

Package leaflet: Information for the user

Prednisolon Omet Pharma 2.5 mg tablet

Prednisolon Omet Pharma 5 mg tablet

Prednisolon Omet Pharma 10 mg tablet

Prednisolon Omet Pharma 25 mg tablet

prednisolone

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Prednisolon Omet Pharma is and what it is used for
2. What you need to know before you take Prednisolon Omet Pharma
3. How to take Prednisolon Omet Pharma
4. Possible side effects
5. How to store Prednisolon Omet Pharma
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1. What Prednisolon Omet Pharma is and what it is used for

Prednisolon Omet Pharma is a corticosteroid that prevents and suppresses allergic disorders, inflammation and rheumatic disorders.

The medicine is used in conditions where you need to suppress the body's reaction, such as e.g. the inflammatory reaction in joint rheumatism (rheumatoid arthritis). Other examples that can be mentioned are connective tissue disease (SLE), inflammation of vessel walls, connective tissue changes, asthma, severe inflammation of the large intestine (ulcerative colitis), in certain blood diseases, severe allergic conditions, tumor treatment.

2. What you need to know before you take Prednisolon Omet Pharma

Do not take Prednisolon Omet Pharma

- if you are allergic to prednisolone or any of the other ingredients of this medicine (listed in section 6).
- if you have a fungal infection that has spread to the blood or other organs (not only affecting the skin or mouth).

You should not be vaccinated with live vaccines while taking immunosuppressive doses of cortisone preparations.

Warnings and precautions

Talk to your doctor or pharmacist before taking Prednisolon Omet Pharma if you have:

- an infection or get an infection while you are being treated with prednisolone
- underactive thyroid gland (also called hypothyroidism)

- liver disease or kidney failure
- or have had seizures
- tuberculosis or have ever been treated for tuberculosis
- peptic ulcer, duodenal ulcer or an inflammatory bowel disease (e.g. ulcerative colitis or diverticulitis)
- diabetes
- heart disease, e.g. heart failure or high blood pressure
- had blood clots in the past (e.g. venous thrombosis) or are prone to blood clots
- mood swings or psychotic tendencies
- any drug allergy
- osteoporosis
- tumor in the adrenal gland (phaeochromocytoma)
- newly formed blood vessels or intestinal connections
- scleroderma (also called systemic sclerosis, an autoimmune disease) because daily doses of 15 mg or more may increase the risk of a serious complication called acute renal crisis. Signs of acute kidney injury include high blood pressure and decreased urine output. The doctor may advise you to regularly check your blood pressure and urine values.
- extreme muscle weakness (myasthenia gravis)

Contact a doctor if during treatment you:

- get serious psychological side effects, e.g. depression and suicidal thoughts. These can also occur when you stop taking prednisolone.
- experience blurred vision or other visual disturbances.
- are exposed to unusually severe physical or mental stress of any kind (e.g. infection, surgery, trauma) while you are being treated with prednisolone. The dose may need to be increased.

Prednisolone treatment can reduce your resistance to infections, making you more susceptible to infections during treatment. Chickenpox and measles can become more serious when taking cortisone preparations. If you have not previously had these diseases, you should therefore avoid exposing yourself to chicken pox or measles during treatment and talk to your doctor if this should still happen.

If you must be vaccinated during prednisolone treatment, you must inform the doctor about your treatment before receiving the vaccination.

Tumor lysis syndrome can occur when corticosteroids are used in cancer treatment. Tell your doctor if you have cancer and have symptoms of tumor lysis syndrome such as muscle cramps, muscle weakness, confusion, irregular heartbeat, vision loss or disturbances, and shortness of breath.

Corticosteroids can cause growth retardation in infants, children and adolescents and long-term use should therefore be avoided. If long-term use is necessary, the growth of infants and children will be closely monitored by the physician.

Other medicines and Prednisolon Omet Pharma

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those without a prescription.

