

Hydrocortisone 10mg Tablets

Your medicine is known by the above name but will be referred to as Hydrocortisone Tablets throughout this leaflet. Please note that this medicine is also available in other strengths.

Patient Information Leaflet

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.

- **Hydrocortisone Tablets are a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor - you may need to reduce the dose gradually.
- **Hydrocortisone Tablets can cause side effects in some people** (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 **see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, or developing a rounder face (read 'Possible side effects' section for more information).
- **If you take it for more than 3 weeks, you will get a blue 'steroid card'**: always keep it with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chicken-pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, **see your doctor straight away**.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

What is in this leaflet

- 1) What Hydrocortisone Tablets are and what they are used for
- 2) What you need to know before you take Hydrocortisone Tablets
- 3) How to take Hydrocortisone Tablets
- 4) Possible side effects
- 5) How to store Hydrocortisone Tablets
- 6) Contents of the pack and other information

1) What Hydrocortisone Tablets are and what they are 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:

- adults, 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).

Hydrocortisone which is contained in Hydrocortisone 10 mg Tablets is also authorised to treat other conditions which are not mentioned in this leaflet. Ask your doctor or pharmacist if you have further questions.

2) What you need to know before you take Hydrocortisone Tablets

Do not take Hydrocortisone Tablets:

- if you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6)
- if you have tuberculosis or any other acute or chronic bacterial, fungal, viral or parasitic infections without appropriate antimicrobial drug therapy.

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 before taking Hydrocortisone Tablets, if you have or have had:

- diabetes
- stomach or bowel ulcers
- osteoporosis (thinning of the bones)
- glaucoma – increased eye pressure
- heart problems (heart failure, recent heart attack)
- high blood pressure
- kidney or liver problems
- epilepsy
- inflammatory bowel diseases
- recently undergone a surgery in which an artificial opening between two normally separate spaces is created (anastomosis)
- mood disorder
- thyroid problems
- *myasthenia gravis* (a condition affecting the muscles) and use concomitantly anticholinesterases
- chicken pox, measles, or shingles. Avoid contact with people who are infected or have chicken pox, measles or shingles. If you are exposed to these diseases, contact a doctor straight away.
- an infection caused by gut worms (e.g. amoebiasis or strongyloidiasis). Hydrocortisone may activate or exacerbate such infections.
- tuberculosis
- *herpes simplex* infection in the eye. Hydrocortisone may activate or exacerbate fungal and viral eye infections
- muscle weakness after taking steroids in the past.
- suspected or diagnosed pheochromocytoma (a rare tumour of adrenal gland tissue).

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.

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 may be 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 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, surgeries

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 usually. Some vaccines need to be avoided during corticosteroid treatment, see section "Do not use Hydrocortisone Tablets".

Blood coagulation

Corticosteroid therapy may affect blood coagulation, so caution is advised if you use concomitantly any medicines affecting blood coagulation (see section "Other medicines and Hydrocortisone Tablets").

Children

Corticosteroid treatment may cause growth retardation and increase risks of side effects.

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

Other medicines and Hydrocortisone Tablets

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

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)
- rifampicin and rifabutin (antitubercular drugs)
- herbal medicines containing St. John's wort (*Hypericum perforatum*)
- efavirenz and nevirapine (HIV medicines)
- antifungal medicines (ketoconazole, itraconazole, posaconazole, voriconazole, amphotericin B)
- erythromycin, telithromycin, clarithromycin, fluoroquinolones (antibiotics)
- oestrogen products and oral contraceptives
- antihypertensive medication
- 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
- theophylline and beta2 sympathomimetics e.g. bambuterol, fenoterol, formoterol, ritodrine, salmeterol, salbutamol, terbutaline (used to treat asthma or other breathing problems)
- anti-inflammatory analgesics (i.e. NSAIDs), e.g. ibuprofen, diclofenac or naproxen
- somatropin (growth hormone)
- mifepristone (termination of pregnancy)
- 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 section "Do not take Hydrocortisone Tablets").

