

Hydrocortisone 10 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

- **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 Section 4: 'Possible side effects' 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 Section 4: 'Possible side effects' for more information).
- **If you take this medicine 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 chickenpox or shingles**, even if you have had them previously (read Section 2 for further information). 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 10 mg Tablets (referred to as Hydrocortisone Tablets in this leaflet) contain a medicine called hydrocortisone. This 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 Tablets) is an effective way to treat various illnesses involving inflammation in the body.

Hydrocortisone Tablets reduce 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:

- in children: as replacement therapy for children with congenital adrenal hyperplasia which affects the body's natural production of steroids;
- treatment of adrenocortical insufficiency;
- for adding hydrocortisone before surgery and during/after injuries or other stressful events or illness.
- in adults, adolescents and children: to treat severe asthma and allergic reactions.

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 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 **thrush, candida** or any **other fungal infection**;
- if you have any **other infections** and you have not yet started anti-infective treatment;
- if you have been **vaccinated recently** or are **going to have any vaccinations**.

If you are not sure, talk to your doctor or pharmacist before taking Hydrocortisone Tablets.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Hydrocortisone Tablets 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 Tablets or if any of your close family have had these illnesses.
- have recently had a heart attack
- have a heart condition called congestive heart disease
- have septicaemia, tuberculosis (TB) or have had it in the past
- have a stomach ulcer or other digestive problem
- have chicken pox or shingles
- come in contact with people who have chicken pox, shingles or measles, especially if you have not already had these illnesses or are not sure if you have had them
- have a weakened immune system
- have a herpes infection in the eye called ocular herpes simplex
- had muscle weakness after taking steroids in the past
- have recently visited a tropical country
- have bowel problems such as ulcerative colitis
- have 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)
- are taking Hydrocortisone Tablets for a long time, as it increases your chance of getting infections
- have amoebic dysentery and an infestation of a gut worm (strongyloidiasis), as it may be activated or become worse.

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 pressure in the eye);
- kidney or liver problems;
- a type of muscle weakening problem called 'myasthenia gravis'
- thinning of the bones (osteoporosis);
- HIV infection;
- existing or previous history of severe mood-related disorders;
- thyroid problems;
- if you experience an increase of body temperature (fever due to any reason), feeling unwell, undergoing a stressful situation or if you are undergoing any minor surgical procedure inform your doctor or pharmacist as your daily dose may be increased temporarily.

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.

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.

Mental Problems while taking Hydrocortisone Tablets

Mental problems can happen while taking steroids like Hydrocortisone Tablets (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 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. In a few cases, mental problems have happened when doses are being lowered or stopped.

Contact your doctor if you experience blurred vision or other visual disturbances.

Children and adolescents

If hydrocortisone is given to a prematurely born baby, monitoring of heart function and structure may be needed. If the patient is a child, it is important that the doctor monitors growth and development at intervals during treatment.

Elderly

Hydrocortisone Tablets should be used with caution in the elderly as side effects can be heightened in this age group. If you are taking or have recently taken (within the last 3 months) Hydrocortisone Tablets and **you become ill** (particularly important in cases of gastroenteritis or vomiting/diarrhea), **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 for any other reason your general health is declining although you take your medicine as prescribed; seek medical advice immediately.

Particular care should be taken by patients on long-term treatment as there is an increased risk of side effects.

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.

Other medicines and Hydrocortisone Tablets

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

In particular, do not take this medicine if you are taking any of the following:

- salicylates such as aspirin
- medicines for fits (epilepsy) such as phenytoin, phenobarbital, carbamazepine and primidone
- cough and cold medicines that contain a decongestant called ephedrine
- medicines used for TB (tuberculosis) called rifabutin or rifampicin
- medicines used to thin the blood (anticoagulants such as warfarin)
- water tablets (diuretics)
- some medicines for fungal infections such as amphotericin and ketoconazole, itraconazole, posaconazole or voriconazole
- a medicine used in the treatment of cancer called aminoglutethimide)
- some medicines for heart failure and irregular heartbeat such as digoxin, furosemide or bumetanide
- a medicine used for some infections called erythromycin, telithromycin or clarithromycin
- oral contraceptive pills and hormone replacement therapy (HRT)
- a type of growth hormone called somatropin
- some medicines for high blood pressure
- some medicines for heart disease such as guanethidine, isosorbide mononitrate, isosorbide dinitrate and theophylline
- medicines sometimes used for asthma, low blood pressure or in cough and cold remedies called sympathomimetics (e.g. bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline)
- calcium supplements
- medicines for pain and inflammation called NSAIDs such as ibuprofen, diclofenac or naproxen
- a medicine for urea cycle disorder called sodium phenylbutyrate (usually started by a specialist doctor or consultant)
- medicines for diabetes (including insulin)
- ritonavir (a medicine used in the treatment of HIV infections)
- methotrexate (a medicine used to treat rheumatoid arthritis)
- ciclosporin (a medicine used for psoriasis or in patients who have organ transplants)
- minoxidil & hydralazine (used as antihypertensives)
- 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).
- efavirenz or nevirapine (medicines used in the treatment of HIV infections)
- acetazolamide (a medicine used to treat glaucoma)
- mifepristone (a medicine used to assist medical termination of pregnancy)
- carbenoxolone (a medicine used to treat ulcers)
- St. John's Wort (a herbal medicine used for treating depression)

