

# HYDROCORTISONE 10 mg AND 20 mg TABLETS

Package leaflet: Information for the patient
<p><b>Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.</b></p> <ul style="list-style-type: none"><li>• Keep this leaflet. You may need to read it again.</li><li>• If you have any further questions, ask your doctor or pharmacist.</li><li>• 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.</li><li>• 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.</li><li>• <b>Hydrocortisone is a steroid medicine</b>, prescribed for many different conditions, including serious illnesses.</li><li>• <b>You need to take it regularly</b> to get the maximum benefit.</li><li>• <b>Do not stop taking this medicine</b> without talking to your doctor - you may need to reduce the dose gradually.</li><li>• <b>Hydrocortisone can cause side effects in some people</b> (read ‘Possible side effects’ section below). 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, but <b>see your doctor straight away</b>.</li><li>• <b>Some side effects only happen after weeks or months.</b> These include weakness of arms and legs or developing a rounder face (read ‘Possible side effects’ section for more information).</li><li>• <b>If you take it for more than 3 weeks, you will get a blue ‘steroid card’:</b> always keep it with you and show it to any doctor or nurse treating you.</li><li>• <b>Keep away from people who have chickenpox or shingles</b>, if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, <b>see your doctor straight away</b>.</li></ul> <p><b>Now read the rest of this leaflet.</b> It includes other important information on the safe and effective use of this medicine that might be especially important for you.</p>

What is in this leaflet:
<p><b>1. What Hydrocortisone is and what it is used for</b></p> <p><b>2. What you need to know before you take Hydrocortisone</b></p> <p><b>3. How to take Hydrocortisone</b></p> <p><b>4. Possible side effects</b></p> <p><b>5. How to store Hydrocortisone</b></p> <p><b>6. Contents of the pack and other information</b></p>

## 1 What Hydrocortisone is and what it is used for

Hydrocortisone tablets contain a medicine called 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.

Hydrocortisone tablets are used for:

- children and adolescents to replace hydrocortisone because part of the adrenal gland is not working properly
- emergency treatment of severe asthma, drug hypersensitivity reactions, serum sickness (hypersensitivity reaction to proteins), localised swelling of the skin and/or mucous membranes (angioedema) and life-threatening allergic reactions (anaphylaxis).
- adding hydrocortisone after injuries, surgery or other stressful events
- some other types of illness.

Ask your doctor to explain why you have been given Hydrocortisone Tablets if you are unsure.

## 2 What you need to know before you take Hydrocortisone

**Do not take Hydrocortisone if you:**

- are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6)
- 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.

**Before you take Hydrocortisone tablets**

Check with your doctor first 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.

If either of these applies to you, **talk to a doctor before taking hydrocortisone**.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Hydrocortisone if you have or have had:

- stomach or bowel ulcers or other digestive problem
- heart problems (heart failure, recent heart attack) epilepsy
- have thrombophlebitis (swelling and redness along a vein which is extremely tender when touched)
- have exanthematous disease (disease affecting the skin, rash)
- have 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
- have amoebic dysentery and an infestation of a gut worm (e.g. amebiasis or strongyloidiasis). Hydrocortisone may activate or exacerbate such infections
- have septicaemia, tuberculosis (TB) or have had it in the past
- have a 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.
- have recently visited a tropical country
- an over-active thyroid gland (hyperthyroidism)

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using hydrocortisone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis, which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with hydrocortisone. You may need additional treatment to alleviate this condition.

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

- diabetes
- heart problems
- high blood pressure
- an eye condition called glaucoma – increased eye pressure
- kidney or liver problems
- a type of muscle weakening problem called myasthenia gravis 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 you have them, talk to your doctor or pharmacist before taking a tablet.

Contact your doctor if you develop any new infections while taking Hydrocortisone tablets. 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 section 4 ‘Possible 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 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 tablets and you become ill, suffer stress, get injured or are about to have surgery, tell your doctor. Your dose of Hydrocortisone tablets may need to be increased (or you may have to start taking it 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 section ‘Do not take Hydrocortisone’).

**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 section ‘Other medicines and Hydrocortisone’).

**Children and adolescents**

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

**Other medicines and Hydrocortisone**

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

In particular do not take this medicine and tell your doctor or pharmacist if you are taking any of the following:

- 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)
- some medicines for high blood pressure
- 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 section ‘Do not take Hydrocortisone’).

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).

**Hydrocortisone with food and drink**

Hydrocortisone tablets can be taken with or without food.

Avoid drinking grapefruit juice during treatment as this might raise blood hydrocortisone levels.

