Package leaflet: Information for the user

Hydrocortisone 10 mg Soluble Tablets Hydrocortisone 20 mg Soluble Tablets

Important things you need to know about Hydrocortisone

- **Hydrocortisone is a steroid medicine**, prescribed for many different conditions, including replacement therapy, emergency treatment of asthma, the treatment of drug reactions, serum sickness and severe allergic reactions in adults and children.
- **You will need to take it as prescribed,** to get the maximum benefit.
- **Do not stop taking this medicine** without first 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 side effects may happen straight away. If you feel unwell in any way, **see your doctor as soon as possible.**
- **Some side effects only happen after weeks or months.** (Read section 4 below for more information).
- **If you take this medicine for more than 3 weeks, you will get a blue 'Steroid Treatment Card':** always keep this with you and show it to any doctor or nurse treating you.
- **Keep away from people who have chicken-pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken-pox or shingles, **consult 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 may be especially important for you.

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 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.

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

The name of this medicine is Hydrocortisone 10 mg Soluble Tablets or Hydrocortisone 20 mg Soluble Tablets (called Hydrocortisone tablets throughout this leaflet).
Hydrocortisone 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 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 as prescribed by your doctor in order to get the maximum benefit from it.

Hydrocortisone is a steroid medicine, prescribed for use as replacement therapy for children with congenital adrenal hyperplasia (which affects the body's natural production of steroids), emergency treatment of asthma, the treatment of drug reactions, serum sickness (hypersensitivity reaction to proteins), localised swelling of the skin and/or mucous membranes (angioedema) and severe allergic reactions in adults and children.

It is also used for the treatment of adrenal insufficiency in children and adolescents less than 18 years of age.

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 the Hydrocortisone tablets if you:

- are allergic to hydrocortisone or any of the other ingredients of Hydrocortisone tablets (see section 6);
- have thrush, candida or any other fungal infection.

If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions
Talk to your doctor or pharmacist before taking Hydrocortisone tablets if:

- you have ever had severe depression or manic depression (bipolar disorder). This includes having had manic depression before, or whilst taking steroid medicines like Hydrocortisone tablets.
- any of your close family has experienced these illnesses.
- you have an over-active thyroid gland (hyperthyroidism).

If either of these apply to you, talk to your doctor before taking this medicine.

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.

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

Also check with your doctor before taking this medicine if:

- you have a heart condition called congestive heart disease
- you have septicaemia, tuberculosis (TB) or have had it in the past
- you have a fungal infection
- you have a stomach ulcer or other digestive problem
- you have chicken pox or shingles or are likely to come in contact with anyone who has chicken pox or shingles, especially if you have not already had these illnesses or are not sure if you have had them
- you have recently had a heart attack
- you have a herpes infection in the eye called ocular herpes simplex
- you had muscle weakness after taking steroids in the past
- you have malaria or have recently visited a tropical country
- you have bowel problems such as ulcerative colitis
- you have epilepsy
- you have thrombophlebitis (swelling and redness along a vein which is extremely tender when touched)
- you have exanthematous disease (disease causing a widespread skin rash)
- you have metastatic carcinoma (cancer that has spread from one part of the body to another)
- you have amoebic dysentery or an infestation of a gut worm (strongyloidiasis)

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).

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.

Your doctor may suggest that you reduce the amount of salt you eat and that you take potassium supplements. You can ask your doctor if this applies to you.

Mental health problems while taking hydrocortisone tablets
Problems with mental health can occur or be seen whilst 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), shows any signs of mental health problems. This is particularly important if you are depressed or might be experiencing suicidal thoughts. In a few cases, mental health problems have occurred when doses are being reduced or stopped.

Treatment with this medicine may cause pheochromocytoma crisis, which can be fatal. Pheochromocytoma is a rare tumor of the adrenal glands. Crisis can occur with following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience these signs.

Talk to your doctor before taking Hydrocortisone Tablets if you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands).

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

Other medicines and Hydrocortisone tablets
Please tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Hydrocortisone tablets can affect the way some medicines work. Also, some other medicines can affect the way Hydrocortisone tablets work.