The treatment effect can be affected if this medicine is taken at the same time as certain other medicines. It is especially important that the doctor knows if you are using any of the following medicines:

- rifampicin, isoniazid (used to treat tuberculosis)
- blood-thinning medicines (medicines that affect the blood's ability to clot)
- carbamazepine, phenobarbital, phenytoin (medicines against epilepsy)
- anticholinergics (medicines that counteract the effect of the body's own substance acetylcholine, used for treatment of e.g. Parkinson's disease and asthma)
- cholinesterase inhibitors (used to treat myasthenia gravis and Alzheimer's disease)

- insulin and diabetes medicines in the form of tablets. Cortisone preparations can worsen the blood sugar-lowering effect of diabetes drugs.
- cobicistat (medicine against HIV infection)
- estrogens (used e.g. in birth control pills)
- aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs) (used to treat pain and inflammation). The risk of stomach ulcers may increase when combined with cortisone products.
- thiazides, furosemide, ethacrynic acid (potassium-lowering diuretics)
- xanthines (eg theophylline, used to treat asthma)
- beta-2 stimulants (eg salbutamol, terbutaline, salmeterol, formoterol, used to treat asthma)
- amphotericin B (antibiotic for fungal infection)

If you must be vaccinated, tell the doctor that you are taking Prednisolon Omet Pharma.

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 or pharmacist for advice before taking this medicine.

Pregnancy

There is a risk that the foetus is affected.

Breast-feeding

Prednisolon Omet Pharma passes into the mother's milk, but is unlikely to affect children who are breastfed.

Driving and using machines

Dizziness, visual disturbances and fatigue may occur when using prednisolone. If you experience such symptoms, do not drive or operate machinery.

Prednisolon Omet Pharma contains lactose

If you have an intolerance to some sugars, you should consult your doctor before taking this medicine.

3. How to take Prednisolon Omet Pharma

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

The dose is determined by the doctor, who adjusts it individually for you.

Treatment is usually started with a higher dose which is then reduced to a fixed maintenance dose when a satisfactory effect has been obtained. When the treatment is to be ended, the dose should be slowly tapered to eventually stop completely. Do not stop treatment without consulting a doctor. Contact your doctor in the event of strain such as fever and stress, as a dose change may be necessary.

Prednisolon Omet Pharma should be swallowed with water. You can take Prednisolon Omet Pharma before or after a meal. The score line is not intended for breaking the tablet.

If you take more Prednisolon Omet Pharma than you should

If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any, contact your nearest hospital casualty department or tell your doctor immediately. Show any left-over medicines or the empty packet to the doctor.

If you forget to take Prednisolon Omet Pharma

If you forget to take a dose, take one as soon as you remember and then your next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Prednisolon Omet Pharma

If you have been taking Prednisolon Omet Pharma for a long time, the treatment must be tapered off gradually according to your doctor's instructions. It must not be stopped suddenly, as this can lead to severe side effects.

"Steroid withdrawal syndrome" can occur after suddenly stopping treatment with Prednisolon Omet Pharma. This syndrome includes symptoms such as loss of appetite, nausea, vomiting, fatigue, headache, fever, joint pain, flaky skin, muscle pain, weight loss, and/or low blood pressure. Contact your doctor if you experience any of these symptoms after you stop taking Prednisolon Omet Pharma.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects mainly occur with long-term treatment but also depend on dose size and individual sensitivity.

Contact a doctor immediately if the following serious side effects occur:

Serious allergic reaction, including angioedema (Not known)

Symptoms may include:

- swelling of the face, tongue or throat
- difficulty swallowing
- hives and breathing difficulties
- fever
- drop in blood pressure

Pheochromocytosis-related crisis (Not known) .

Symptoms may include:

- attack-like headache
- palpitations
- sweating
- pallor

Acute renal crisis (in patients already suffering from scleroderma, an autoimmune disease, see section 2, Warnings and precautions) (Not known) .