Hydrocortisone Tablets 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 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 in treatment doses during pregnancy, the neonate should be monitored for inadequate hormone production by the adrenal gland.

Breast-feeding

The active substance of Hydrocortisone Tablets is excreted in breast milk. Prolonged use of high doses of Hydrocortisone Tablets 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 Tablets 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). Changes in your eyesight or muscle weakness may also happen. If you are affected you should not drive or operate machinery.

Important – Steroid Treatment Card

Information you should carry while you are taking Hydrocortisone Tablets

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 contain lactose

One Hydrocortisone Tablet contains 64.6 mg 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 Tablets

Always take this medicine exactly as your doctor 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.

Adults for emergency treatment

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

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

Hydrocortisone 10 mg Tablets can be used in children aged from 1 month to 18 years where the dose of 10 mg and tablet formulation is 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.

Adults for replacement therapy

The replacement dose is usually 15-25 mg daily, divided in 2-3 doses. The doctor will adjust the dose according to the patients response to the treatment.

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, or problems with the adrenal glands, stress, injuries or infections, or if a surgery is planned for you.

If you take more Hydrocortisone Tablets than you should

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

If a large overdose has been taken, activated charcoal can be administered as first aid, but in addition to that a doctor must be contacted as soon as possible for other treatment.

If you forget to take Hydrocortisone Tablets

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 Tablets

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 Tablets, you may experience withdrawal symptoms like pains in muscles or joints, fever, weakness, feeling sick, 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):

- a possibly life-threatening allergic reaction which causes e.g. skin rash, swelling of the face or wheezing
- irregular or very fast or slow pulse, faintness
- in children, headaches with vomiting, listlessness and drowsiness. These are symptoms of *pseudotumour cerebri* that can raise pressure within the skull and that usually occurs 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 the 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
- 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).

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 reported with hydrocortisone:

Common (may affect up to 1 in 10 people):

- high blood pressure
- 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

- cramps and spasms due to the loss of the potassium salts from your body. In rare cases, loss of potassium can lead to palpitations (an uneven beating of your heart that you become aware of)
- accumulation of sodium in the body
- thin or delicate skin, slow healing of cuts and wounds, scarring, red or purple spots, acne, stretch marks, bruising
- muscle weakness or wasting, osteoporosis (brittle bones - bones that break easily).

Uncommon (may affect up to 1 in 100 people):

- 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).

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

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

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

- increase in the number of white blood cells
- poor response to stress (like injury, surgery or illness)
- increase in blood sugar levels
- loss of potassium and calcium, loss of nitrogen due to breakdown of body protein stores, fluid retention
- mood disorders, behavioural problems, feeling irritated or anxious, having problems sleeping, difficulty in thinking (including being confused and losing your memory)
- vertigo, headache
- swelling of optic nerve head (papilledema), thinning of the surface of the eyes, bulging eyes, blurred vision
- rupture of the heart muscle following recent heart attack
- thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies
- hiccups
- ulcerative inflammation of the 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
- weight increased, feeling sick, feeling of bodily discomfort and tiredness.

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 via the Yellow Card Scheme at: 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 Tablets

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the blister and the outer carton after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special temperature storage conditions.
- Store in original package in order to protect from light and moisture.
- If the tablets become discoloured or show any other signs of deterioration, you should consult your pharmacist who will advise you what to do.
- 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 contain:

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

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

What Hydrocortisone Tablets look like and the contents of the pack

Hydrocortisone 10mg Tablets are white, smooth, scored tablets with flat, bevelled edges and diameter of about 7 mm, marked ORN35.

Hydrocortisone 10mg Tablets comes in blisters packs of 30 and 100 tablets.

PL 46420/0300

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Who makes and repackages your medicine?

Your medicine is manufactured by Orion Corporation, Orionintie 1, FI-02200 Espoo, Finland.

Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 17.07.2024

For any information about this medicine or to request for a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Ltd on 020 8839 3000.