

Cortiment[®] 9mg Prolonged Release Tablets

Budesonide 9mg

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1. What Cortiment is used for

Cortiment is indicated in adults for induction of remission in patients with mild to moderate active ulcerative colitis (UC) where 5-aminosalicylic acid (5-ASA) treatment is not sufficient.

2. How Cortiment works

Cortiment contains the active substance *budesonide*.

This is an intestinal *antiinflammatory agent*, corticosteroids acting locally. In general, *budesonide* inhibits many inflammatory processes. The mode of action of Cortiment is based on a local action in the gut.

3. Before you take Cortiment

When you must not use it:

Do not take Cortiment

- **if you are allergic** to budesonide, soya oil, peanut oil or to any of the other ingredients of Cortiment (listed in ingredients section)
- if you have rare hereditary problems such as galactose intolerance, the Lapp lactase deficiency or glucose - galactose malabsorption.

→ If this applies to you, **do not take Cortiment and tell your doctor immediately.**

Before you start to use it:

Warning and precautions

• Tell your doctor or pharmacist if you have or have had any of the following conditions:

- infections
- hypertension
- diabetes mellitus
- osteoporosis
- peptic ulcer
- glaucoma or cataracts
- family history of diabetes or glaucoma
- with any other condition where the use of glucocorticoids may have unwanted effects.
- reduced liver function

Visual disturbance may be reported with systemic and topical corticosteroid use. If you presents with symptoms such as blurred vision or other visual disturbances, you should consult your doctor or pharmacist for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Do not suddenly stop taking Cortiment. When treatment is to be discontinued, it may be useful to gradually reduce the dose at the discretion of the treating physician.

Do not transfer from other steroid therapy, because it may result in symptoms relating to the change in systemic steroid levels. Some patients may feel unwell in a non-specific way during the withdrawal phase, e.g., pain in muscles and joints. A general insufficient corticosteroid effect should be suspected if, in rare cases, symptoms such as tiredness, headache, nausea and vomiting should occur. In these cases a temporary increase in the dose of systemic corticosteroids is sometimes necessary.

As corticosteroids are known to have

immunological effects, the co-administration of Cortiment tablets is likely to reduce the immune response to vaccines.

→ If any of these applies to you, **talk to your doctor or pharmacist before taking Cortiment.**

Children and adolescents:

Do not give this medicine to children.

Cortiment was not studied in the paediatric population.

Taking other medicines:

Other medicines and Cortiment

Tell your doctor or pharmacist if you are taking, have recently taken or might take, any other medicines.

Cortiment may interact with other medicines. As a result, the amounts of Cortiment or other medicines in your blood may change. This may stop your medicines from working properly, or may make any side effects worse.

Talk to your doctor or pharmacist if you are taking any of the following medicines as special care may be required for:

Ketoconazole, itraconazole, HIV protease inhibitors (including cobicistat-containing products) and grapefruit juice.

Co-treatment with **CYP3A inhibitors** is expected to increase systemic exposure to budesonide several times and the risk of systemic side effects.

The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects. If treatments are combined, the period between dosing of the combined treatments should be as long as possible and a reduction of the budesonide dose could also be considered.

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Concomitant treatment with **CYP3A inducers such as carbamazepine** may reduce budesonide exposure, which may require a dose increase.

Corticosteroid interactions that may present a significant hazard to selected patients are those with **heart glycosides (increased effect due to reduced potassium levels) and diuretics (increased elimination of potassium).**

Increased plasma concentrations of and enhanced effects of corticosteroids have been observed in women also treated **with oestrogens and contraceptive steroids**, but no such effect has been observed with budesonide and concomitant intake of low-dose combination oral contraceptives.

Although not studied, concomitant administration of **cholestyramine or antacids** may reduce budesonide uptake, in common with other drugs.

Therefore, these preparations should not be taken simultaneously, but at least two hours apart

At recommended doses, omeprazole does not affect the pharmacokinetics of oral budesonide, whereas cimetidine has a slight but clinically insignificant effect.

Because adrenal and/or pituitary function may be suppressed, an ACTH stimulation test for diagnosing pituitary or adrenal insufficiency might show false results (low values of cortisol).

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Cortiment should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.
- Budesonide is excreted in breast milk. A decision must be made whether to discontinue breast-feeding or to discontinue/ abstain from budesonide therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

4. How to take Cortiment

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

How much to use it:

The recommended dose is **one tablet once daily**, orally in the morning, with or without food, for up to 8 weeks.

