop using your inhaler unless your doctor tells you to.

- Things to be careful of

- **Pregnancy and Breast-feeding:** If you are pregnant, planning to become pregnant or are breast-feeding, ask your doctor for advice before taking this medicine.
- **Driving and using machines:** Ibicar S Inhaler is not known to affect your ability to drive or operate machinery.

Side effects

Like all medicines, Ibicar S Inhaler can cause side effects, although not everybody gets them.

If immediately after taking a puff of this inhaler you feel wheezy or tight chest do not take any more puffs. Use your reliever inhaler to help your breathing and contact your doctor immediately. Stop using your inhaler and tell your doctor immediately or go to the casualty department at your nearest hospital if the following happens:

- An allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rashes or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalization.

Treatment with Ibicar S Inhaler may affect the normal production of corticosteroids in the body. Keep using your inhaler but see your doctor as soon as possible if you become unwell.

The following side effects may also occur in patients taking Salbutamol and Beclometasone dipropionate, if you experience any of these effects, keep using your inhaler but see your doctor if they last for a while or if they are worrying you:

- Adrenal suppression
- Growth retardation in children and adolescents.
- Increase in bone mineral density
- Hoarseness
- Sore mouth or thrush (white spots in your mouth and throat)
- Feeling sick
- Headache
- Feeling dizzy or faint
- Tremors of muscle
- Increase in wheezing, shortness of breath and cough
- Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children.
- Constriction of bronchioles
- Skin rashes, itching, redness of skin and swelling of the eyes, face, lips and throat.
- Faster heart beat.

At high doses, taken for prolonged periods the following side effects have been reported:

- Bone thinning
- Clouding of the lens of the eye (cataract) resulting in blurred vision
- Loss of vision due to abnormally high pressure in the eye

Children or adolescents who are using the inhaler for a prolonged period may grow more slowly. Your doctor may therefore wish to monitor the height of a child receiving prolonged treatment with Ibicar S inhaler. If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Ibicar S

Storage

Keep out of reach and sight of children.
Store below 30°C. Do not freeze.

Disposal

Do not use the inhaler after the expiry date that is stated on the outer packaging (shown as EXP). The expiry date refers to the last day of the month.

Medicines should not be disposed via wastewater or household waste. If your doctor decides to stop treatment, return the inhaler to your doctor or pharmacist for safe disposal. These measures will help to save the environment.

Product Description

What it looks like

White to off white colour suspension filled in aluminium aerosol can with silver ferrule valve provided with actuator suitable for

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oral inhalation when actuated a metered spray is produced.

Ingredients

- **Active ingredients**

Salbutamol Sulphate BP equivalent to Salbutamol 100 mcg.
Beclometasone Dipropionate Anh. Ph. Eur 50 µg.

- **Inactive ingredients**

Ethanol BP 3.5 % w/w (5.23 % v/v) (2.52 mg).
Oleic acid 0.146 mg.
Propellant 1, 1, 1, 2-Tetrafluoroethane (HFA 134a) 69.2 mg.

MAL Number: MAL14115007AZ

Manufacturer

Glenmark Pharmaceuticals Ltd,
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Product Registration Holder

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