

**Patient package insert according to
Pharmacists' Regulations (Preparations)- 1986**

This medicine can be sold with a physician's prescription only

HYDROCORTISONE 10 mg, Tablets

Each tablet contains: 10 mg Hydrocortisone.

Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is 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 "Side effects".

- **Hydrocortisone is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Do not stop taking this medicine** without talking to your doctor- you may need to reduce the dose gradually.
- **Hydrocortisone can cause side effects in some people** (see section 4 "Side effects"). Some problems such as mood changes (feeling depressed or "high") or stomach problems can happen straight away. If you feel unwell in any way, keep taking your tablets and **see your doctor straight away**.
- **Some side effects only happen after weeks or months.** These side effects include weakness of arms and legs or developing a rounder face (see in section 4 "Side effects" for more information).
- **Keep away from people who have chickenpox or shingles**, if you have never had them, as these could affect you severely. If you do come into contact with chickenpox or shingles, **see your doctor straight away**.

1. What is the medicine intended for?

Hydrocortisone 10 mg is a glucocorticosteroid medicine indicated for treatment and relief of inflammations, swelling, itching, severe allergies, skin problems, asthma and rheumatic diseases.

Therapeutic group: Corticosteroids for systemic use, Glucocorticoids.

The medicine **Hydrocortisone 10 mg** contains Hydrocortisone. Hydrocortisone belongs to a group of medicines called steroids, their full name is corticosteroids. These corticosteroids occur naturally in the body and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as Hydrocortisone) is an effective way to treat various illnesses involving inflammation in the body. Hydrocortisone reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

2. Before using this medicine

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient (Hydrocortisone) or to any of the other ingredients this medicine contains (see section 6 "Additional information").
 - You have tuberculosis or any other acute or chronic bacterial, fungal, viral or parasitic infections without appropriate antimicrobial drug therapy.
 - Have been vaccinated recently or are going to have any vaccinations.
- High doses of corticosteroid may weaken your immune system. If this is the case, you must not be given vaccines containing live, attenuated viruses or bacteria as this might cause you an infection.

Special warnings regarding the use of this medicine

Before using Hydrocortisone 10 mg, tell the doctor if:

- **You have ever had severe depression** or manic depression (bipolar disorder). This includes having had depression before or while taking steroid medicines like Hydrocortisone.
- **Any of your close family** has had these illnesses.

Talk to your doctor or pharmacist before taking **Hydrocortisone 10 mg** if you have, or have had:

- Stomach or bowel ulcers or other digestive problem.
- Heart problems (heart failure, recent heart attack).
- Epilepsy.
- Thrombophlebitis (swelling and redness along a vein which is extremely tender when touched).
- Exanthematous disease (disease affecting the skin, rash).
- Metastatic carcinoma (cancer that has spread from one part of the body to another).
- Inflammatory bowel diseases.
- Recently undergone a surgery in which an artificial opening between two normally separate spaces is created (anastomosis).
- Mood disorder.
- Thyroid problems.
- Chickenpox, measles or shingles. Avoid contact with people who are infected or have chickenpox, measles or shingles. If you are exposed to these diseases, **contact a doctor straight away**.
- Weakened immune system.
- Amoebic dysentery and an infestation of a gut worm (e.g., amebiasis or strongyloidiasis). Hydrocortisone may activate or exacerbate such infections.
- Septicaemia, tuberculosis (TB) or have had it in the past.
- Herpes infection in the eye called ocular herpes simplex. Hydrocortisone may activate or exacerbate fungal and viral eye infections.
- Muscle weakness after taking steroids in the past.
- Recently visited a tropical country.

Also, check with your doctor if any of the following problems run in your family, or if you suffer from any of them:

- Diabetes.
- Heart problems.
- High blood pressure.
- Glaucoma— increased eye pressure.
- Kidney or liver problems.
- Myasthenia gravis (a type of muscle weakening problem) and are taking anticholinesterases.
- Osteoporosis (thinning of the bones).
- Low thyroid levels (hypothyroidism).

If you are not sure if any of the above run in your family, or if you suffer from it, talk to your doctor or pharmacist before taking a tablet. Contact your doctor if you develop any new infections while taking **Hydrocortisone 10 mg**. Taking Hydrocortisone for a long time and at high doses may increase the chances of getting infections as Hydrocortisone treatment can hide the usual symptoms of infection. Contact your doctor if you experience blurred vision or other visual disturbances.

If Hydrocortisone is given to a prematurely born baby, monitoring of heart function and structure may be needed.

Mental problems while taking Hydrocortisone

Mental health problems can happen while taking steroids like Hydrocortisone (see also in section 4 "Side effects").

- These illnesses can be serious.
- Usually, they start within a few days or weeks of starting the medicine.
- They are more likely to happen at high doses.
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if these problems do happen, they might need treatment.

Talk to a doctor **straight away** if you (or someone taking this medicine), show any signs of mental problems. This is particularly important if you are depressed or might be thinking about suicide and when doses are being lowered or stopped. In a few cases, mental problems have happened during this time.

