

Cortiment® 9 mg prolonged release tablets

budesonide

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard

Ireland: HPRA Pharmacovigilance, Website: www.hpra.ie

Malta: ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Cortiment

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 on the blister pack after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

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.

6. Contents of the pack and other information

What Cortiment contains

- The active substance in this medicine is budesonide. Each tablet contains 9 mg of budesonide.
- The other ingredients (excipients) in this medicine are:
tablet core: stearic acid (E570), lecithin (soya) (E322), microcrystalline cellulose (E460), hydroxypropylcellulose (E463), lactose monohydrate, silica colloidal hydrated (E551), magnesium stearate (E470b)
film coating: methacrylic acid-methyl methacrylate copolymer (1:1), methacrylic acid-methyl methacrylate copolymer (1:2), talc (E553b), titanium dioxide (E171), triethyl citrate

What Cortiment looks like and contents of the pack

Cortiment is supplied as white to off-white, round, double convex tablets with a film coating, and 'MX9' engraved on one side of the tablet. The tablets are supplied in blister packs with aluminium press-through foil in a cardboard carton.

This medicine is available in packs of 10, 20, 30, 50, 60 or 80 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

UK: Ferring Pharmaceuticals Ltd., Drayton Hall, Church Road, West Drayton, UB7 7PS, UK
PL 03194/0113

Ireland/Malta: Ferring Ireland Ltd., United Drug House, Magna Drive, Magna Business Park, Citywest Road, Dublin 24
Ireland: PA 1009/026/001
Malta: MA1314/00601

Manufacturer: Cosmo S.p.A, Via C. Colombo 1, 20045 Lainate, Milan, Italy

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

Austria, Bulgaria, Cyprus, Czech republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Malta, the Netherlands, Norway, Romania, Slovakia, Spain, Sweden, UK: **Cortiment**
Croatia, Poland: **Cortiment^{MMX}**
Portugal: **Coramen**
Belgium, Latvia, Lithuania, Luxembourg: **Budesonide Ferring**
Slovenia: **Budezonid Ferring**

This leaflet was last revised in December 2020.

Read all of this leaflet carefully before you start taking 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Cortiment is and what it is used for
- What you need to know before you take Cortiment
- How to take Cortiment
- Possible side effects
- How to store Cortiment
- Contents of the pack and other information

1. What Cortiment is and what it is used for

Cortiment tablets contain a medicinal substance called budesonide. Budesonide belongs to a category of medicinal products called 'corticosteroids', which are used to reduce inflammation.

Cortiment tablets are used in adults to treat:

- ulcerative colitis which is an inflammation of the large intestine (colon) and the rectum.
- acute episodes of microscopic colitis which is a disease with chronic inflammation of the large intestine (colon) typically with chronic watery diarrhea.

2. What you need to know before you take Cortiment

Do not take Cortiment

If you are allergic to budesonide or one of the other ingredients of this medicine (listed in section 6).

If you are allergic to peanut or soya since Cortiment contains lecithin, which is a derivative from soya oil.

Warnings and precautions

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

Talk to your doctor before taking Cortiment:

- if you have an infection, such as a virus infection, a bacterial infection or a fungal infection;
- if you have ever had high blood pressure;
- if you have diabetes;
- if you ever had brittle bones;
- if you ever had a stomach ulcer;
- if you ever had elevated eyeball pressure (glaucoma) or grey cataract;
- if a family member has ever had diabetes or elevated eyeball pressure (glaucoma);
- if you ever had liver problems;
- if you transfer from other cortisone therapy to Cortiment as this may result in e.g. pain in the muscles and joints, tiredness, headache, nausea, and vomiting;
- if you know that you need to be vaccinated;
- if you have been treated with a stronger cortisone preparation before starting treatment with Cortiment, your symptoms may reappear;
- if you get an infection during the treatment, Cortiment can hide the signs of infection and the infection may get worse. You may get infections easier during the treatment with Cortiment, since your body's resistance towards infections may be reduced;
- if you are scheduled to undergo surgery soon or are going through a stressful period;
- if you have not yet had measles or chicken pox. While taking Cortiment tablets, try to avoid people with measles or chicken pox. Inform your doctor if you think you have been infected with chicken pox or measles while taking this medicine.
- if you or a close family member have had problems with mental health.

Taking cortisone preparations at high doses and for a prolonged period may affect all

parts of the body and in very rare cases psychological problems (see section 4, Possible side effects).

If you have any doubts about whether one of the above applies to you, contact your doctor before you take Cortiment tablets.

Other medicines and Cortiment

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is necessary because Cortiment tablets affect how some medicines work and some medicines may affect how Cortiment works. Some medicines may increase the effects of Cortiment and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV; ritonavir, cobicistat).

