

Package leaflet: Information for the user

Hydrocortisone 10 mg Tablets Hydrocortisone 20 mg Tablets Hydrocortisone

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.
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- **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** (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).
- **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 chickenpox 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 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:

- as replacement therapy in primary, secondary or acute adrenocortical insufficiency

- pre-operatively, and during serious trauma or illness in patients with known adrenal insufficiency or doubtful adrenocortical reserve.

Corticosteroid therapy should be used only when simpler proven diagnosis and therapy is not feasible or has failed (unless there is a life-threatening situation).

What is Adrenocortical insufficiency

The adrenal cortex, part of the adrenal glands situated near the kidneys, produces hormones called corticosteroids. Your adrenal cortex is not producing sufficient amounts of these corticosteroids to keep your body working properly. The hydrocortisone in your tablets replaces the natural steroids that you lack and helps to keep you healthy.

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 in this medicine (listed in section 6). An allergic reaction may be recognised as a rash, itching, swollen face or lips, or shortness of breath.
- If you have thrush, Candida or any other fungal infection
- If you have any other infection.
- If you have been vaccinated recently or are going to have any vaccinations.

Warnings and precautions

Talk to your doctor before taking Hydrocortisone Tablets:

- If you have ever had severe depression or manic-depressive illness (bipolar disorder). This includes having had symptoms of depression in the past, including while taking steroid medicines like Hydrocortisone Tablets.
- If any of your close family has had these illnesses.

Check with your doctor before taking this medicine if you currently have or have had any of the following:

- tuberculosis
- liver problems
- kidney problems
- high blood pressure
- heart problems including recent heart attacks
- diabetes (or a family history of diabetes)
- osteoporosis (thinning of the bones)
- glaucoma (increased pressure in the eye) or a family history of glaucoma.
- epilepsy
- stomach ulcers or other digestive problems
- muscle weakness with steroids
- existing or previous history of severe mood related disorders
- thyroid problems
- chicken-pox, shingles or measles
- a weakened immune system
- amoebic dysentery and an infestation of a gut worm (strongyloidiasis), it may be activated or become worse by hydrocortisone tablets.

You should see your doctor if you develop any new infections whilst taking these tablets.

Taking hydrocortisone for a long period of time increases your chance of getting infections, which might be worse than normal and may very rarely be fatal.

If you are taking or have recently taken (within the last 3 months) Hydrocortisone Tablets and you become ill, suffer stress, get injured or are about to have a surgical procedure you must tell your doctor immediately

that you are taking Hydrocortisone Tablets. Your dose of hydrocortisone 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.

If you have been on Hydrocortisone Tablets for longer than 3 weeks and wish to stop taking them, do not stop suddenly as this could result in a severe drop in blood pressure which could be fatal. Your doctor will advise on how to reduce the number of tablets you are taking.

It is important to avoid exposure to people who have chicken pox, measles or shingles, especially if you have not already had these illnesses or are not sure if you have had them. Hydrocortisone increases the risk of a severe bout of chicken-pox. If exposed you must contact your doctor immediately.

Children

For children, it is important that a doctor monitors their growth and development at intervals throughout the treatment.

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

Elderly

Steroids should be used cautiously in elderly patients, particularly if long term, since adverse events are enhanced in old age especially osteoporosis, hypertension, low potassium levels in the blood (hypokalaemia), diabetes, susceptibility to infection and thinning of the skin.

Mental health problems while taking hydrocortisone

Mental health problems can occur while taking steroids like hydrocortisone (see also section 4).

- These illnesses can be severe
- 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 occur they might need treatment.

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

Important - Steroid treatment card

All patients taking steroids for more than a few weeks should carry a '**steroid treatment card**', which is available from your doctor or pharmacist. These cards have the details of the medicine you are taking. Always keep it with you and show it to any doctor or nurse treating you.

Other Medicines and Hydrocortisone Tablets

Tell your doctor or pharmacist before taking Hydrocortisone Tablets if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is because some medicines can affect or be affected by the use of Hydrocortisone Tablets.

The side effects of this medicine may be increased if certain medicines are taken at the same time. On the other hand, this medicine may increase or decrease the effect of other medicines or increase their side effects when taken at the same time.

