

Patient Package Insert according to Pharmacists’ Regulations (Preparations), 1986

This medicine can be sold with a doctor’s prescription only

Cortiment^{MMX}

Prolonged release tablets

Composition:

Each prolonged release tablet of Cortiment^{MMX} contains 9 mg budesonide.

Inactive ingredients: see section 6 “further information”.

Read this leaflet carefully in its entirety before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, refer to your doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar. This medicine is intended for adults over 18 years of age.

1. What is the medicine intended for?

The medicine is used for treating mild to moderate active ulcerative colitis in the large intestine.

Therapeutic group: glucocorticoids.

2. Before using this medicine:

❗ Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient or one of the ingredients of this medicine (see section 6).
- You are allergic to peanuts or soybeans, since Cortiment^{MMX} tablets contain lecithin produced from soybean oil.

⚠ Special warnings regarding the use of this medicine

Tell your doctor if you suffer from blurred vision or other vision disorders.

Before treatment with the medicine, tell your doctor if:

- you have an infection, such as a viral, bacterial or fungal infection.
- you have ever had high blood pressure.
- you have diabetes.
- you have ever had brittle bones.
- you have ever had a peptic ulcer.
- you have ever had elevated intraocular pressure (glaucoma) or cataract.
- a family member of yours has ever had diabetes or elevated intraocular pressure (glaucoma).
- you have ever had liver problems.
- before treatment with Cortiment^{MMX} you have been treated with other steroids, since this may cause muscle and joint pain, fatigue, headache, nausea and vomiting.
- you need to get vaccinated.
- before starting treatment with Cortiment^{MMX} you have been treated with a stronger steroid medicine, these symptoms may appear again.
- you get an infection during the course of the treatment, Cortiment^{MMX} may suppress the symptoms of the infection, and the infection may exacerbate. You may get infections easier, since your immune system may be weakened.
- you are scheduled to undergo surgery soon or are going through a stressful period.
- you have never suffered from chickenpox or measles. During the course of the treatment with Cortiment^{MMX} try to avoid contact with people who have chickenpox or measles. Tell your doctor if you think you have been infected with chickenpox or measles while taking this medicine.
- you or a family member has ever had mental health problems.
- Taking high doses of steroids for a long period of time may affect all parts of the body and cause psychological problems in very rare cases (see Side Effects section).

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

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell your doctor or pharmacist, since this medicine may affect the activity of the other medicines, and the other medicines may affect this medicine’s activity.

Especially inform your doctor or pharmacist if you are taking:

- Cholestyramine (which is used to lower cholesterol levels).
- Antacids to neutralize stomach acidity.
- Ketoconazole or itraconazole (medicines used to treat fungal infections).
- Medicines that contain estrogen, such as hormone replacement therapy (HRT) medicines and some oral contraceptives.
- Cardiac glycosides and diuretics.
- Medicines for treatment of HIV such as: ritonavir, nelfinavir, cobicistat containing medicines.
- Carbamazepine, which is used for treatment of epilepsy.

Use of the medicine and food:

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

Pregnancy, breastfeeding and fertility:

Prior to using the medicine, consult your doctor if you are pregnant or breastfeeding, think you might be pregnant or are planning a pregnancy.

Driving and use of machinery:

It is unlikely that Cortiment^{MMX} tablets will affect your ability to drive or operate machinery. However, you must pay attention and be cautious since the medicine may cause dizziness or fatigue.

Important information about some ingredients of this medicine:

Cortiment^{MMX} tablets contain lactose. If you have been told by your doctor that you have an intolerance to certain types of sugar due to lactose intolerance for instance, contact your doctor before taking this medicine. Cortiment^{MMX} also contains lecithin (soybean oil). If you are allergic to peanuts and soybeans, do not use this medicine.

3. How to use this medicine

Always take this medicine according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain.

The dosage and manner of treatment will be determined by the doctor only.

The recommended dose is usually one tablet, in the morning, with or without food.

Do not exceed the recommended dose.

