

# GRAIN DIRECTION

SAME SIZE ARTWORK  
LEAFLET: 225 mm x 270 mm  
FOLDING SIZE: 38 mm x 135 mm



135 mm

25 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

## Ibicar 250 Inhaler

Beclometasone dipropionate  
pressurised inhalation BP

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Ibicar 250 is and what it is used for?
2. Before you use Ibicar 250.
3. How to use Ibicar 250.
4. Possible side effects.
5. How to store Ibicar 250.
6. Further information.

### 1. What Ibicar 250 is and what it is used for?

Ibicar 250 pressurised inhalation solution is used to help prevent the symptoms of mild, moderate or severe asthma. The active ingredient, beclometasone dipropionate, is one of a group of medicines called corticosteroids, which are often referred to simply as steroids. Steroids have an anti-inflammatory action reducing the swelling and irritation in the walls of the small air passages in the lungs, and so ease breathing problems.

### 2. Before you use Ibicar 250.

#### Do not use Ibicar 250:

1. If you are allergic to any of the ingredients of this medicine or to any other medicines used to treat asthma.
2. To treat 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.

Take SPECIAL care with Ibicar 250 and always tell your doctor if:

1. You are being, or have ever been, treated for tuberculosis (TB).
2. You must avoid alcohol for any reason.
3. 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.
4. When transferring from steroid tablets to an inhaler you find that, even if your chest is getting better, you feel generally unwell, you DEVELOP a rash, eczema or a runny nose and sneezing (rhinitis). Do not stop treatment with your inhaler unless your doctor tells you to.

If you have been treated for a long time with high doses of inhaled steroid, you may require a course of steroid tablets or possibly a steroid injection in times of stress. For example, during admission to hospital after a serious accident, before an operation, during an acute attack of asthma or if you have a chest infection or other serious illness. Your doctor will decide if you need any extra steroid 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 are using Ibicar 250 instead of, or as well as taking steroid tablets, or if your doctor is trying to reduce the dose of your steroid tablets, you should carry a steroid warning card until your doctor tells you that you don't need to.

#### Taking other medicines:

Before starting treatment, please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Remember to take these medicines and your inhalers with you if you have to go into hospital.

Some medicines may increase the effects of Ibicar 250 and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

#### Pregnancy and breast-feeding:

If you are pregnant or breast-feeding, or could become pregnant, talk to your doctor before using your inhaler.

Effects on ability to drive and use machines: None reported

#### Important information about some of the ingredients of Ibicar 250:

Ibicar 250 contains a small amount of alcohol. There is a theoretical potential for interaction in particularly sensitive patients taking disulfiram or metronidazole.

### 3. How to use Ibicar 250.

Always use your inhaler exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Instructions for using your inhaler are given after the dosage section. It takes a few days for your inhaler to work. It is very important that you use it regularly.

Do not stop treatment even if you feel better unless told to do so by your doctor. Do not stop using your inhaler abruptly.

While you are using Ibicar 250 your doctor will want to check your asthma regularly by carrying out simple breathing tests and may need to carry out blood tests from time to time.

#### Dosage:

The starting dose will depend on how severe your asthma is and will be decided by your doctor. It may be higher than the doses given below. Your doctor will prescribe the lower dose of Ibicar 250 that will control your symptoms.

A device called a Volumatic spacer should always be used when: adults, the elderly and adolescents 16 years of age and older are taking total daily doses of Ibicar 250 of 1,000 micrograms or more Ibicar 250 is not suitable for children.

#### The common starting dose is:

Adults and the elderly only: 500 micrograms (2 puffs) twice a day Usually the most you would take in a day is: 2,000 micrograms (8 puffs) The total daily dose may be divided into 2, 3 or 4 doses per day.

It takes a few days for this medicine to work. It is very important that you use it regularly.

Do not stop treatment even if you feel better unless told to do so by your doctor. Do not stop using your inhaler abruptly.

If you use more Ibicar 250 than you should: Tell your doctor as soon as possible. Your doctor may want to check the cortisol levels in your blood and therefore, may need to take a blood sample (cortisol is a steroid hormone which occurs naturally in the body).

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 forget to use Ibicar 250:

If you forget to take your Ibicar 250, miss out your forgotten dose and take the next dose when it is due. Do not take more puffs than you were told to take.

## INSTRUCTIONS FOR PATIENT FOR USING THE INHALER

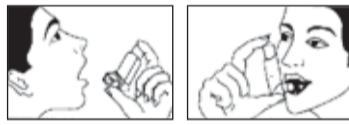
**Important:** Follow instructions carefully. Shake the inhaler well immediately before each use.