It is particularly important that you tell your doctor if you are taking, have recently taken or might take one of the following medicines:

- ketoconazole or itraconazole, which are substances used to treat fungal infections;
- medicines used for HIV treatment (e.g. ritonavir, nelfinavir, cobicistat-containing products);
- carbamazepine, which is used for treatment of epilepsy;
- cardiac glycosides and diuretics;
- medicines that contain oestrogens, such as hormone replacement therapy (HRT) and some oral contraceptives;
- cholestyramine, which is used to lower cholesterol levels or treat itching caused by liver problems, or antacids which is used to neutralise the acid made by your stomach.

Cortiment with food, drink and alcohol

Do not drink grapefruit juice when taking Cortiment tablets. This may affect the way the medicine works.

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 for advice before taking this medicine.

Driving and using machines

It is unlikely that Cortiment will affect your ability to drive and use machines. Care is required because this type of medicine may sometimes cause dizziness or fatigue.

Cortiment contains lactose and lecithin (soya oil)

Cortiment tablets contain lactose, a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Cortiment contains lecithin (soya oil). If you are allergic to peanuts or soya, do not use this medicinal product.

3. How to take Cortiment

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

- The recommended dose for ulcerative colitis and microscopic colitis is one tablet in the morning before or with breakfast.
- Swallow the tablet whole with a glass of water; the tablet must not be broken, crushed or chewed.
- Usually you will take this medicine daily for a maximum of eight weeks. Your doctor may then gradually lower the number of times you take the medicine.
- Keep taking Cortiment tablets as your doctor has told you, even if you start feeling better.

Additional information when taking Cortiment tablets

If you will undergo surgery soon or are going through a stressful period, the doctor may ask you to take other steroid tablets as well.

Use in patients with reduced kidney or liver function

Cortiment was not studied specifically in patients with kidney or liver problems. Talk to your doctor.

Use in children

Cortiment tablets are not recommended for use in children.

If you take more Cortiment than you should

If you take more Cortiment tablets than you should, inform your doctor immediately.

If you forget to take Cortiment

- If you forget to take a Cortiment tablet, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose.
- Do not take a double dose to make up for a forgotten tablet.

If you stop taking Cortiment

Do not stop taking Cortiment tablets without discussing it with your doctor first. You may need to stop the treatment gradually. If you suddenly stop taking the medicine, you may become ill.

If you have any further questions about the use of this medicine, ask your doctor.

4. Possible side effects

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

If you have an allergic reaction, immediately contact your doctor or go to a hospital. Signs may include hives or swelling of the face, lips, mouth, tongue and throat. This can make it difficult to breathe.

The following side effects may occur when taking Cortiment; most of the side effects mentioned below can also be expected with other steroid treatment.

Common (may affect up to 1 in 10 people)

- Cushing-like symptoms, such as a round face, acne, weight gain and a tendency to bruise easily
- Low potassium levels in the blood, which can cause muscle weakness or fatigue, thirst or a tingling sensation
- Change in behaviour, such as nervousness, insomnia and mood swings
- Depression
- Headache
- Pounding heart beats (palpitations)
- Nausea
- Stomach ache
- Bloating abdomen
- Dry mouth
- Indigestion (dyspepsia)
- Skin rash or itchiness
- Acne
- Muscle pain, muscle cramps
- Heavy or irregular menstruation in women
- Extreme tiredness (fatigue)
- Decrease of the hormone cortisol in the blood

Uncommon (may affect up to 1 in 100 people)

- Influenza
- Rise in white blood cells
- Change in behaviour, such as mood swings
- Feeling of restlessness with hyperactivity
- Anxiety
- Dizziness
- Shaking
- Flatulence
- Back pain
- Muscle spasms
- Swelling of the legs

Rare (may affect up to 1 in 1,000 people)

- Aggression
- Glaucoma (increased pressure in the eye)
- Opacity of the lens or capsule of the eye (cataract)
- Blurred vision
- Purple or black-and-blue spots on the skin

Very rare (may affect up to 1 in 10,000 people)

- A serious allergic reaction (called anaphylaxis) which can lead to breathing difficulties and potential shock

Some of the side effects mentioned above are typical for steroid medication and may occur depending on your dose, period of treatment, whether you have or have had treatment with other cortisone preparations, and your individual susceptibility.

Psychological problems may develop when taking steroids like Cortiment. Discuss it with your doctor if you (or someone who uses this medicine) have (has) symptoms of psychological problems. This is particularly important if you are depressed and may be thinking about committing suicide. In very rare cases, psychological problems have developed when high doses were taken for a long time.