

Patient leaflet in accordance with the pharmacists' regulations (preparations)-1986

The medicine is dispensed with a doctor's prescription only

CORTIMENT^{®MMX}

Prolonged release tablets

Active ingredient:

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

Inactive ingredients and allergens: see section 2 under "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about the medicine. If you have further questions, consult 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 to yours.

This medicine is intended for adults above 18 years of age.

1. What is this medicine intended for?

The medicine is used to induce remission in patients with mild to moderate active ulcerative colitis (UC).

Therapeutic group: glucocorticoids.

2. Before using this medicine:

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or to any of the other ingredients in this medicine (see section 6)
- you are allergic to peanuts or soya, since Cortiment^{®MMX} tablets contain lecithin which is produced from soya oil.

Special Warning about using this medicine

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

Before starting 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 stomach ulcer
- you have ever had elevated eye pressure (glaucoma) or cataract
- a family member has ever had diabetes or elevated eye pressure (glaucoma)
- you have ever had liver problems
- you took other steroid therapy before starting treatment with Cortiment^{®MMX} as this may result in pain in the muscles and joints, tiredness, headache, nausea, and vomiting
- you need to be vaccinated
- you were treated with a stronger steroid product before starting treatment with Cortiment^{®MMX}; your symptoms may reappear
- you get an infection during the treatment; Cortiment^{®MMX} might suppress the signs of infection and the infection may get worse. You may get infections more easily, since your body's resistance to infections may be reduced
- you are scheduled to undergo surgery soon or are going through a stressful period; your doctor may advise you to take an additional type of steroid

- you have not yet had measles or chicken pox. While taking Cortiment^{®MMX} tablets, try to avoid contact with people who have chicken pox or measles. Notify your doctor if you think you have been infected with chicken pox or measles while taking this medicine.
- you or a family member has ever had mental health problems

Taking steroids at high doses and for a prolonged period may affect all parts of the body and in very rare cases can cause psychological problems (see the section “Side effects”).

If you are concerned that any of the conditions above apply to you, contact your doctor.

Drug interactions

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

Particularly, inform your doctor or pharmacist if you are taking:

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

Using this medicine and food

Do not drink grapefruit juice when taking Cortiment^{®MMX} tablets, it may affect how the medicine works.

Pregnancy, breast-feeding, and fertility

If you are pregnant or breast-feeding, think you might be pregnant, or are planning to have a baby, consult your doctor or pharmacist before taking this medicine.

Driving and using machines

Cortiment^{®MMX} is unlikely to affect your ability to drive and operate machines. Nevertheless, pay attention and take care because this type of medicine may sometimes cause dizziness or fatigue.

Important information about some of this medicine’s ingredients

Cortiment^{®MMX} tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars due to lactose intolerance for instance, contact your doctor before taking this medicine.

Cortiment^{®MMX} contains lecithin (soya oil). If you are allergic to peanuts or soya, do not use this medicine.

3. How to use this medicine?

Always take this medicine according to your doctor’s instructions. Check with the doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

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

Do not exceed the recommended dose.

Directions for use:

- Swallow the tablet whole, with a glass of water.
- Do not chew, crush or break the tablet.
- Usually you will take this medicine daily for up to eight (8) weeks. Your doctor will then gradually reduce the number of times you take the medicine.
- Keep taking the medicine as your doctor has told you, even if you start feeling better.

Use in patients with reduced kidney or liver function: This medicine was not studied in patients with kidney or liver problems. Consult your doctor.

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

If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take this medicine at the scheduled 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.

Adhere to the treatment as recommended by your doctor.

Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine

Do not stop taking this medicine without directions from your doctor. You may need to stop the treatment gradually. If you suddenly stop your Cortiment^{®MMX} treatment, your condition may get worse.

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

If you have further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Cortiment^{®MMX} may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

If you have an allergic reaction, see your doctor immediately. Signs of this include itchy rash, swelling of the face, lips, mouth, tongue, and throat. These reactions can make it difficult to breathe.

The following additional side effects may occur when taking Cortiment^{®MMX}. Most of the side effects listed below can also be expected with other steroid treatments.

Common side effects (may affect 1 in 10 users)

- bloated abdomen
- muscle pain, muscle spasms
- stomach pain
- dry mouth
- indigestion
- 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
- headache

- changes in behaviour, such as nervousness, insomnia, mood swings
- depression
- acne
- tiredness
- decreased level of the hormone cortisol in the blood

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

- increased white blood cells
- changes in behaviour such as mood swings
- flatulence
- dizziness
- feeling of restlessness with hyperactivity
- anxiety
- swelling in your legs
- tremor
- back pain
- muscle cramps
- flu

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

- aggression
- glaucoma (increased pressure in the eye)
- opacity of the eye (cataract)
- blurred vision
- purple or black-and-blue spots on the skin

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

- a serious allergic reaction called anaphylaxis which can lead to breathing difficulties and shock

Some of the side effects mentioned above are typical of steroid medication and may occur depending on your dose, period of treatment, past or present treatment with other steroid medications, and your individual susceptibility. Psychological problems may develop when taking steroids like Cortiment[®]MMX tablets. Discuss it with your doctor if you (or someone who uses this medicine) have psychological problems. This is particularly important if you are depressed or thinking about committing suicide. In very rare cases, psychological problems have developed when high doses were taken for a long time.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants.

Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package.

The expiry date refers to the last day of that month.

Storage: Store below 30°C.

6. Additional information

In addition to the active ingredient, this 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 A, methacrylic acid-copolymer B, talc, titanium dioxide, triethylcitrate.

What this medicine looks like and contents of the pack:

This medicine is supplied as white to off-white, round, double convex, film-coated tablets with 'MX9' engraved on one side of the tablet. The tablets are supplied in blister packs with aluminium press-through foil packaged 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., Industrial Park, Caesarea 3088900.

Name and Address of the manufacturer: Cosmo S.p.A, Milan, Italy.

This leaflet was revised in April 2023 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
155-34-34254