Taking 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)



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)



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)



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)



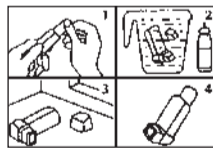
Remove the inhaler from your mouth and hold breath for 10 seconds or for as long as it is comfortable. Breathe out slowly. (see pic no. 5)

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.



#### 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)



#### Cleansing:

It is important to clean your inhaler at least once a week, to stop it blocking up.

1. Gently pull the metal canister out of the plastic body of the inhaler. Remove the mouthpiece cover.
2. Rinse the plastic case and the mouthpiece cover in warm water. If you use a mild liquid detergent, rinse carefully with clean water before drying. Do not put the metal canister into water.
3. Dry thoroughly. Avoid excess heat.
4. Replace the canister and the mouthpiece cover correctly.
5. Store the spacer by hygienically. Discard the canister after using the labeled number of inhalation.

#### 3. Possible side effects.

Like all medicines, Ibicar 250 can cause side effects, although not everybody gets them.

If you notice an immediate increase in wheezing, shortness of breath and cough straight after using your inhaler, stop using Ibicar 250 and use a quick-acting 'reliever' inhaler immediately. Contact your doctor straightaway. Your doctor will review your asthma and may change your treatment and may prescribe a different inhaler to treat your asthma.

The following side effects have been reported. Tell your doctor as soon as possible if you suffer from any of these side effects but do not stop treatment unless told to do so. Your doctor will try to prevent these effects by prescribing Ibicar 250 in the lower dose possible to control your asthma.

1. Allergic reactions including skin rashes, hives, itching or redness, or swelling of the face, eyes, lips and throat.
2. Thrush in the mouth and throat. This is more likely if the daily dose taken is greater than 400 micrograms. Thrush can be treated with anti-fungal medicines while you continue to use Ibicar 250. Brushing your teeth, or thoroughly rinsing your mouth with water immediately after each dose may help prevent thrush.
3. Hoarse voice or a sore throat or tongue. Using a Volumatic spacer device or rinsing your mouth with water immediately after using your inhaler may help prevent this.
4. Changes to the normal production of the steroids in the body, particularly after treatment with Ibicar 250 at high doses over a long period of time.
5. If you become unwell or develop symptoms such as loss of appetite, abdominal pain, WEIGHT LOSS, tiredness, nausea (feeling sick), vomiting (being sick), feeling faint, sweating and possible convulsions (fits), you should consult your doctor. This is particularly important if you have been exposed to stress such as surgery, infection, an acute attack of asthma, or other serious illness. Your doctor may carry out blood test from time to time to monitor the levels of steroids in your body.
6. Children and adolescents may grow more slowly and may need to have their height checked regularly by their doctor. This occurs particularly after treatment with Ibicar 250 at high doses over a long period of time.
7. A decrease in bone mineral density (thinning and weakening of the bones) and eye problems which include the formation of CATARACTS and glaucoma (increased pressure in the eye).
8. Sleeping problems, depression or feeling worried, restless, nervous, over-excited or irritable. These effects are more likely to occur in children.
9. Headaches
10. Nausea (feeling sick)

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.

#### 5. How to store Ibicar 250.

##### 1. Keep out of the reach and sight of children.

2. Do not use Ibicar 250 after the expiry date which is dated on the carton and label. The expiry date refers to the last day of that month.
  3. Do not store the inhaler above 30°C. Protect from frost and direct sunlight.
  4. 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.
  5. 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.
- Warning: The canister contains a pressurised liquid. Keep away from heat and direct sunlight, do not expose to high temperatures (above 50°C) and do not puncture or burn (incinerate), even when empty.

##### 6. Further information

###### What Ibicar 250 contains

Each actuation delivers: Beclometasone Dipropionate Anhydrous EP 250 µg  
Excipients: Ethanol BP 14.0%w/w (20%v/v)  
Oleic Acid USP/NF  
Propellant 1,1,1,2 Tetrafluoro Ethane (HFA 134a)

###### Marketing Authorization Holder and Manufacturer

Glenmark Pharmaceuticals Ltd.  
(Unit III) Village Kishanpura, Baddi-Nalagarh Road, Tehsil Baddi, Dist.Solan, (H.P.) 173 205, India

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Manufactured by :

**Glenmark**

Pharmaceuticals Ltd.

B/2, Mahalaxmi Chambers,

22, Bhulabhai Desai Road,

Mumbai - 400 026, (India).

At: (Unit III), Village: Kishanpura,

Baddi - Nalagarh Road,

Tehsil Baddi, Distt. Solan

(H.P.) - 173 205, (India).

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