Stress, injuries, surgery

If you are taking or have recently been taking **Hydrocortisone 10 mg** and you become ill, suffer stress, get injured or are about to have surgery, tell your doctor. The dose of the medicine may need to be increased (or you may have to start taking the medicine again for a short time), to prevent a sharp fall in blood pressure.

Vaccines

If you need vaccines during corticosteroid treatment, you should be aware that vaccine protection may not be as effective as usual. Some vaccines need to be avoided during corticosteroid treatment (see also "Do not use this medicine if:" in section 2).

Blood coagulation

Corticosteroid therapy may affect blood coagulation, so caution is advised if you use any medicines affecting blood coagulation at the same time (see also "Drug interactions:" in section 2).

Children and adolescents:

Corticosteroid treatment may cause growth retardation and increase the risks of side effects in children and adolescents.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- Phenytoin, carbamazepine and barbiturates (antiepileptics)
- Cough and cold medicines that contain a decongestant called ephedrine
- Rifampicin and rifabutin (antitubercular drugs)
- Herbal medicines containing St. John's wort (*Hypericum perforatum*)
- Ritonavir, efavirenz and nevirapine (HIV medicines)
- Antifungal medicines (ketoconazole, itraconazole, posaconazole, voriconazole, amphotericin B)
- A medicine for cancer called aminoglutethimide
- Erythromycin, telithromycin, clarithromycin, fluoroquinolones (antibiotics)
- Oestrogen products
- Oral contraceptive pills and hormone replacement therapy (HRT)
- Antihypertensive medication (minoxidil and hydralazine)
- Medicines that thin the blood (anticoagulants), e.g. warfarin
- Acetyl salicylic acid (aspirin)
- Medicines used to treat diabetes
- Anticholinesterases (e.g. pyridostigmine)
- "Water tablets" (diuretics)
- Cardiac glycosides (treatment of heart failure), e.g. digoxin, furosemide or bumetanide
- Medicines sometimes used for asthma, low blood pressure or in cough and cold remedies called sympathomimetics (e.g. bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol, terbutaline)
- Calcium supplements
- Anti-inflammatory analgesics (i.e. NSAIDs), e.g. ibuprofen, diclofenac or naproxen
- Somatropin (growth hormone)
- Mifepristone (termination of pregnancy)
- Some medicines for heart disease such as guanethidine, isosorbide mononitrate, isosorbide dinitrate and theophylline
- A medicine for urea cycle disorder called sodium phenylbutyrate (usually started by a specialist doctor or consultant)
- Methotrexate (a medicine used to treat rheumatoid arthritis)
- Ciclosporin (a medicine used for psoriasis or in patients who have organ transplants)
- Vaccines. Corticosteroids may reduce efficacy of vaccines and increase the risk of neurological complications. Vaccines containing live, attenuated viruses or bacteria should be avoided altogether (see also "Do not use this medicine if:" in section 2).

Some medicines may increase the effects of Hydrocortisone and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Use of this medicine and food

Hydrocortisone 10 mg can be taken with or without food.

Avoid drinking grapefruit juice during the use of this medicine, as this might raise blood Hydrocortisone levels.

Pregnancy, breastfeeding and fertility:

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.

Pregnancy

Hydrocortisone crosses the placenta. Corticosteroid therapy affecting the whole body should be regarded with caution during pregnancy. If you have received Hydrocortisone treatment during pregnancy, the newborn baby should be monitored for inadequate hormone production by the adrenal gland.

Breastfeeding

Hydrocortisone is excreted in breast milk. Prolonged use of high doses of Hydrocortisone during breastfeeding may weaken the infant's ability to produce adequate amounts of steroid hormones.

Fertility

Corticosteroids may affect fertility as they may impair semen quality and cause loss of menstrual periods (amenorrhoea).

Driving and using machines:

Hydrocortisone does not usually impair the ability to drive or use machines. However, in some patients steroids may cause a feeling of movement, even while you are still, and this can cause you to feel dizzy (vertigo). Extreme tiredness and episodes of short lasting dizziness (vertigo) have been reported. Changes in your eyesight or muscle weakness may also happen. If you are affected you should not drive or operate machines.

Important information about some of the ingredients of this medicine

- **Hydrocortisone 10 mg** contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to use this medicine?

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

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

Dosage and duration of treatment will depend on your illness.

Do not exceed the recommended dose.

Method of administration:

Take the medicine with some water, with or without food.

Take antacid between meals.

If needed, the tablet can be halved, divided into equal quarters, or crushed.

Use in special patient groups or special situations

Your doctor may want to change the dose or monitor your treatment carefully if you are elderly, have liver problems, problems with the adrenal glands, stress, injuries, infections or if surgery is planned for you.

If you have accidentally taken a higher dosage

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

If a large overdose has been taken, activated charcoal can be administered as first aid. However, a doctor must be contacted **as soon as possible** for other treatment.

If you forgot to take the medicine

If you forgot to take the medicine at the designated time, skip the missed dose and then take the next dose as normal. Do not take a double dose to make up for a forgotten dose. If you are not sure whether to skip the dose, consult the doctor or pharmacist.

