

**Gastro-resistant Prolonged-release Tablets**
beclometasone dipropionate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This leaflet was last updated in May 2019.

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 Clipper Tablets is and what it is used for
2. What you need to know before you take Clipper Tablets
3. How to take Clipper Tablets
4. Possible side effects
5. How to store Clipper Tablets
6. Contents of the pack and other information

1. What Clipper Tablets is and what it is used for

Clipper tablets contain the active substance beclometasone dipropionate belonging to a group of medicines called steroids. Their full name is *corticosteroids*. These corticosteroids occur naturally in the body, and help to maintain health and well-being. Boosting your body with extra corticosteroids (such as beclometasone dipropionate) is an effective way to treat various illnesses involving inflammation in the body.

Beclometasone dipropionate reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Clipper Tablets have been prescribed by your doctor to treat your ulcerative colitis. This is a disease which affects the colon (the large intestine or bowel), the rectum (the lower end of the large intestine), and causes the lining of the colon to become ulcerated and inflamed, resulting in pain, redness and swelling. These tablets act locally in the affected area to reduce the inflammation.

They are called gastro-resistant prolonged release tablets because they are made with a coating that allows them to pass through the stomach without dissolving until they reach the large intestine or bowel, where the coating breaks down for the beclometasone dipropionate to be released slowly.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Clipper Tablets**Do not take Clipper Tablets:**

- if you are allergic (hypersensitive) to beclometasone dipropionate or any of the other ingredients of this medicine (listed in section 6).
- if you have tuberculosis (TB)
- if you have an infection of the colon or rectum caused by a fungus or virus.
- if you have a serious liver disease

Warning and precautions:

Talk to your doctor, pharmacist or nurse before taking Clipper Tablets

Take special care with Clipper Tablets and always tell your doctor if you have:

- liver problems
- kidney problems
- diabetes
- an ulcer of the stomach or intestine
- high blood pressure
- osteoporosis, a condition where loss of bony tissue results in brittle bones
- Addison's disease or hypoadrenalism, a condition caused by low secretions of corticosteroid hormone from the adrenal glands
- increased pressure in your eyes, called glaucoma
- a cataract, a condition where the lens of the eye becomes opaque leading to poor vision or blindness
- an infection of the bowel
- **severe depression or manic-depression (bipolar disorder), or if any of your close family has had these illnesses.** This includes having had depression while taking steroid medicines like beclometasone dipropionate. If this applies to you, talk to a doctor before taking beclometasone dipropionate.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you are going to start taking, or are already taking steroid medicines, such as Clipper, for more than three weeks, your doctor or pharmacist will give you a "steroid warning card". It is important that you always carry this card with you until your doctor tells you that you don't need to.

If you have never had **chickenpox, shingles or measles**, do not have close contact with people whom you know have these diseases. If you become ill, or are exposed to someone with chickenpox, shingles, measles or an infectious disease **contact your doctor immediately.**

Mental problems while taking beclometasone dipropionate

Mental health problems can happen while taking steroids like beclometasone dipropionate (see also section 4 – Possible side effects):

- these illnesses can be serious
- usually they start within a few days or weeks of starting the medicine
- they are more likely to happen at high doses
- most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen they might need treatment.

Talk to a doctor if you (or someone taking this medicine), show any signs of mental problems. This is particularly important if you are depressed, or might be thinking of suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Other medicines and Clipper Tablets

Before starting treatment, please tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, if you are already using or taking other steroid medicines.

Some medicines may increase the effects of Clipper Tablets 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, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines:

Clipper Tablets should not affect your ability to drive or operate machinery. However, some patients may feel sleepy or drowsy after taking this medicine. If these tablets affect you in this way after taking them, you must not drive or operate machinery or perform any tasks which require you to concentrate and remain alert.

Clipper Tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Clipper Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. It is important that you take your tablets regularly.

Clipper Tablets are specially formulated so that you only have to take your tablets **once a day**, preferably in the morning. It is best to take your tablets on an empty stomach or after a light breakfast. Take your tablets with a glass of liquid, e.g. water. **Do not break or chew your tablets.**

Dosage:

The usual adult dose, including the elderly is one 5 mg tablet once a day. Your treatment will usually last up to four weeks. Do not stop taking your medicine until your doctor tells you.

Use in children:

Children must not take this medicine.

If you take more Clipper Tablets than you should:

If you take more Clipper Tablets than you should, immediately contact your doctor or pharmacist.

If you forget to take Clipper Tablets:

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose, just take the next dose when it is due. Do not take a double dose to make up for a forgotten dose.

If you stop taking Clipper Tablets:

Do not stop taking your tablets, even if you feel better, unless told to do so by your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects: tell a doctor straight away

Steroids including dexamethasone can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like dexamethasone:

- feeling depressed, including thinking about suicide
- feeling high (mania) or moods that go up and down
- feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory
- feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

If you notice any of these problems talk to a doctor straight away.

The following side effects have also 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. If you are not sure what the side effects below are, ask your doctor to explain them to you.

Uncommon: may affect up to 1 in 100 people:

- feeling sick (nausea)
- constipation
- stomach pain
- flu-like illness
- fever
- very heavy periods
- headache
- anxiety
- sleepiness
- muscle cramps.

Taking high doses of beclometasone dipropionate over a long period of time can cause systematic effects. These are rare side effects which may affect up to 1 in 1000 people and include:

- problems with how your adrenal glands work (adrenosuppression)
- a round, puffy face (called "moon face")
- a build up of fat on the back of the neck (called "buffalo hump")
- a build up of excess fat in the body (obesity)
- yeast infection in the mouth
- a decrease in the number of white blood cells called leucocytes and monocytes, which help the body fight infection by destroying harmful micro-organisms in the blood
- an abnormal increase in the number of white blood cells called granulocytes
- severe redness and inflammation of facial skin
- headache
- raised pressure within the skull
- decrease in bone mineral density (thinning of the bones)
- increased pressure in your eyes (glaucoma)
- cataracts

Not known side effects (frequency cannot be estimated from the available data) have been identified as class risk effect of corticosteroids: blurred vision, hiccups.

If you experience any of the above side effects and they cause you distress, are severe or last for several days, please tell your doctor or pharmacist. Whilst taking these tablets if you notice anything unusual or a side effect which is not mentioned in this leaflet, contact your doctor or pharmacist immediately.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clipper Tablets

- 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 carton and label. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.
- 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 to protect the environment.

6. Contents of the pack and other information**What Clipper Tablets contains**

- The active substance is beclometasone dipropionate.
- The other ingredients are lactose monohydrate, hypromellose (E464), microcrystalline cellulose, maize starch, magnesium stearate, macrogol 4000, methacrylic acid-methyl methacrylate copolymer, titanium dioxide (E171) and talc.

What Clipper Tablets looks like and the contents of the pack

Clipper 5 mg Gastro-resistant Prolonged-release Tablets are ivory white and are round and convex in shape. They are available in blister packs of 10 and 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder of Clipper is Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, United Kingdom.

The manufacturer of Clipper is Doppel Farmaceutici S.r.l., Via Martiri delle Foibe 1, Cortemaggiore (Piacenza), Italy.

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

Italy	Bidiclin
Belgium	Clipper
Luxembourg	Clipper
Spain	Bidiclin
UK	Clipper

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