

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Hydrocortisone 20 mg Tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- **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 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 as soon as possible**.
- **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 this medicine 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 have had them previously (read Section 2 for further information). 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.

Hydrocortisone - benefit information.

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.

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1. WHAT HYDROCORTISONE TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in your medicine is hydrocortisone. This belongs to a group of medicines known as corticosteroids. These are used to replace adrenal hormones in your body, which you may be lacking.

This medicine is used:

- as replacement therapy for patients with low levels of adrenal hormones, Addison's disease or congenital adrenal hyperplasia which affects your body's natural production of steroids;
- to treat severe asthma and allergic reactions.

2. BEFORE YOU TAKE HYDROCORTISONE TABLETS

Do not take the tablets if you:

- are allergic (hypersensitive) to hydrocortisone or any of the other ingredients in Hydrocortisone Tablets (see Section 6);
- have an infection;
- have been vaccinated recently or are going to have any vaccinations.

Take special care with Hydrocortisone Tablets

Talk to your doctor before taking this medicine if:

- **you have 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;
- **any of your close family** has had these illnesses.

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

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

- tuberculosis (TB);
- liver problems;
- kidney problems;
- high blood pressure;
- heart problems including recent heart attacks;
- diabetes (or a family history of diabetes);
- osteoporosis (thinning of the bones);
- glaucoma (increased pressure in the eye) or family history of glaucoma;
- epilepsy;
- stomach ulcers or other digestive problems;
- muscle weakness with steroids;
- existing or previous history of severe mood-related disorders;

- thyroid problems;
- chicken-pox, shingles or measles.

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 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.

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, 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 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.

Taking other medicines

Before taking Hydrocortisone Tablets please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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).

The effectiveness of Hydrocortisone Tablets may be altered if other medicines are being taken at the same time.

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

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

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- asthma and other breathing problems);
- antihypertensives (medicines used to treat high blood pressure).

Test results while taking Hydrocortisone Tablets

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

Taking Hydrocortisone Tablets with food and drink

Hydrocortisone Tablets can be taken with or without food.

Pregnancy and breast-feeding

Tell the doctor if you are pregnant, think you might be pregnant or are trying to become pregnant before taking any medicine. Your doctor will decide whether you should take Hydrocortisone Tablets during this time.

Small amounts of hydrocortisone may pass into breast milk. Therefore you should talk to your doctor before taking Hydrocortisone Tablets if you are breast-feeding or intend to breast-feed.

Driving and using machines

Medicines such as hydrocortisone may cause changes in vision and/or muscle weakness. If you have any of these symptoms you should not drive or operate machinery.

Important information about some of the ingredients of Hydrocortisone Tablets

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

3 HOW TO TAKE HYDROCORTISONE TABLETS

Always take Hydrocortisone Tablets exactly as your doctor has told you. You should 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.

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.

Dosage for Replacement Therapy

The usual dose for adults is 20-30 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.

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

When used for replacement therapy, the usual dose for children is 10-30 mg divided into two doses each day.

If you take more Hydrocortisone Tablets than you should

If you take more tablets than have been prescribed for you, contact your doctor as soon as possible.

If you forget to take Hydrocortisone Tablets

Skip the missed dose and then 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).

Stopping Hydrocortisone tablets may leave you without enough steroid hormones in your body. This may cause withdrawal symptoms such as fever, muscle and joint pain, blocked/runny nose, swelling of the eye, painful itchy skin rash and weight loss.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hydrocortisone Tablets can cause side effects, although not everyone gets them. If you are taking the medicine as a replacement steroid, you should be less likely to get side effects than people taking steroids for other illnesses. Side effects can be heightened when this medicine is used by elderly patients.

Tell your doctor immediately if you notice:

- itching or skin rashes;
- swelling of the face, lips or throat;
- difficulty breathing or wheeziness.

These may be signs of an allergic reaction.

Severe side effects:

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

Tell your doctor immediately if you are:

- depressed, including thinking about suicide;
- high (mania) or having moods that go up and down;
- anxious, having problems sleeping, having difficulty in thinking or being confused and losing your memory;
- feeling, seeing or hearing things which do not exist;
- having strange and frightening thoughts, changing how you act or having feelings of being alone.

Other side effects

Tell your doctor if you experience any of the following:

Heart problems: Increased damage to the heart in the event of a heart attack, heart failure, high blood pressure, formation of blood clots.

Frequency not known (cannot be estimated from the available data): Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies.

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

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

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

Bone, muscle and joints: Muscle weakness or wasting, thinning of bones which makes fractures more likely (osteoporosis), broken bones or fractures, hip or shoulder pain due to poor blood circulation, risk of torn tendons, joint inflammation in the knee and groin (aseptic necrosis).

Eyes: Changes in vision as a result of cataracts or glaucoma (increased pressure inside the eye), thinning of the surface of the eye, existing eye infections may get worse.

Frequency rare (may affect up to 1 in 1,000 people): Blurred vision.

Blood and lymphatic system: Increased number of white blood cells.

Psychiatric disorders: Psychological dependence, worsening of schizophrenia.

Reproductive system:

In Women: Irregular or lack of periods.

Endocrine system: Development of Cushingoid facies (round or moon-shaped face), increased appetite and weight gain, suppression of normal growth in children, low adrenal gland function which reduces the production of steroids in your body (particularly after surgery, an accident or illness).

Weight increased:

Frequency not known (cannot be estimated from the available data).

Skin: Slow healing of cuts or wounds, thin or delicate skin, redness, acne, bruising, stretch marks, growth of body hair.

General: Generally feeling unwell (malaise).

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

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

5. HOW TO STORE HYDROCORTISONE TABLETS

Keep out of the reach and sight of children.

Do not use Hydrocortisone Tablets 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 a cool and dry place.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Hydrocortisone Tablets contain

- The active substance in these tablets is hydrocortisone. Each tablet contains 20 mg of hydrocortisone.
- Other ingredients are lactose, pregelatinised starch and calcium stearate.

What Hydrocortisone Tablets look like and contents of the pack

Hydrocortisone 20 mg Tablets are white, round, biconvex tablets which are scored on one side.

This medicine is in an amber glass bottle containing 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Sovereign Medical, Sovereign House, Miles Gray Road, Basildon, Essex. SS14 3FR.

Manufacturer responsible for release:

Aesica Queenborough Ltd, North Road, Queenborough, Kent. ME11 5EL.

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