Please tell your doctor or pharmacist if you are taking:

- anticoagulants such as warfarin (medicines used to thin the blood)
- salicylates such as aspirin
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, diclofenac or naproxen (medicines used to treat mild to moderate pain)
- cough and cold medicines that contain a decongestant called ephedrine
- medicines for diabetes (including insulin)

- erythromycin (a medicine used to treat bacterial infections)
- an oral contraceptive pill
- somatropin (a type of growth hormone)
- ritonavir (a medicine used in the treatment of HIV infections)
- acetazolamide (a medicine used to treat glaucoma)
- amphotericin or ketoconazole (used to treat fungal infections)
- mifepristone (a medicine used to assist medical termination of pregnancy)
- diuretics (water tablets)
- carbenoxolone (a medicine used to treat ulcers)
- methotrexate (a medicine used to treat rheumatoid arthritis)
- medicines used to treat epilepsy such as phenytoin, phenobarbital, carbamazepine and primidone
- rifabutin and rifampicin (antibiotics used to treat TB)
- aminoglutethimide (a medicine used in the treatment of cancer)
- cardiac glycosides, such as digoxin (used to treat heart failure and irregular heartbeat)
- theophylline and sympathomimetics such as bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline (used to treat asthma and other breathing problems)
- antihypertensives (medicines used to treat high blood pressure)
- CYP3A inhibitors, including cobicistat-containing products

Test Results while taking Hydrocortisone Tablets

Hydrocortisone tablets could affect the results of some tests performed by your doctor or in the hospital, so tell your doctor or nurse that you are taking these tablets before any tests are carried out.

Hydrocortisone with food, drink and alcohol

Hydrocortisone can be taken with or without food.

Pregnancy, breast-feeding and fertility

Pregnancy

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. Your doctor will decide whether you should take Hydrocortisone during this time.

Breast feeding

Small amounts of hydrocortisone may pass into breast milk. Please ask your doctor for advice before taking these tablets if you are breast-feeding or intend to breast-feed.

Fertility

If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Hydrocortisone may have minor influence on your ability to drive and use machines. Extreme tiredness and episodes of short-lasting dizziness (vertigo) have been reported. Poorly treated or untreated adrenal insufficiency reduces your ability to concentrate and will affect your ability to drive and use machines. It is therefore important to take this medicine as directed by your doctor when driving or using machines. If you are affected do not drive or use machines, until you have discussed the issue with your doctor.

Hydrocortisone Tablets contain lactose

This medicine contains lactose (a kind of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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.

The usual adult dose is: 20 to 30 mg a day, sometimes taken together with 4 to 6 g of sodium chloride or 50 to 300 micrograms of fludrocortisone.

Your doctor may want to prescribe more. The exact dose depends on your condition.

Use in children

The dosage should be approximately 0.4 to 0.8 mg/kg given as two or three doses per day, adjusted to the needs of the individual child. Treatment should be limited to the minimum dosage for the shortest possible time.

Take the tablets by mouth exactly as the doctor, pharmacist or medicine label tells you to. Do not take more or less than your doctor has advised.

It is dangerous to reduce the dose of Hydrocortisone too quickly (e.g. post illness) as this may leave you without sufficient quantities of vital hormones. It may also cause withdrawal symptoms, including pains in muscles or joints, fever, and general discomfort. Your doctor will give you advice on reducing the amount of Hydrocortisone tablets gradually if necessary.

If you take more Hydrocortisone than you should

If you take too much Hydrocortisone by mistake, contact your doctor as soon as possible.

If you forget to take Hydrocortisone

If you miss a dose, just carry on with the next one as normal. Do not take a double dose to make up for a forgotten one.

If you stop taking Hydrocortisone

Do NOT stop taking this medicine without talking to your doctor first – you may need to reduce the dose gradually.

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 everyone gets them. If you are taking the medicine as a replacement steroid, you should be less likely to get side effects than people taking steroids for other illnesses.

Tell your doctor immediately if you notice:

- Itching or skin rashes
- Swelling of the face, lips or throat
- Difficulty breathing or wheeziness

These may be signs of an allergic reaction.

Severe side effects:

Steroids including hydrocortisone can cause severe mental health problems. These side effects are common in both adults and children. They can affect about 5 in every 100 people taking medicines like hydrocortisone.

Tell your doctor immediately if you are:

- depressed including thinking about suicide
- high (mania) or having moods that go up and down
- Anxious, having problems sleeping, having 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

Other side effects

Tell your doctor if you experience any of the following:

Heart problems

Increased damage to the heart in the event of a heart attack, heart failure; high blood pressure; blood clots. Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies.