Symptoms may include:

- high blood pressure and decreased urine production

Suicidal ideation (see section 2, Warnings and precautions) (Not known)

Other side effects:

Common (may affect up to 1 in 10 users)

- infections, prednisolone's immunosuppressive effect can also cause infections to flare up again (e.g., tuberculosis)
- lower concentration of certain hormones, Cushing-like appearance, growth retardation in children
- low levels of potassium, accumulation of sodium in the body, elevated sugar levels in the

- blood and urine
- osteoporosis
- swelling due to fluid retention, high blood pressure
- thinner skin, impaired wound healing
- muscle atrophy.

Uncommon (may affect up to 1 in 100 users)

- activation of mental disorder (at high doses)
- cataracts, glaucoma

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

- depression
- mania in patients without previous mental illness
- benign increase in pressure in the skull
- breakdown of bone tissue, tendon rupture

Not known (frequency cannot be estimated from the available data)

- increased number of white blood cells (leukocytosis)
- hypersensitivity to the drug
- withdrawal syndrome when tapering off (see section 3)
- lowered pH in the blood, reduced amount of potassium in the blood, elevated blood fats, worsened glucose tolerance, worsening of diabetes, accumulation of fat on separated places in the body, increased appetite (which can lead to weight gain).
- emotional symptoms (such as elation, emotional instability, drug addiction), , mental disorder (such as delusions, hallucinations and schizophrenia), personality change, confusion, anxiety, mood swings, abnormal behavior, sleep problems, irritability
- convulsions, problems with memory, intellectual disturbance, dizziness, headache, increased amount of fat around the spinal cord
- visual impairment (central serous chorioretinopathy), protruding eyes, blurred vision
- heart failure (in sensitive patients), slow heartbeat
- blood clots
- hiccups
- stomach ulcer, hole (perforation) in the intestine, inflammation of the pancreas, inflammation and ulceration of the oesophagus, swollen abdomen, stomach pain, diarrhoea, digestive problems, nausea
- increased hair growth in women, bleeding in the skin, bruising, reddened skin, sweating, stretch marks (blue-red marks on the chest and abdomen), itching, hives, acne
- muscle weakness, muscle pain, bone fracture without previous trauma, joint breakdown, joint pain
- irregular periods
- tiredness, malaise
- increased amount of calcium in the urine; elevated liver values (alanine aminotransferase, aspartate aminotransferase), increased alkaline phosphatase in the blood, increased levels of blood urea (seen in blood tests), weaker reaction to skin tests.

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.
[To be completed nationally]

5. How to store Prednisolon Omet Pharma

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

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 Prednisolon Omet Pharma contains

- The active substance is prednisolone 2.5, 5, 10 and 25 mg respectively per tablet.
- 2.5 mg: The other ingredients are cellulose microcrystalline, silica, colloidal anhydrous, lactose monohydrate, maize starch, magnesium stearate, iron oxide red (E172)
- 5 mg: The other ingredients are cellulose microcrystalline, silicon dioxide colloidal, lactose monohydrate, maize starch, magnesium stearate, quinoline yellow (E104)
- 10 mg: The other ingredients are cellulose microcrystalline, silicon dioxide colloidal, lactose monohydrate, maize starch, magnesium stearate.
- 25 mg: The other ingredients are cellulose microcrystalline, silicon dioxide colloidal, lactose monohydrate, maize starch, magnesium stearate

What Prednisolon Omet Pharma looks like and contents of the pack

2.5 mg tablet: slightly red, round, plain tablet

5 mg tablet: slightly yellow, round, plain tablet with score line on one side and '5' embosses on the other side

10 mg tablet: white, round, plain tablet with score line on one side

25 mg tablet: white, round, biconvex tablet with score line on one side.

The score line is not for dividing the tablets in equal doses but only for tablets presentation.

Pack sizes: 10, 25 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Omet Pharma AB
Tippvägen 2.
296 35 Åhus
Sweden

Manufacturer

Kleva Pharmaceuticals S.A.
Parnithos Avenue 189
136 75 Acharnes
Greece

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