

Hydrocortison Orion 10 mg Tablet

Hydrocortisone (10 mg)

What is in this leaflet

1. What Hydrocortison is used for
2. How Hydrocortison works
3. Before you start to take Hydrocortison
4. How to take Hydrocortison
5. While you are taking it
6. Side effects
7. Storage and Disposal of Hydrocortison
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Hydrocortison is used for

Hydrocortisone is used:

- to treat low hydrocortisone levels caused by diseases of the adrenal gland (such as Addison's disease, adrenocortical insufficiency);
- in the treatment of hypopituitarism (a condition in which the pituitary gland does not produce normal amounts of some or all of its hormones);
- to treat congenital adrenal hyperplasia which affects your body's natural production of steroids;
- in conditions where systemic (oral or injectable) glucocorticoid therapy is needed

Your doctor will tell you for which disease or symptom (s) he has prescribed Hydrocortison for you.

How Hydrocortison works

Hydrocortisone or cortisol is a natural glucocorticoid (corticosteroid hormone). It acts by binding to steroid receptors in the cytoplasm. It acts mainly by reducing the local inflammation reaction. It e.g. alleviates inflammation symptoms and eliminates allergic symptoms.

Before you start to take Hydrocortison

- When you must not take it

Do not take Hydrocortison if you are allergic to hydrocortisone, or the ingredients listed at the end of this leaflet.

- Before you start to take it

Talk to your doctor or pharmacist before taking Hydrocortison, if you have:

- bacterial, fungal, viral or parasitic infections.
- gastric or duodenal ulcer
- diabetes
- bone loss (osteoporosis)
- serious mood disorder, or psychosis
- high blood pressure
- increased eye pressure
- liver failure
- tuberculosis
- severe heart failure
- seizure
- skeletal muscle disorder
- increased and decreased thyroid hormone production
- severe inflammation of the colon (ulcerative colitis) with threatened perforation, with abscesses or purulent inflammation
- inflamed pouches in the bowel wall (diverticulitis)
- undergoing certain intestinal surgeries recently
- if you are using a medicine that inhibits blood coagulation; if you will soon undergo a surgery; or if you plan to get vaccinations.

Also tell your doctor about any other diseases or allergies. The Hydrocortison dosage may need to be adjusted if you become ill (e.g. infections) or suffer from increased stress; in such a case, contact your doctor.

Children and adolescents; due to the risk of growth inhibition in children, the benefit-risk balance of treatment with hydrocortisone should be carefully weighed by doctor.

Thickened heart muscle observed in premature babies after hydrocortisone treatment.

- Taking other medicines

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

The efficacy of some medicines or that of Hydrocortison may change, or you may experience adverse effects if you take some medicines concomitantly.

Such medicines are e.g.:

- antiepileptics, medication used to control seizure (e.g. phenytoin, phenobarbital, carbamazepine and primidone)
- thyroid drugs (thyrostatics)
- medicines that inhibit blood coagulation
- medicines used to treat diabetes
- antibiotics (eg. rifabutin, rifampicin, erythromycin, telithromycin, clarithromycin and fluoroquinolone)
- various vaccines
- St. John's wort
- antifungal (e.g. ketaconazole, itraconazole, posaconazole, voriconazole and amphotericin B)
- antidepressant (e.g. barbiturates)
- antiretroviral (e.g. efavirenz, nevirapine and ritonavir)
- cobicistat for treatment of HIV infection
- oral contraceptive (e.g. oestrogen)
- antihypertensive
- nonsteroidal anti-inflammatory drugs (NSAIDs), acetylsalicylic acid and salicylate used to relieve pain and reduce inflammation and fever
- diuretic used to excrete salt in the urine
- cardiac glycosides (e.g. digoxin) used to treat heart problem and irregular heartbeats
- theophylline and beta2 sympathomimetics used to treat breathing problems
- somatropin used to treat growth failure to in children and adult
- mifepristone used to terminate pregnancy

Hydrocortison Orion 10 mg Tablet

Hydrocortisone (10 mg)

Remember to mention about your Hydrocortison use when you next time go to see a doctor.

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.

Hydrocortison contains lactose

Hydrocortison contains lactose

If you do not tolerate glucose or galactose sugar, ask your doctor whether you can use this medicinal product.

How to take Hydrocortison

- How much to take

Your doctor has prescribed a suitable dose for you. Follow your doctor's instruction carefully.

- When to take it

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

- How long to take it

Continue taking Hydrocortison for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten tablet.

Before travelling make sure that you have an adequate stock of the medicine.

- If you use too much (overdose)

Overdose with Hydrocortison does not usually cause serious adverse effects.

