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Package leaflet: Information for the patient

Hydrocortisone 10 mg and 20 mg Tablets

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.
- Pre-operatively, and during serious trauma or illness in children with known adrenal insufficiency or doubtful adrenocortical reserve.

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.

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

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
- a weakened immune system
- amoebic dysentery and an infestation of a gut worm (strongyloidiasis), it may be activated or become worse by hydrocortisone tablets.

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 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 effect 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 (a medicine used to treat bacterial infections);
- an oral contraceptive pill;
- somatotropin (a type of growth hormone);
- ritonavir or cobicistat (medicines 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 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 the hospital, so tell your doctor or nurse that you are taking these tablets before any tests are carried out.

Hydrocortisone with food, drink and alcohol

Hydrocortisone can be taken with or without food.

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,

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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

If you are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Hydrocortisone 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. It is therefore important to take this medicine as directed by your doctor when driving or using machines. If you are affected do not drive or use machines, until you have discussed the issue with your doctor.

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.

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.

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.

Taking this medicine

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. The usual doses of Hydrocortisone Tablets are:

Children:

0.4 to 0.8 mg/kg given as two or three doses per day.
Children will be prescribed the lowest possible dose.
The doctor will keep an eye on their growth and development.

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.

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, 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, 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.

Tell your doctor immediately if you notice:

- itching or skin rashes
- swelling on the face, lips or throat
- difficulty in 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 5 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 that 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 heart in the event of a heart attack; heart failure; high blood pressure; blood clots.

Infections: Taking Hydrocortisone 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 tuberculosis may recur.

Blood and lymphatic system: Increased number of white blood cells

Endocrine: Development of 'Cushingoid' state (cheeks and stomach increase in size, limbs become thin with flushed face and increased appetite); stunted growth in children; failure of the adrenal and pituitary glands to produce hormones, particularly after surgery, an accident or illness.

Metabolism and nutrition: Weight gain, increased appetite

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

Psychiatric disorders: Psychological dependence, worsening of schizophrenia

Eyes: Changes in vision as a result of cataract; blurred vision; thinning of the surface of the eye; existing eye infections may get worse; glaucoma (increased pressure in the eye); bulging eyes

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.

Skin: Slow healing of cuts and wounds; thin or delicate skin; redness, stretch marks; bruising; red or purple spots; acne; sweating; wrong results from skin tests; growth of body hair.

Bone, muscle and joints: Muscle weakness or wasting; osteoporosis (thinner bones with a higher risk of breaking them, especially in older women); 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).

Reproductive System:

In women: Irregular or lack of periods

General: Generally feeling unwell (malaise)

Investigations: Changes in 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 does occur, or you notice any other unusual feelings or symptoms or the side effects become severe, keep taking your tablets but contact your doctor or pharmacist as soon as possible.

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 as below

In UK: via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard.

In Ireland: via the HPRA website: www.hpra.ie or email to: medsafety@hpra.ie 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.

Marketing Authorisation Holder and Manufacturer

Name and address: Bristol Laboratories Ltd,
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This medicinal product is authorised in the Member States of the EEA under the following name:

Ireland: Hydrocortisone 10 mg & 20 mg Tablets; PA 1240/013/001 & PA 1240/013/002
United Kingdom: Hydrocortisone 10 mg & 20 mg Tablets; PL 17907/0439 & PL 17907/0440

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[back](#)