

Package leaflet: Information for the patient**Hydrocortisone 10 mg and 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. It includes any possible side effects not listed in this leaflet. See section 4.

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

- **Hydrocortisone is 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 can cause side effects in some people** (read section 4 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 for more information).
- **If you take it for more than 3 weeks, you will get a blue 'Steroid Treatment 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**, even if you had them previously (see section 2 for further information). 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.

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.

1. What Hydrocortisone Tablets are and what they are used for

It is indicated

- For use as replacement therapy for children with congenital adrenal hyperplasia which affects your body's natural production of steroids.
- Treatment of adrenal insufficiency in children and adolescents <18 years of age.
- 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 this product is also authorised to treat other sub-groups of patients 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. 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 infections
- 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 or pharmacist before taking Hydrocortisone Tablets
- if you ever had severe depression or manic-depressive illness (bipolar disorder). This includes having had symptoms of depression in the past while taking steroid medicines like Hydrocortisone Tablets.
- if any of your close family has had these illnesses
- if you have 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.

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

- septicaemia, tuberculosis (TB) or have had it in the past
- liver problems
- kidney problems
- high blood pressure
- a heart condition called congestive heart disease
- 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 family history of glaucoma
- *herpes simplex* infection in the eye. Hydrocortisone may activate or exacerbate fungal and viral eye infections
- epilepsy
- stomach ulcers or other digestive problems
- muscle weakness with steroids a type of muscle weakening problem called 'myasthenia gravis'
- existing or previous history of severe mood-related disorders
- hypothyroidism (low thyroid levels)
- 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
- a weakened immune system
- amoebic dysentery and an infestation of a gut worm (strongyloidiasis), it may be activated or become worse by hydrocortisone tablets
- have recently visited a tropical country
- bowel problems such as ulcerative colitis
- thrombophlebitis (swelling and redness along a vein which is extremely tender when touched)
- exanthematous disease (disease affecting the skin, rash)
- metastatic carcinoma (cancer that has spread from one part of the body to another)
- are taking Hydrocortisone Tablets for a long time, it increases your chance of getting infections

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

It is important that the doctor monitors growth and development at intervals during treatment of children

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

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.

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 the 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 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 and your doctor may wish to monitor you carefully if you are taking the below medicines.

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, telithromycin, clarithromycin, fluoroquinolones (antibiotics)
- an oral contraceptive pill; and hormone replacement therapy (HRT)
- somatotropin (a type of growth hormone);
- efavirenz, nevirapine, ritonavir or cobicistat (medicines used in the treatment of HIV infections);
- acetazolamide (a medicine used to treat glaucoma);

- antifungal medicines (ketoconazole, itraconazole, posaconazole, voriconazole, amphotericin B)
 - 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, furosemide or bumetanide (used to treat heart failure and irregular heartbeat);
 - 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 including minoxidil & hydralazine).
 - herbal medicines containing St. John's wort (*Hypericum perforatum*)
 - anticholinesterases (e.g. pyridostigmine)
 - 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)
 - calcium supplements
 - ciclosporin (a medicine used for psoriasis or in patients who have organ transplants)
- 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.

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

Hydrocortisone with food, drink and alcohol

Hydrocortisone 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**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

Corticosteroids may affect fertility as they may impair semen quality and cause loss of menstrual periods (amenorrhoea).

Driving and using machines

Hydrocortisone may have minor influence on your ability to drive and use machines. Extreme tiredness, changes in your eyesight, muscle weakness 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.

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

Having surgery while you are taking Hydrocortisone Tablets

If you are having surgery requiring an anaesthetic tell your doctor you are taking this medicine.

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 this medicine, 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

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

Information on sodium content

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.

Remember to always carry a Steroid Treatment Card. Make sure your doctor or pharmacist gives you this and has filled out the details including the dose and how long you will have the treatment.

You should take this medicine by mouth. The amount you take each day will depend on your illness.

Taking this medicine

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. The usual doses of Hydrocortisone Tablets are:

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.

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 than you should

If you take more Hydrocortisone Tablets than you should, contact a doctor or nearest hospital/emergency department. 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 a dose, wait and take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking Hydrocortisone Tablets

Do not stop taking this medicine just because you feel better. You must follow your doctor’s instructions on stopping these tablets. Your doctor may want you to reduce gradually the number of tablets before you finally stop taking them. Never let your tablets run out before receiving the next prescription. It may be dangerous to stop treatment without your doctor’s advice (See section 2).

Stopping Hydrocortisone Tablets may leave you without enough steroid hormones in your body. This may cause withdrawal symptoms such as fever, weakness, nausea, increased pressure inside the skull, muscle and joint pain, blocked/runny nose, swelling of the eye, painful itchy skin rash, general discomfort and weight loss.

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):

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

- An allergic reaction such as itching or skin rash; swelling of the face, lips or throat; or difficulty in breathing or wheezing.
- Pseudotumorcerebri 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).
- 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).
- Aseptic necrosis - broken bones or fractures; breakdown of bone 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 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.

- 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:

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

- if you are getting infections more frequently
- increase in white blood cell count
- oral thrush
- swollen abdomen
- ulcers or thrush in the gullet (discomfort on swallowing)
- indigestion
- bloating
- feeling sick
- fits
- headache
- loss of balance and spinning sensation
- high blood pressure
- feeling excited or excessively happy
- insomnia
- swelling in your hands and legs
- 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)
- torn muscle tendons (pain and/or swelling).
- 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).
- irregular or no periods in women
- increased hair on the body and face in women
- round or moon-shaped face
- 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, sweating, 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 the eye
- eye infections may get worse
- bulging eyes
- blurred vision.

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.

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 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 blister, carton or bottle after EXP. The expiry date refers to the last day of that month.
- Store below 25°C.
- 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 10 mg or 20 mg hydrocortisone.
- The other ingredients in the tablet are microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal anhydrous silica, and magnesium stearate.

What Hydrocortisone Tablets look like and contents of the pack

- Hydrocortisone 10 mg Tablets: White to off white, elliptical shaped, flat, bevelled edge tablet with ‘BL 10’ on one side and crossed break lines on other side. The tablet can be divided into equal doses.
- Hydrocortisone 20 mg Tablets: White to off white, elliptical shaped, flat, bevelled edge tablet with ‘BL20’ on one side and a break line on other side. The tablet can be divided into equal doses.
- These are available in: blister of 30 tablets & glass bottles of 50 and 100 tablets. Not all pack sizes may be marketed.

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