If you stop taking the medicine

You may only discontinue or stop the treatment following consultation with your doctor. It is dangerous to reduce your dose of **Hydrocortisone 10 mg** too quickly. Your doctor will gradually reduce your dose.

Stopping **Hydrocortisone 10 mg** may leave you without enough steroid hormones in your body. If you suddenly stop taking Hydrocortisone, you may experience withdrawal symptoms like pains in muscles or joints, fever, weakness, feeling sick, general discomfort, raised pressure within the skull and low blood pressure.

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

4. Side effects

As with any medicine, the use of **Hydrocortisone 10 mg** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Side effects may be stronger in elderly patients and in children.

Your doctor will want to see you now and then to look out for these effects.

Treatment with this medicine may sometimes cause **serious side effects**. **Stop taking this medicine and refer to the doctor or to a hospital emergency room immediately with the appearance of one or more of the following serious side effects, or if you think you are at increased risk of infection** (e.g. you have been in contact with someone who has an infection):

Side effects of unknown frequency (effects for which a frequency has not yet been determined):

- A life-threatening allergic reaction which causes e.g. skin rash; swelling of the face, lips or throat; or difficulty in breathing or wheezing.
- In children, headaches with vomiting, listlessness and drowsiness. These are symptoms of pseudotumour cerebri that can raise pressure within the skull and usually occur after treatment is stopped.

- Burst or bleeding gut ulcers (indicated by stomach pain, especially if it seems to spread to your back, bleeding from the back passage, black stools or blood in your vomit).
- Acute inflammation of the pancreas (abdominal pain, possibly accompanied by shock, i.e. low blood pressure with decreased output of urine and often loss of consciousness).
- A blood clot in a vein (thrombosis) in your leg, symptoms of which are a swollen, red, hot, tender muscle.
- Thromboembolism- a blood clot which may go to the lung, symptoms of which are sudden shortness of breath and chest pain and coughing up blood.
- Heart failure– problems with the pumping of your heart indicated by swollen ankles, chest pain, difficulty in breathing and palpitations or irregular beating of the heart, irregular or very fast or slow pulse; hypertension (high blood pressure, indicated by headaches or generally feeling unwell).
- Aseptic necrosis- broken bones or fractures; breakdown of bones due to poor circulation of blood (pain in the hip); joint inflammation in the knee and groin; risk of torn tendons (pain and/ or swelling).
- Cushing's syndrome- reddish stretch marks; rounded red face; weak muscle bones; swollen abdomen and "Buffalo hump" from fat deposits around the stomach and neck; mood changes; headache.

Serious effects: tell a doctor straight away

Steroids, including Hydrocortisone, can cause serious mental health problems. These are common in both adults and children, and can affect about 5 in every 100 people taking medicines like Hydrocortisone:

- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or moods that go up and down.
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing of your memory.
- Feeling, seeing or hearing things which do not exist, having strange and frightening thoughts, changing how you act or having feelings of being alone.

If you notice any of these problems **talk to a doctor straight away.**

Other side effects

Tell your doctor if you experience any of the following:

Side effects of unknown frequency (effects for which a frequency has not yet been determined):

- If you are getting infections more frequently
- Increase in the number of white blood cells
- Oral thrush
- Ulcerative inflammation of the gullet, bloating, indigestion, thrush in the gullet
- Feeling sick, feeling of bodily discomfort and tiredness
- High blood pressure
- Feeling excited or excessively happy
- Low mood (depression)
- Insomnia
- Worsening of epilepsy
- Muscle weakness or wasting
- Osteoporosis (brittle bones– bones that break easily)
- Cramps and spasms due to the loss of potassium salts from your body. In rare cases, loss of potassium salts from your body, can lead to palpitations (an uneven beating of heart that you become aware of)
- Irregular or no periods in women
- Increased hair on the body and face in women
- Increased appetite and weight gain
- Increase in blood sugar levels, breakdown of body protein stores (loss of weight and muscle loss in arms or legs), loss of calcium and nitrogen
- Thin or delicate skin, bruising, red or purple spots
- Slow healing of cuts or wounds
- Acne, redness
- Stretch marks
- Worsening of sight or changes in vision as a result of cataracts or glaucoma (increased pressure inside the eye); thinning of the surface of eye; blurred vision
- Worsening of eye infection

Additional side effects in children

Side effects of unknown frequency (effects for which a frequency has not yet been determined):

- Suppression of normal growth in children
- Thickening of the heart muscles (hypertrophic cardiomyopathy) in prematurely born babies

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Report of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by 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.
- **Storage conditions:** Store in a dry place below 25°C.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

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

Starch, Lactose, Microcrystalline Cellulose, Sodium Starch Glycolate, Povidone K-30, Talc, Magnesium Stearate, Colloidal Silicon Dioxide.

What the medicine looks like and what the package contains:

A white round shaped tablet, scored for quarters on one side and "HN" engraved on the other.

Approved package size: The tablets are packed in aluminum blisters in a carton package, containing 30 tablets.

Manufacturer and registration holder:

Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St., Holon, 5881904, Israel.

Revised in January 2025 according to MOH guidelines.

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

135-35-22570-00