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Hydrocortisone Tablets.

Hydrocortisone Tablets and infections

Infections are easier to get and harder to spot while you are taking Hydrocortisone Tablets. Stay away from anyone you know with:

- chickenpox
- shingles
- measles.

See your doctor if you think you may have picked up an infection.

Hydrocortisone Tablets with food, drink and alcohol

Do not take this medicine with grapefruit juice as the juice may affect the action of this medicine.

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.

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.

Pregnancy

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

Driving and using machines

Hydrocortisone Tablets 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. Changes in your eyesight or muscle weakness may also happen. If you are affected, you should not drive or operate machinery.

Having vaccines or tests while you are taking Hydrocortisone Tablets

Tell your doctor that you are taking Hydrocortisone Tablets if you are to receive any vaccinations or have any diagnostic or laboratory tests. This is because steroids can affect the results of some tests. **Having surgery while you are taking Hydrocortisone Tablets**

If you are having surgery requiring an anaesthetic, tell your doctor you are taking Hydrocortisone Tablets.

Information you should carry while you are taking Hydrocortisone Tablets

If you are taking Hydrocortisone Tablets, get a steroid card from your pharmacist, and carry it with you. It shows what you are taking and who your doctor is in case of an emergency.

If you have an accident, fall ill or see a different doctor while taking Hydrocortisone Tablets, show them your steroid card or tell whoever treats you that you are taking Hydrocortisone Tablets, because your dose may need to be changed.

Hydrocortisone Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Hydrocortisone Tablets

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

You should take this medicine by mouth. The amount you take each day will depend on your illness. The number of tablets to be taken will be on the label of your medicine. If you are unsure about the dose you should take, you must talk to your doctor or pharmacist.

Always remember to carry your 'Steroid Treatment' card with you. Make sure your doctor or pharmacist gives you this and has filled out the details, including the dose and how long you will have treatment.

The recommended dose is:

Dosage for Acute Emergencies

The recommended dose for adults is 60-80 mg every 4-6 hours for 24 hours then gradually lowering the dose over several days.

The dosage regimen in adult and pediatric patients should be based on the current guidelines for each condition.

Replacement Therapy

Adults

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

Use in children and adolescents

When used for replacement therapy in congenital adrenal hyperplasia, the recommended dose for children is 10-30 mg divided into two doses each day. The first dose taken in the morning may be larger than the second dose taken in the evening.

In chronic adrenocortical insufficiency

- 0.4 to 0.8mg 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.

Hydrocortisone Tablets can be taken with or without food. Do not take this medicine with grapefruit juice as the juice may affect the action of this medicine.

If you take more Hydrocortisone Tablets than you should

If you take too many tablets by mistake, contact your doctor as soon as possible. Symptoms of overdose include feeling or being sick, salt and fluid retention, high blood sugar and gastrointestinal bleeding.

If you forget to take Hydrocortisone Tablets

- If you forget to take your dose, skip the missed dose.
- 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

Do not stop taking this medicine just because you feel better. You should follow your doctor's instructions on stopping this medicine. Your doctor may want you to reduce gradually the number of tablets you take before stopping completely. Never let your tablets run out before receiving the next prescription. It may be dangerous to go without treatment (see Section 2).