The tablet should be swallowed with a glass of water and must not be broken, crushed or chewed as the film coating is intended to ensure a prolonged release.

When treatment is discontinued, it may be useful to gradually reduce the dose at the discretion of the treating physician.

When to use it:

Always use Cortiment exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.

How long to use it:

You should continue to use Cortiment for as long as your doctor recommends.

If you forget to take Cortiment:

It is important not to miss a dose of Cortiment. If you do miss a dose, take it as soon as you can, unless it is nearly time for your next dose. Do not take a double dose to make up for the missed dose.

If you take more Cortiment than you

should (overdose):

If you accidentally take more than the recommended dose of Cortiment you may be at increased risk of experiencing possible side effects with this medicine.

Contact your doctor or nearest emergency department immediately for advice. Keep the tablet packaged in polyamide/ aluminium/ PVC foil blister packs with aluminium push through foil with you so that you can easily describe what you have taken.

Due to the low systemic availability of Cortiment tablets, acute overdosage even at very high doses is not expected to lead to an acute clinical crisis. In the event of acute overdosage, no specific antidote is available. Treatment consists of supportive and symptomatic therapy.

5. While you are taking Cortiment

Things you must do:

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

Things you must not do:

Do not suddenly change the dose or stop taking Cortiment tablets unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Cortiment to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of:

Cortiment with drink

Avoid grapefruit juice during treatment with Cortiment. Following significant intake of grapefruit juice (which inhibits CYP3A activity predominantly in the intestinal mucosa), the systemic exposure for oral budesonide increased by approximately twofold.

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Driving and using machines

If Cortiment make you feel dizzy or tired, do not drive or use machines and contact your doctor immediately.

6. Side effects

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

The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people)

- Insomnia
- Headache
- Nausea
- Upper stomach pain
- Stomach distension
- Stomach pain
- Dry mouth
- Indigestion (dyspepsia)
- Acne
- Muscle pain, muscle cramps
- Fatigue
- Blood cortisol decrease
- Pounding heart beats (palpitations)
- Cushing-like symptoms, such as a round face, acne, weight gain and a tendency to bruise easily
- Low potassium levels in the blood
- Change in behaviour, such as nervousness, insomnia and mood swings
- Heavy or irregular menstruation in women
- Skin reaction such as skin rash or itchiness

Uncommon (may affect up to 1 in 100 people)

- Influenza
- High white blood cell count (Leukocytosis)
- Mood altered
- Dizziness
- Flatulence
- Back Pain
- Muscle spasm

- Swelling of the legs (Oedema peripheral)
- Shaking
- Feeling of restlessness with hyperactivity

Rare (may affect up to 1 in 1000 people)

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

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

- Growth retardation in children*
- Anaphylactic reaction

* Cortiment is not recommended for use in children.

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.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. 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))].

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

7. Storage and disposal of Cortiment

Storage

Store below 30°C

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 blister and carton after "EXP". The expiry date refers to the last day of that month.

Disposal

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.

8. Product Description

What Cortiment looks like and contents of the pack:

The prolonged release tablet are white to off-white, round, biconvex, film-coated, gastro-resistant tablet, approximately 9.5 mm diameter, approximately 4.7 mm thickness, debossed on one side with "MX9".

The tablets are packaged in polyamide/ aluminium/ PVC foil blister packs with aluminium push through foil, contained in a cardboard carton. Each pack containing 30 tablets.

What Cortiment contains:

The active substance is budesonide.

The other ingredients are:

Tablet core:

Stearic Acid, Lecithin (soya), Microcrystalline cellulose, Hydroxypropylcellulose, Lactose Monohydrate, Silica, Colloidal Hydrated, Magnesium Stearate.

Tablet Film-coating:

Methacrylic acid – methyl methacrylate copolymer, Methacrylic acid – methyl methacrylate copolymer, Talc, Titanium Dioxide, Triethyl citrate

MAL number

MAL18066050ACZ

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9. Manufacturer and Product Registration Holder

Manufacturer

Cosmo S.P.A

Via C. Colombo, 1-20045 Lainate (MI),
Italy

Product Registration Holder

Ferring Sdn Bhd

21-6, Block B, Jaya One, No. 72-A,
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46200 Petaling Jaya, Selangor, Malaysia

10. Date of Revision

06-Mar-2024

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