

Hydrocortisone

5 mg, 10 mg and 20 mg Dispersible 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. This includes any possible side effects not listed in this leaflet. See section 4.

- **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 Dispersible Tablets can cause side effects in some people** (read 'Possible side effects' section 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 'Possible side effects' section 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 chickenpox or shingles**, even if you have had them previously. 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 Dispersible Tablets are and what they are used for
2. What you need to know before you take Hydrocortisone Dispersible Tablets
3. How to take Hydrocortisone Dispersible Tablets
4. Possible side effects
5. How to store Hydrocortisone Dispersible Tablets
6. Contents of the pack and other information

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

The name of your medicine is Hydrocortisone 5 mg, 10 mg and 20 mg Dispersible Tablets (referred to as Hydrocortisone Dispersible Tablets in this leaflet). 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.

Hydrocortisone Dispersible Tablets are used:

- in children: as replacement therapy for children with congenital adrenal hyperplasia which affects the body's natural production of steroids,
- treatment of adrenal insufficiency in children and adolescents < 18 years of age,
- in adults and children: to treat severe asthma and allergic reactions.

2. What you need to know before you take Hydrocortisone Dispersible Tablets

Do not take Hydrocortisone Dispersible Tablets if you

- are allergic to hydrocortisone or any of the other ingredients of 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 Dispersible Tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hydrocortisone Dispersible 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 Dispersible Tablets,
- **any of your close family** has had these illnesses.

Take special care with Hydrocortisone Dispersible Tablets

Check with your doctor before taking your medicine if:

- you have recently had a heart attack,
- you have a heart condition called congestive heart disease,
- you have septicaemia, tuberculosis (TB) or have had it in the past,
- you have a stomach ulcer or other digestive problem,
- you have chicken pox or shingles,
- you 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,
- you have a weakened immune system,
- you have a herpes infection in the eye called ocular herpes simplex,
- you had muscle weakness after taking steroids in the past,
- you 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 affecting the skin, rash),
- you have metastatic carcinoma (cancer that has spread from one part of the body to another),
- you are taking Hydrocortisone Dispersible Tablets for a long time increases your chance of getting infections,
- you have amoebic dysentery and an infestation of a gut worm (strongyloidiasis), 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 Dispersible Tablets

Mental problems can happen while taking steroids like Hydrocortisone Dispersible 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.

Other medicines and Hydrocortisone Dispersible Tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without a prescription. This includes herbal medicines. This is because Hydrocortisone Dispersible Tablets can affect the way some medicines work.

Also, some other medicines can affect the way Hydrocortisone Dispersible Tablets work.

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,
- 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 for antihypertensive),
- some medicines may increase the effects of Hydrocortisone Dispersible 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 Dispersible Tablets.

Hydrocortisone Dispersible Tablets and infections

Infections are easier to get and harder to spot while you are taking Hydrocortisone Dispersible Tablets. Stay away from anyone you know with:

- chickenpox,
- shingles,
- measles.

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

Hydrocortisone Dispersible Tablets with food

Hydrocortisone Dispersible 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 or pharmacist for advice before taking this medicine. Your doctor will decide whether you should take Hydrocortisone Dispersible Tablets 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.

Driving and using machines

Hydrocortisone Dispersible 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 Dispersible Tablets

Tell your doctor that you are taking Hydrocortisone Dispersible 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 Dispersible Tablets

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

Information you should carry while you are taking Hydrocortisone Dispersible Tablets

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



Hydrocortisone Dispersible Tablets contains 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 Dispersible 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.

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.

The recommended dose is:

Adults

20 to 30mg a day.

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

When used for replacement therapy, the recommended dose for children is 10-30 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.

Method of administration

Hydrocortisone Dispersible Tablets are best taken dispersed in approximately 50ml of water. The suspension should be swallowed immediately, following which a further 200 ml of water, approximately, should be used to rinse around the glass 2 -3 times, and swallowed. This is to ensure no residual drug particles are left behind in the glass and that the entire dose is consumed. Hydrocortisone dispersible tablets may also be swallowed whole if desired.

If you take more Hydrocortisone Dispersible 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 Dispersible 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 Dispersible Tablets

Do not stop taking this medicine just because you feel better. You should follow your doctor's instructions on stopping this medicine. It is dangerous to reduce your dose of Hydrocortisone Dispersible Tablets too quickly. Stopping Hydrocortisone Dispersible 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.

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):

- An allergic reaction such as skin rash, swelling of the face or wheezing.
- Irregular or very fast or slow pulse, faintness.
- 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; hypertension (high blood pressure, indicated by headaches, or generally feeling unwell).

Steroids including Hydrocortisone Dispersible 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 Dispersible 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.

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,
- swollen abdomen,
- ulcers or thrush in the gullet (discomfort on swallowing),
- indigestion,
- bloating,
- hiccups,
- 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),
- aseptic necrosis (joint inflammation in the knee and groin),
- 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),

- suppression of normal growth in children,
- irregular or no periods in women,
- increased hair on the body and face in women,
- round or moon-shaped face,
- increased appetite and weight gain,
- 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,
- 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.

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 Dispersible Tablets

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after EXP. 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 medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Hydrocortisone Dispersible Tablets contain

- The active substance is hydrocortisone.
Each 5 mg tablet contains 5mg hydrocortisone.
Each 10 mg tablet contains 10mg hydrocortisone.
Each 20 mg tablet contains 20mg hydrocortisone.

- The other excipients are: lactose monohydrate, basic butylated methacrylate copolymer, microcrystalline cellulose, low-substituted hydroxypropylcellulose, colloidal anhydrous silica, crospovidone, sucralose, magnesium stearate and pineapple flavour.

What Hydrocortisone Dispersible Tablets look like and contents of the pack

Hydrocortisone 5 mg Dispersible Tablets are white to off-white, flat, bevel edged, round tablet with "A1" debossed on one side, 7.0mm in diameter.

Hydrocortisone 10 mg Dispersible Tablets are white to off-white, flat, bevel edged, round tablet with "A2" debossed on one side, 10.0mm in diameter.

Hydrocortisone 20 mg Dispersible Tablets are white to off-white, flat, bevel edged, round tablet with "A3" debossed on one side, 13.2mm in diameter.

They are supplied in blister packs of 4, 7, 10, 14, 20, 24, 28, 30, 50, 56, 60, 84, 90, 100, 112 and 120 tablets.

Not all pack sizes may be marketed.

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