Instructions for use:

- Swallow the tablet whole with a glass of water.
- The tablet must not be chewed, crushed or broken.
- Usually this medicine is taken daily for 8 weeks. Your doctor will then gradually lower the number of times you take the medicine.
- Continue taking the medicine according to your doctor’s instructions even if you start feeling better.

Additional information while taking Cortiment^{MMX} tablets:

If you are scheduled to undergo surgery soon or are going through a stressful period, the doctor may recommend you to take another type of steroid as well.

Use in patients with reduced renal or hepatic function: the medicine was not examined in patients with renal or hepatic disorders. Consult your doctor.

Use in children: this medicine is not recommended for use in children.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take this medicine at the designated time, take a dose as soon as you remember. If it is almost time for your next dose, skip the missed dose. Do not take a double dose.

Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine:

Do not stop taking the medicine without instruction from your doctor. You may be required to stop taking the medicine gradually. An abrupt stop of the treatment with Cortiment^{MMX} may worsen your condition.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. Side Effects

As with any medicine, use of Cortiment^{MMX} may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

If you have an allergic reaction, refer to your doctor immediately. Signs may include itchy rash, swelling of the face, lips, mouth, tongue and throat. These conditions may cause breathing difficulties.

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

Common side effects (may affect 1 in 10 people)

- Abdominal swelling
- Muscle pain, muscle cramps
- Abdominal pain
- Dry mouth
- Digestive disorders
- Rapid heartbeat
- Skin rash or irritation
- Heavy or irregular menstruation in women
- Low potassium levels in the blood, which can cause muscle weakness or fatigue, thirst or a tingling sensation
- Cushing-like symptoms, such as a round face, acne, weight gain and a tendency to bruise easily
- Nausea
- Headaches
- Changes in behavior such as nervousness, insomnia or mood swings
- Depression
- Acne
- Fatigue
- Decrease in cortisol level in the blood

Uncommon side effects (may affect up to 1 in 100 people)

- Increase in white blood cells
- Behavioral changes such as mood swings
- Gas
- Dizziness
- Restlessness and hyperactivity
- Anxiety
- Leg swelling
- Tremor
- Muscle spasms
- Back pain
- Influenza

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

- Aggression
- Glaucoma (high intraocular pressure)
- Eye lens clouding (cataract)
- Blurred vision
- Red or blue and black spots on the skin

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

- Acute allergic reaction known as anaphylaxis which may cause breathing difficulties and shock.

Some of the above mentioned side effects are common for steroid medicines, and they may appear depending on the dose that has been taken, duration of treatment, prior or current treatment with other steroid medicines, and personal predispositions.

Psychological problems may appear when taking steroids like Cortiment^{MMX}. Consult your doctor if you (or whoever uses this medicine) suffer from psychological disorders. This is particularly important if you are depressed or have suicidal thoughts. In very rare cases mental problems have developed when high doses were taken for a long period of time.

If a side effect appears, if any side effect worsens, or if you experience a side effect not listed in this leaflet, contact your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health via the link “Report Side Effects of Drug Treatment” found on the home page of the Ministry of Health’s website (www.health.gov.il), which directs to the online form for reporting side effects or via the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine

Avoid poisoning! This medicine and any other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning.

Do not induce vomiting without explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

Store below 30°C.

6. Further Information

In addition to the active ingredient, the medicine also contains:

Stearic acid, lecithin (soya), microcrystalline cellulose, hydroxypropylcellulose, lactose monohydrate, silica colloidal hydrated, magnesium stearate

The ingredients of the tablet coating are:

Methacrylic acid-copolymer type A, methacrylic acid-copolymer type B, talc, titanium dioxide, tri-ethylcitrate

What the medicine looks like and contents of the pack:

This medicine 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 aluminum press-through foil in a small cardboard box.

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

Name and address of the registration holder:

Ferring Pharmaceuticals Ltd., 8 Hashita St., Caesarea 3088900.

Name and address of the manufacturer:

Cosmo S.p.A, Italy.

This leaflet was checked and approved by the Ministry of Health on January 2016, and updated according to the Ministry of Health order on June 2018.

Drug registration number at the national registry of the Ministry of Health:

155-34-34254

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