

- 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 Accord 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 Accord 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
- ulcers in the gullet (discomfort on swallowing)
- indigestion
- bloating
- feeling sick
- high blood pressure
- feeling excited or excessively happy
- low mood (depression)
- insomnia
- worsening of epilepsy
- muscle weakness or wasting
- osteoporosis (brittle bones – bones that break easily)
- 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
- 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, 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; blurred vision
- eye infections may get worse.

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 directly via the Yellow Card Scheme at: 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 Accord Tablets

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store them in the original package and out of the light.
- Do not put your tablets into another container, in case they get mixed up.
- Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hydrocortisone Accord Tablets contain

The active substance is hydrocortisone.

The other ingredients are lactose, magnesium stearate, maize starch.

What Hydrocortisone Accord Tablets look like and contents of the pack

Hydrocortisone Accord Tablets are available in two strengths.

- 10mg tablets: White, quarter-scored tablets, marked 'HYD 10'. The tablets are scored so that they can be divided into equal halves or quarters. This can allow you to take lower doses of half of a tablet (5mg) or quarter of a tablet (2.5mg).
- 20mg tablets: White, half-scored tablets, marked 'HYD 20'. The tablets are scored so that they can be divided into equal doses. This can allow you to take a lower dose of half of a tablet (10mg).

Hydrocortisone Accord Tablets come in packs of 30 tablets.

Marketing Authorisation Holder: Accord Healthcare Limited, Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom

Manufacturers: Tiofarma BV, Benjamin Franklinstraat 5-10, 3261 LW Oud-Beijerland, The Netherlands.
Tiofarma BV, Hermanus Boerhaavestraat 1, 3261 ME Oud-Beijerland, The Netherlands.

Further information about your condition may be available from The Pituitary Foundation, P.O. Box 1944, Bristol, BS99 2UB Telephone: 0845 450 0375.

(The Pituitary Foundation is an independent organisation, it is not associated with Accord Healthcare Limited).

If you would like a leaflet with larger text, please contact 01271 385257.

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Package leaflet: Information for the patient

Hydrocortisone Accord 10mg and 20mg 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 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. This includes any possible side effects not listed in this leaflet. See section 4.

- **Hydrocortisone Accord Tablets are 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 Accord Tablets can cause side effects in some people** (read section 4: 'Possible side effects' 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: 'Possible side effects' for more information)
- **If you take it for more than 3 weeks, you will get 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 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, **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 Accord Tablets are and what are they used for
2. What you need to know before you take Hydrocortisone Accord Tablets
3. How to take Hydrocortisone Accord Tablets
4. Possible side effects
5. How to store Hydrocortisone Accord Tablets
6. Contents of the pack and other information

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

Hydrocortisone Accord 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 Accord Tablets) is an effective way to treat various illnesses involving inflammation in the body.

Hydrocortisone Accord 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 Accord Tablets are used for:

- adding hydrocortisone usually made naturally in the body because part of the adrenal gland is not working properly
- adding hydrocortisone after injuries, surgery or other stressful events
- some other types of illness.

Ask your doctor to explain why you have been given Hydrocortisone Accord Tablets if you are unsure.

2. What you need to know before taking Hydrocortisone Accord Tablets

Do not take Hydrocortisone Accord Tablets if you:

- are **allergic** to hydrocortisone or any of the other ingredients in this medicine (listed in section 6).
- have **thrush, candida** or any **other fungal infection**.
- have any **other infections**.
- 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 Accord Tablets.

Warnings and precautions

Talk to your doctor before taking Hydrocortisone Accord Tablets 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 Accord Tablets or if any of your close family have had these illnesses
- have recently had a heart attack
- have a heart condition called congestive heart disease
- have septicaemia, tuberculosis (TB) or have had it in the past
- have a stomach ulcer or other digestive problem
- 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

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- have a weakened immune system
- have a herpes infection in the eye called ocular herpes simplex
- had muscle weakness after taking steroids in the past
- have recently visited a tropical country
- have bowel problems such as ulcerative colitis
- have epilepsy
- have thrombophlebitis (swelling and redness along a vein which is extremely tender when touched)
- have exanthematous disease (disease affecting the skin, rash)
- have metastatic carcinoma (cancer that has spread from one part of the body to another)
- are taking Hydrocortisone Accord Tablets for a long time, as it increases your chance of getting infections
- have amoebic dysentery and an infestation of a gut worm (strongyloidiasis), as it may be activated or become worse.

Also, check with 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.

Mental Problems while taking Hydrocortisone Accord Tablets

Mental problems can happen while taking steroids like Hydrocortisone Accord 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 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.

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

Children

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

Other medicines and Hydrocortisone Accord 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.

- 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 and ketoconazole
- 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
- 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 (e.g. bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol, terbutaline)
- 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)
- ciclosporin (a medicine used for psoriasis or in patients who have organ transplants)
- minoxidil & hydralazine (used as antihypertensives)
- some medicines may increase the effects of Hydrocortisone Accord Tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Hydrocortisone Accord Tablets.

Hydrocortisone Accord Tablets and infections

Infections are easier to get and harder to spot while you are taking Hydrocortisone Accord Tablets.

Stay away from anyone you know with:

- chickenpox
- shingles
- measles.

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

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.

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.

Driving and using machines

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

Having vaccines or tests while you are taking Hydrocortisone Accord Tablets

Tell your doctor that you are taking Hydrocortisone Accord 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 Accord Tablets

If you are having surgery requiring an anaesthetic, tell your doctor you are taking Hydrocortisone Accord Tablets.

Information you should carry while you are taking Hydrocortisone Accord Tablets

If you are taking Hydrocortisone Accord 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 Hydrocortisone Accord Tablets, show them your steroid card or tell whoever treats you that you are taking Hydrocortisone Accord Tablets, because your dose may need to be changed.

Hydrocortisone Accord Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Hydrocortisone Accord Tablets

Always take this medicine exactly as your doctor 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. 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 recommended dose is

Adults

- 20 to 30mg a day.
- Sometimes it is taken twice a day with 4 to 6g of salt (sodium chloride) or 50 to 300 micrograms of fludrocortisone.

Children and adolescents

- 0.4 to 0.8mg a day, for every kilogram of your child's weight in two or three separate doses.
- Children will be prescribed the lowest possible dose.
- The doctor will keep an eye on their growth and development.

Hydrocortisone Accord Tablets can be taken with or without food.

If you take more Hydrocortisone Accord Tablets than you should

If you take too many tablets by mistake, contact your doctor as soon as possible. Symptoms of overdose include feeling or being sick, salt and fluid retention, high blood sugar and gastrointestinal bleeding.

If you forget to take Hydrocortisone Accord 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 Accord Tablets

It is dangerous to reduce your dose of Hydrocortisone Accord Tablets too quickly. Stopping Hydrocortisone Accord 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 **immediately** 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.
- Pseudotumourcerebri in children - raised pressure within the skull, indicated by headaches with vomiting, listlessness and drowsiness; this usually occurs after treatment is stopped.
- 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 shortness of breath and 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).