**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**

Hydrocortisone crosses the placenta. Besides replacement therapy, other 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



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- Table
- Figure
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- Diagram
- Bibliography
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## Breast-feeding

Hydrocortisone is excreted in breast milk. Prolonged use of high doses of hydrocortisone during breast-feeding 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 machinery.

## Information you should carry while you are taking Hydrocortisone

All patients taking hydrocortisone tablets for more than a few weeks should carry a steroid card, which is available from your doctor or pharmacist. This card shows the details of the medicine you are taking. Always keep it with you and show it to any doctor or nurse treating you.

## Hydrocortisone tablets 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.

# 3 How to take Hydrocortisone

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

Dosage and duration of treatment will depend on your illness.

In replacement therapy, the first dose in the morning is usually higher than the other doses, to simulate the normal rhythm of corticosteroid secretion during a day.

The tablet can be divided into equal doses.

Swallow the tablets with some liquid, with or without meals.

If you feel that the effect of the treatment is too strong or too weak, discuss this with your doctor.

## The recommended dose for adults

- 20 to 30 mg a day
- Sometimes it is taken twice a day with 4 to 6 g of salt (sodium chloride) or 50 to 300 micrograms of fludrocortisone.

## The recommended dose for children and adolescents

- 0.4 to 0.8 mg a day, for every kilogram of your child's weight in two or three separate doses.
- Children will be prescribed the lowest possible dose.
- The doctor will keep an eye on their growth and development.

## Adults for emergency treatment

- Take 60-80 mg (6-8 of the 10 mg or 3-4 of the 20 mg tablets) every 4-6 hours for 24 hours. Then gradually reduce the dose as instructed by your doctor over several days.

## Children and adolescents (aged 1 month to 18 years) for replacement therapy

Hydrocortisone tablets can be used in children aged from 1 month to 18 years where the doses of 10 mg and 20 mg and tablet formulation are considered appropriate.

- **Inherently increased number of adrenal gland cells (congenital adrenal hyperplasia):** The doctor will determine an individual dose based on the patient's height and weight. The daily dose is divided into 3 doses. The doctor will adjust the dose according to the patient's response to the treatment.
- **Inadequate production of steroid hormones by the adrenal gland (adrenal insufficiency):** The doctor will determine an individual dose based on the patient's height and weight. The daily dose is divided into 3 doses. The doctor will adjust the dose according to the patient's response to the treatment: higher doses may be needed.

## 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 take more Hydrocortisone than you should

Contact your doctor or emergency unit if you have taken more Hydrocortisone than your doctor has prescribed.

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 forget to take Hydrocortisone

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 stop taking Hydrocortisone

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

Stopping Hydrocortisone tablets 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.

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 may be stronger in elderly patients and in children.

People taking hydrocortisone to replace similar naturally occurring hormones, should be less likely to get side effects than people taking it for other illnesses. 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. Tell your doctor straight away if you notice any of these problems or if you think you are at increased risk of infection** (e.g. you have been in contact with someone who has an infection):

## Not known: the frequency of side effects cannot be estimated from the available data

- 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).
- Asceptic 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. They 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 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:

## Not known: the frequency of side effects cannot be estimated from the available data

- if you are getting infections more frequently
- increase in the number of white blood cells
- oral thrush
- ulcerative inflammation of the gut, bloating, indigestion, thrush in the gut
- weight gain, 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. In rare cases, loss of potassium 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 increased
- 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
- eye infection may get worse

## Additional side effects in children

## Not known: the frequency of side effects cannot be estimated from the available data

- suppression of normal growth in children
- thickening of the heart muscles (hypertrophic cardiomyopathy) in prematurely born babies.

## Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

# 5 How to store Hydrocortisone

## 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 and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light.

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 Hydrocortisone tablets contains

- The active substance is hydrocortisone.
- The other ingredients are lactose monohydrate, maize starch, povidone K30, colloidal anhydrous silica and magnesium stearate.

## What Hydrocortisone tablets looks like and contents of the pack

The 10 mg tablets are white, oval shaped tablets, with engraved "H10" on one side and bisect breakline on the other.

The 20 mg tablets are white, oval shaped tablets, with engraved "H20" on one side and bisect breakline on the other.

Hydrocortisone is available in blister packs of 30 and 100 tablets.

Not all pack sizes may be marketed.

## Marketing Authorisation Holder and Manufacturer

### Marketing Authorisation Holder

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

### Manufacturer

Teva Pharmaceutical Works Private Limited, Pallagi út 13, Debrecen, 4042, Hungary

## This leaflet was last revised in June 2025.

PL 00289/2035

PL 00289/2036