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

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

- aspirin
- medicines for fits (epilepsy) such as phenytoin, phenobarbital, carbamazepine and primidone
- 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 and ketoconazole
- a medicine for cancer called aminoglutethimide
- some medicines for heart failure such as digoxin, furosemide or bumetanide
- medicines used for some infections called erythromycin, clarithromycin or telithromycin
- oral contraceptive pills and hormone replacement therapy (HRT)
- a type of growth hormone called somatropin
- medicines for high blood pressure, including diltiazem, verapamil, minoxidil, hydralazine and many others
- some medicines for heart disease such as guanethidine, isosorbide mononitrate, isosorbide dinitrate
- medicines sometimes used for asthma, low blood pressure or in cough and cold remedies called sympathomimetics, such as ephedrine, pseudoephedrine and others
- 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
- ritonavir (a medicine used in the treatment of HIV infections)
- methotrexate (a medicine used to treat rheumatoid arthritis and other conditions)
- ciclosporin (a medicine used for psoriasis or in patients who have organ transplant)
- theophylline, a medicine for breathing disorders
- mifepristone, a medicine used to cause an abortion

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. Avoid contact with anyone you know to have viral infections such as:

- chickenpox
- shingles
- measles

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

Hydrocortisone tablets with food, drink and alcohol
Hydrocortisone tablets can be taken with or without food.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think

you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
Hydrocortisone may cause you to feel dizzy (vertigo). Changes in your eyesight or muscle weakness may also occur. 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 reduce the effectiveness of some vaccines and 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 or dentist you are taking these tablets.

Information you should carry while you are taking Hydrocortisone tablets
If you are taking Hydrocortisone tablets for more than three weeks you will be given a blue steroid alert card by your pharmacist. It shows what medication 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 these tablets, because your dose may need to be adjusted.

Hydrocortisone tablets contain sodium benzoate and sodium.
This medicine contains 2.53 mg sodium benzoate in each 10 mg soluble tablet or 5.06 mg sodium benzoate in each 20 mg soluble tablet. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine contains 18.53 mg sodium (main component of cooking/table salt) in each 10 mg soluble tablet or 37.08 mg sodium in each 20 mg soluble tablet which is equivalent to 0.9 % or 1.9 % of recommended maximum daily dietary intake of sodium for adults.

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.

Dosage for Acute Emergencies
The recommended dose for adults is 60-80 mg every 4 to 6 hours for 24 hours then gradually reducing the dose over several days.

Use in children and adolescents (aged 1 month to 18 years) for replacement therapy
Hydrocortisone Soluble Tablets can be used in children aged from 1 month to 18 years where the dose of 10 mg or 20 mg soluble 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.

Method of administration
Hydrocortisone Soluble Tablets should be dissolved in water (at least 50 ml) before use. Once dissolved, take immediately.

If you take more Hydrocortisone tablets than you should
If you take too many tablets by mistake, contact your doctor as soon as possible.

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
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
- 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody 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. Your doctor will want to review you 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) need surgery or you are involved in an accident:
- an increase in white cell count as shown in a blood test
- an allergic reaction such as skin rash, swelling of the face or wheezing
- irregular or very fast or slow pulse, feeling faint
- 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
- 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
- thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies
- high blood pressure, indicated by headaches or generally feeling unwell

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. They can happen while you are taking steroids or when you stop taking them.
- feeling depressed, having suicidal thoughts
- 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 or a worsening of these signs

Tell your doctor if you experience any of the following:

Effects on your digestive system
- swollen abdomen
- ulcers or thrush in the gullet (discomfort on swallowing)
- indigestion
- bloating

Effects on your muscles and bones
- 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)

Effects on your body water and salts
- 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).
- sodium and fluid retention, possibly causing swelling

Effects on your hormones and metabolic system
- suppression of normal growth in children
- irregular or no periods in women
- increased hair on the body and face in women
- increased or decreased numbers and/or active movement of sperm
- round or moon-shaped face
- increased appetite, weight increased (frequency not known)
- increase in blood sugar levels, loss of weight and muscle loss in arms or legs, reduced tolerance to carbohydrates
- loss of calcium and nitrogen

Effects on your skin
- thin or delicate skin, bruising, red or purple spots
- slow healing of cuts or wounds
- acne, sweating, redness
- stretch marks

Effects on your eyes
- 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

Other effects
- hiccups
- a general feeling of being unwell
- fits

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 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 and blister after EXP. The expiry date refers to the last day of that month.
Store below 25ºC. Store in the original package to protect from moisture.
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 of hydrocortisone (as hydrocortisone sodium phosphate ester).
- The other ingredients are: sodium hydrogen carbonate (E500), disodium hydrogen citrate (E331), povidone K30 (E1201), mannitol (E421), idacol erythrosine 603087 (E127), sodium benzoate (E211) and macrogol 6000.

What Hydrocortisone tablets look like and contents of the pack
Hydrocortisone 10 mg Soluble Tablets are pink, flat, round tablets marked with "HS 10" with diameter of approx. 7 mm.
Hydrocortisone 20 mg Soluble Tablets are pink, biconvex, oblong tablets marked with "HS 20" with length of approx. 11 mm.
They are available in aluminium/aluminium blisters in pack sizes of 4, 10, 20, 30, 50 or 100 tablets.
Not all pack sizes may be marketed.

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