

Package leaflet: Information for the patient
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.

Your medicine name is Hydrocortisone 10 mg Tablets.

Important things you need to know about Hydrocortisone

- **Hydrocortisone is a steroid medicine.** This can be 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 for more information). Some side effects 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 below for more information)
- **If you take this medicine for more than 3 weeks, you will be given 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,** 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 10 mg tablets are and what they are used for
2. What you need to know before you take Hydrocortisone 10 mg tablets
3. How to take Hydrocortisone 10 mg tablets
4. Possible side effects
5. How to store Hydrocortisone 10 mg tablets
6. Contents of the pack and other information

1. What Hydrocortisone 10 mg tablets are and what they are used for

Hydrocortisone 10 mg tablets 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 10 mg tablets) is an effective way to treat various illnesses involving inflammation in the body.

Hydrocortisone 10 mg 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 10 mg tablets are used for:

- adding hydrocortisone in children, which is usually made naturally in the body, when part of the adrenal gland is not working properly
 - to treat severe asthma and allergic reactions in adults and children.
- Ask your doctor to explain why you have been given Hydrocortisone 10 mg tablets if you are not sure.

2. What you need to know before you take Hydrocortisone 10 mg tablets

Before you take Hydrocortisone 10 mg 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 tablets
 - if any of your close family has had these illnesses.
- Talk to your doctor before taking Hydrocortisone 10 mg tablets if any of these applies to you.

Do not take Hydrocortisone 10 mg 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 systemic infections which are yet to be treated
- if you have received a type of vaccine (live vaccines).

Talk to your doctor or pharmacist before taking Hydrocortisone 10 mg tablets if you are not sure.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Hydrocortisone 10 mg tablets if

- you have recently had a heart attack
- you have a heart condition called congestive heart disease
- you have septicaemia, tuberculosis or have had it in the past
- you have a stomach ulcer or other digestive problem
- you have chickenpox or shingles
- you have a herpes infection in the eye called ocular herpes simplex
- you had muscle weakness after taking steroids in the past
- you have recently visited a tropical country;
- you have bowel problems such as ulcerative colitis;
- you have epilepsy;
- you have HIV infection;
- you have cerebral malaria;
- you have thrombophlebitis (swelling and redness along a vein which is tender when touched)
- you have metastatic carcinoma (cancer that has spread from one part of the body to another)
- you have history of drug allergies.

Also, talk to 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'
- kidney or liver problems
- a type of muscle weakening problem called 'myasthenia gravis'

- thinning of the bones (osteoporosis)
- low thyroid levels (hypothyroidism).

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 10 mg 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 10 mg tablets. Your dose of Hydrocortisone 10 mg 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.

If you have been on Hydrocortisone 10 mg 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.

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

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

Talk to your doctor or pharmacist before taking a tablet if you are not sure if any of the above run in your family or if you have them.

Mental problems while taking Hydrocortisone 10 mg tablets

Mental problems can happen while taking steroids like Hydrocortisone 10 mg 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 your doctor if you (or someone taking this medicine), shows 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.

Also talk to your doctor if you are on long term therapy with hydrocortisone and develop lesions of any color on any part of skin or inside mouth, swelling in the arms and legs, which can be very painful, breathlessness, coughing of blood, nausea, vomiting, stomach pain and diarrhoea. These may be symptoms of Kaposi's sarcoma.

Important - Steroid Treatment Card

All patients taking steroids for more than three 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 and who your doctor is, in case of an emergency.

Always keep it with you and show it to any doctor or nurse treating you.

If you have an accident, fall ill or see a different doctor while taking Hydrocortisone 10 mg tablets, show them your steroid card or tell whoever treats you that you are taking Hydrocortisone 10 mg tablets because your dose may need to be changed.

Other medicines and Hydrocortisone 10 mg tablets

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

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).

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

- **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** such as warfarin
- **water tablets** (diuretics)
- some medicines for **fungal infections** such as amphotericin, ketoconazole, itraconazole, posaconazole or voriconazole
- a medicine for **cancer** called aminoglutethimide
- some medicines for **heart failure** 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
- **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**
- efavirenz or nevirapine (medicines used in the treatment of **HIV infections**)
- methotrexate (a medicine used to treat **rheumatoid arthritis**)
- St. John's Wort (a herbal medicine used for treating depression)
- sodium benzoate (a preservative)
- medicines that effect stomach emptying, such as metoclopramide or domperidone
- medicines used to treat myasthenia gravis
- orally ingested chemicals used to make X-rays clearer
- ciclosporin (a medicine used for **psoriasis** or in patients who have **organ transplants**).

Talk to your doctor or pharmacist before taking Hydrocortisone 10 mg tablets if you are not sure if any of the above apply to you.