Infections

Taking hydrocortisone can make it easier for you to pick up infections which may very rarely be fatal. Infections such as chicken-pox and measles can be made worse, or tuberculosis may recur.

Digestive system

Bleeding ulcers (indicated by stomach pain, bleeding from the back passage, black stools or being sick with blood present), inflammation of the pancreas causing abdominal pain, stomach pain and discomfort, bloated feeling, infection or ulceration of the gullet (discomfort on swallowing, which can cause chest pain), indigestion, feeling sick, being sick.

Nervous system

Fits (convulsions), headache (sometimes severe). Raised pressure within the skull (pseudotumor cerebri, indicated by headaches with vomiting, listlessness and drowsiness) has been reported in children; this usually occurs after treatment has stopped.

Bones, muscles and joints

Muscle weakness or wasting, osteoporosis (thinner bones with a higher risk of breaking them, especially in older women); broken bones or fractures, hip or shoulder pain due to poor blood circulation, risk of torn tendons, joint inflammation in the knee and groin (aseptic necrosis).

Eyes

Changes in vision as a result of cataract, blurred vision, thinning of the surface of the eye, existing eye infections may get worse, glaucoma (increased pressure inside the eye), bulging eyes.

Blood and lymphatic system

Increased number of white blood cells.

Psychiatric disorders

Psychological dependence, worsening of schizophrenia.

Reproductive system

In women: Irregular or lack of periods.

Endocrine system

Development of 'Cushingoid' state (cheeks and stomach increase in size, limbs become thin with flushed face and increased appetite); stunted growth in children; failure of the adrenal and pituitary glands to produce hormones, particularly after surgery, an accident or illness.

Metabolism and nutrition

Weight gain, increased appetite

Skin

Slow healing of cuts or wounds, thin or delicate skin, redness, stretch marks, bruising, red or purple spots, acne, sweating, wrong results from skin tests, growth of body hair.

General

Generally feeling unwell (malaise)

Investigations

Changes in the levels of various chemicals in the blood which are usually detected by blood or urine tests, intolerance to carbohydrates, high blood glucose levels (may be seen as an excessive thirst and increased passing of urine), breakdown of body protein stores (loss of weight and loss of muscle in arms and legs), loss of calcium and nitrogen. Loss of potassium salts from your body may result in cramps and spasms. Weight increased.

Because of these potential side effects, your doctor may want to monitor you at intervals during your treatment. If any of the above does occur, or you notice any other unusual feelings or symptoms or the side effects become severe, keep taking your tablets but contact your doctor or pharmacist as soon as possible.

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 HPRC Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydrocortisone Tablets

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 bottle or blister strip after 'EXP'. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 10 mg Tablet contains 10 mg Hydrocortisone.
Each 20 mg Tablet contains 20 mg Hydrocortisone.
- The other ingredients (excipients) are:
 - Lactose monohydrate (see section 2).
 - Maize starch
 - Silica, colloidal anhydrous
 - Povidone
 - Cellulose, microcrystalline
 - Magnesium stearate

What Hydrocortisone Tablets look like and contents of the pack

Hydrocortisone 10 mg tablets are white, oval, flat, bevelled tablets with imprinted "H" on one side and plain on the other side.

Hydrocortisone 20 mg tablets are white, oval, flat, bevelled tablets with imprinted "H" on one side and a single break line on the other side.

Hydrocortisone tablets are available in HDPE bottles with a polypropylene closure containing 100 tablets, or in PVC/Aluminium foil blister packs containing 30 tablets (each pack contains 3 x 10 tablet blister strips).

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Renata Pharmaceuticals (Ireland) Limited
13 – 18 City Quay,
Dublin 2,
Ireland

Distributed by:

Azure Pharmaceuticals Ltd
Blackrock
Co. Louth
Ireland

Manufacturer:

ALTERNO LABS d.o.o.
Brnčičeva ulica 29,
Ljubljana-Črnuče, 1231
Slovenia

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland -Hydrocortisone 10 mg Tablets, 20 mg Tablets
Cyprus – Hydrocortisone Renata 10 mg, 20 mg Tablets
United Kingdom-Hydrocortisone 10 mg, 20 mg Tablets

This leaflet was revised in August 2023