Contact immediately a doctor or hospital, if you or somebody else, e.g. a child, have taken a too high a dose.

While you are using it

- Things you must do

If you are about to be started on any new medicine, remind your doctor that you are using Hydrocortison.

Tell any other doctors, and pharmacists who treat you that you are using Hydrocortison.

If you become pregnant, while taking Hydrocortison, tell your doctor immediately.

- Things you must not do

Do not use Hydrocortison to treat any other complaints unless your doctor tells you to.

Do not give Hydrocortison to anyone else, even if their symptoms seem similar to yours.

Do not change the dosage or stop the treatment by yourself.

Treatment with Hydrocortison should not be altered or stopped without consulting your doctor.

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

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you

a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Replacement therapy with Hydrocortison does not usually cause any adverse effects, and short-term therapy with high doses does not usually result in any adverse effects.

Adverse effects of a long-term Hydrocortison therapy with high doses include facial rounding, weight gain, blood sugar disorders, and in extremely long-term medication also skin thinning and bone fragility. High-dose therapy may also cause depressed mood and sleeplessness.

Other side effects reported with hydrocortisone:

Common (may affect up to 1 in 100 people)

- increased susceptibility to infections, masked infection symptoms
- inadequate hormone secretion by the pituitary gland (adrenocorticotropin hormone, ACTH) and by the adrenal gland (cortisol) in long-term use
- round or moon-shaped face
- worsening or development of diabetes
- accumulation of sodium in the body
- loss of potassium in the body
- exacerbation of cardiac insufficiency
- high blood pressure
- thin or delicate skin, slow healing

Hydrocortison Orion 10 mg Tablet

Hydrocortisone (10 mg)

of cuts and wounds, scarring, red or purple spots, acne, stretch marks, bruising

- muscle weakness or wasting, osteoporosis (brittle bones - bones that break easily).
- growth retardation in children
- swelling under the skin

Uncommon (may affect up to 1 in 1000 from more than 1 in 100 people)

- allergic reactions
- increase in appetite
- mood changes, depression, mania (feeling high), psychoses (feeling, seeing or hearing things which do not exist, or having strange and frightening thoughts, changing how you act or having feelings of being alone), sleeplessness
- changes in vision as a result of cataracts or glaucoma (increased eye pressure).
- blood clots block veins or arteries

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

- convulsions
- inflammation of the pancreas
- breakdown of bone due to poor circulation of blood, torn muscle tendons (pain and/or swelling)

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

- increase in the number of white blood cells
- swelling under the skin
- aggravation of infections
- loss of potassium and calcium, fluid retention, loss of nitrogen due to breakdown of body protein stores

- mood disorders, behavioural problems, feeling irritated or anxious, having problems sleeping, difficulty in thinking (including being confused and losing your memory)
- vertigo, headache
- blurred vision, thinning of the surface of the eyes, bulging eyes
- rupture of the heart muscle following recent heart attack
- abnormal thickening of the heart muscle in premature infants
- hiccups
- ulcerative inflammation of the digestive tract and gullet, bloating, indigestion, thrush in the gullet.
- small round spots in the skin or mucous membranes, redness of the skin, permanent dilation of small blood vessels in the skin or mucous membranes, increased sweating, allergic skin inflammation, hives, increased hair on the body and face in women
- muscle disease caused by steroids, broken bones or fractures
- irregular or no periods in women
- nausea, feeling sick, feeling of bodily discomfort and tiredness
- weight gain
- increase clotting tendency
- high level of fats in blood
- kidney stone
- reduce semen quality

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 nprra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Hydrocortison

- Storage

Store at or 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 package. 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 protect the environment.

Product Description

- What it looks like

White, round, flat bevelled-edged, scored uncoated tablet approx. 7 mm diameter with code ORN 45.

- Ingredients

- Active ingredient

The active substance is hydrocortisone. Each tablet contains 10 mg of hydrocortisone.

- Inactive ingredients

The other ingredients are lactose monohydrate, maize starch, talc, gelatin, and magnesium stearate.

- MAL number:

MAL15085015AZ

Hydrocortison Orion 10 mg Tablet

Hydrocortisone (10 mg)

Manufacturer

Orion Corporation, Orion Pharma
Tengstrominkatu 8 FI-20360 Turku
Finland

Product Registration Holder

Orion Pharma (MY) Sdn Bhd
E-20-01, Menara SUEZCAP 2, KL
Gateway, No. 2, Jalan Kerinchi, Gerbang
Kerinchi Lestari, 59200, Kuala Lumpur,
Malaysia

Date of revision

09/12/2021

Serial Number

NPRA(R2/1)201220/584