Hydrocortisone 10 mg tablets and infections

Infections are easier to get and harder to spot while you are taking Hydrocortisone 10 mg tablets. Stay away from anyone you know with:

- chickenpox
- shingles
- measles.

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

Hydrocortisone 10 mg tablets with food and drink

Hydrocortisone 10 mg tablets can be taken with or without food. Do not take this medicine with grapefruit juice as the juice will conflict with the action of this medicine.

Receiving vaccines or tests while you are taking Hydrocortisone 10 mg tablets

Tell your doctor that you are taking Hydrocortisone 10 mg 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 10 mg tablets

If you are having surgery requiring an anaesthetic tell your doctor you are taking Hydrocortisone 10 mg tablets.

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.

Driving and using machines

Steroids may cause a feeling of movement, even while you are still and this can cause you to feel tired and dizzy (vertigo). Changes in your eyesight or muscle weakness may also happen. If you are affected, do not drive or operate machinery.

Hydrocortisone 10 mg tablets contain lactose

This medicine contains lactose, which is a type 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.

Hydrocortisone 10 mg tablets contain 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 10 mg tablets

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

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.

Taking this medicine

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. Talk to your doctor or pharmacist.

The recommended doses are:

Dosage for Acute Emergencies

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

Use in children and adolescents

- when used for replacement therapy, the usual 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
- children will be prescribed the lowest possible dose
- the doctor will monitor your child's growth and development.

If you take more Hydrocortisone 10 mg tablets than you should

If you take more tablets than prescribed, contact your doctor as soon as possible. Over dosage can cause symptoms such as nausea (feeling sick), vomiting (being sick), sodium and water retention and occasional gastrointestinal bleeding.

If you forget to take Hydrocortisone 10 mg 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 10 mg tablets

It is dangerous to reduce your dose of Hydrocortisone 10 mg tablets too quickly. Stopping Hydrocortisone 10 mg tablets may leave you without enough steroid hormones in your body. This may cause withdrawal symptoms such as:

- pains in muscles or joints
- fever
- 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 or pharmacist.

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.

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):

- An allergic reaction such as skin rash, swelling of the face or wheezing
- Irregular or very fast or slow pulse, faintness
- Muscle cramps or spasms
- Pseudotumourcerebri in children (raised pressure within the skull, indicated by headaches with vomiting, listlessness and drowsiness); this usually occurs after treatment is stopped
- Nausea, vomiting
- 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)
- A worsening of sight
- Change in number and motility of sperm in men
- 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 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)
- increase in white blood cells (leucocytosis).

Steroids including Hydrocortisone 10 mg 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 10 mg tablets.

- Feeling depressed, including thinking about suicide
- Feeling high (mania) or moods that go up and down
- Feeling anxious, irritated, 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.

Tell your doctor if you experience any of the following:

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

- if you are getting infections more frequently
- swollen abdomen
- ulcers or thrush in the gullet (discomfort on swallowing)
- indigestion
- bloating
- hiccups
- low mood (depression)
- worsening of epilepsy
- muscle weakness or wasting
- osteoporosis (brittle bones – bones that break easily)
- broken bones or fractures
- breakdown of bone due to poor circulation of blood (pain in the hip)
- aseptic necrosis (joint inflammation in the knee and groin)
- torn muscle tendons (pain and/or swelling)
- swelling in joints
- 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)
- suppression of normal growth in children
- irregular or no periods in women
- increased hair on the body and face in women
- round or moon-shaped face
- increased appetite
- 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
- low adrenal gland function which reduces the production of steroids in your body (particularly after surgery, an accident or illness)
- thin or delicate skin, bruising, red or purple spots
- slow healing of cuts or wounds
- acne, sweating, redness
- stretch marks
- Kaposi's sarcoma (a type of cancer) has also been reported to occur in patients receiving corticosteroids. However, once the treatment is stopped, this may go away
- changes in vision as a result of cataracts or glaucoma (increased pressure inside the eye)
- thinning of the surface of the eye
- eye infections may get worse
- bulging eyes
- blurred vision
- dry eyes
- thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies.

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 10 mg 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 foil and carton. The expiry date refers to the last day of that month.

Do not store above 30°C. Keep the blister in the outer carton 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 10 mg tablets contain

- The active substance is hydrocortisone. Each tablet contains 10 mg of hydrocortisone.
- The other ingredients are lactose monohydrate, potato starch, gelatin, talc, sodium starch glycolate and magnesium stearate.

What Hydrocortisone 10 mg tablets look like and contents of the pack

Hydrocortisone 10 mg tablets are white, round and flat with a breakline on one side and 'H' imprinted on other side. The tablet can be divided into equal doses.

Hydrocortisone 10 mg tablets are available in blister packs of 30 tablets.

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The marketing authorisation holder will ensure that the package information leaflet is made available on request from patient's organisations in formats appropriate for the blind and partially-sighted.

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