It is dangerous to reduce your dose of Hydrocortisone Tablets too quickly. Stopping Hydrocortisone Tablets may leave you without enough steroid hormones in your body. This may cause withdrawal symptoms such as:

- pains in muscles or joints
- fever
- swelling of the eye
- blocked/runny nose
- painful itchy skin rash
- weight loss
- general discomfort

Your doctor or pharmacist will give you advice on how to reduce the number of tablets you take if you need to do this. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. People taking steroids to replace similar naturally occurring hormones should be less likely to get side effects than people taking steroids for other illnesses. Your doctor will want to see you now and then to look out for these effects. Side effects can be heightened when this medicine is used by elderly patients.

Tell your doctor **immediately** 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 (frequency cannot be estimated from the available data):

- An allergic reaction such as itching or skin rashes; swelling of the face, lips or throat; or difficulty breathing or wheeziness.
- Pseudotumourcerebri in children and adolescents - raised pressure within the skull, indicated by headaches with vomiting, listlessness and drowsiness; this usually occurs after treatment is stopped.
- Burst or bleeding ulcers - indicated by stomach pain especially if it seems to spread to your back, bleeding from the back passage, black stools or vomiting with blood in the vomit.
- Acute pancreatitis - abdominal pain, possibly accompanied by shock, i.e. low blood pressure with decreased output of urine and often loss of consciousness.

- Thrombosis - a blood clot in a vein 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 problems: Increased damage to the heart in the event of a heart attack, 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 bone due to poor circulation of blood (pain in the hip or shoulder); joint inflammation in the knee and groin or other joints; risk of torn tendons (pain and/or swelling).
- Cushing's syndrome – reddish stretch marks; rounded or moon-shaped red face; weak muscles and bones; swollen abdomen and 'Buffalo hump' from fat deposits around the stomach and neck; mood changes; headache;

Steroids including Hydrocortisone Tablets 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 Tablets.

Tell your doctor immediately if you are:

- 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.

Other side effects

Tell your doctor if you experience any of the following:

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

- insomnia
- low mood (depression)
- feeling excited or excessively happy

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

- if you are getting infections more frequently. Taking Hydrocortisone Tablets can make it easier for you to pick up infections which may very rarely be fatal. Infections such as chickenpox and measles can be made worse or TB may recur. Some fungal and viral infections, including herpes, may be activated.
- increase in white blood cell count.
- oral thrush
- tooth decay
- ulcers in the gullet (discomfort on swallowing, which can cause chest pain)
- indigestion
- bloating
- feeling sick
- high blood pressure
- psychological dependence
- worsening of epilepsy
- sedation
- dizziness/spinning sensation
- muscle weakness or wasting
- osteoporosis (brittle bones – bones that break easily)
- salt and water retention (causing swelling and raised blood pressure)
- low adrenal gland function which reduces the production of steroids in your body (particularly after surgery, an accident or illness).
- reduction in blood potassium levels, symptoms of which include fainting due to low blood pressure, feeling your heartbeat (palpitations), muscle weakness, tiredness or cramps, feeling sick or being sick, inability to pass stool regularly and properly, frequent passing of urine, excessive thirst and inability to eat properly
- 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
- decrease in cholesterol (good cholesterol) in the blood (shown in blood tests)
- thin or delicate skin, bruising, red or purple spots/itchy rash
- slow healing of cuts or wounds
- acne, redness
- stretch marks
- worsening of sight or changes in vision as a result of cataracts (clouding of the lens in the eye) or glaucoma (increased pressure inside the eye); dry eyes, thinning of the surface of the eye; blurred vision
- eye infections may get worse.
- generally feeling unwell (malaise)
- tiredness

Additional side effects in children

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

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

Because of these potential side effects, your doctor may want to monitor you at intervals during your treatment.

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 Website: 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 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 after EXP. The expiry date refers to the last day of that month.

Store in the original blister in order to protect from light.

This medicinal product does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any 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 10 mg of hydrocortisone.
- the other ingredients are starch pregelatinised, lactose monohydrate, microcrystalline cellulose, povidone, sodium starch glycolate type A, talc, silica colloidal anhydrous and magnesium stearate.

What Hydrocortisone Tablets look like and contents of the pack

Hydrocortisone 10 mg Tablets are white, round shape tablets of 9 mm diameter, with cross-shaped breakline on one side and 'HN' engraved on the other.

The tablets are packed in opaque white PVC/PVdC/PVC or PVC/PCTFE/PE-EVOH-PE/PVC blister strip, sealed with aluminium foil.

The blister strips are packed in cartons of 30 tablets.

Marketing Authorisation Holder and Manufacturer

Dexcel Pharma Ltd.

7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK.

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