

Package leaflet: Information for the user

Hydrocortisone Hualan 2.5 mg tablets

Hydrocortisone Hualan 5 mg tablets

Hydrocortisone Hualan 10 mg tablets

Hydrocortisone Hualan 15 mg tablets

Hydrocortisone Hualan 20 mg tablets

hydrocortisone

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.
- **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 ‘Possible side effects’ section 4 below).**
- **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).
- **Keep away from people who have chickenpox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, see your doctor straight away.

What is in this leaflet

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2. What you need to know before you take Hydrocortisone Hualan tablets
3. How to take Hydrocortisone Hualan tablets
4. Possible side effects
5. How to store Hydrocortisone Hualan tablets
6. Contents of the pack and other information

1. What Hydrocortisone Hualan tablets are and what are they used for

Hydrocortisone Hualan 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.

Hydrocortisone Hualan tablets are used:

- as replacement therapy in primary or secondary adrenocortical insufficiency and prevention of an acute adrenocortical crisis.
- pre-operatively, and during serious trauma or illness in patients with known adrenal insufficiency or doubtful adrenocortical reserve.

You must take this medicine regularly to get maximum benefit from it.

What adrenocortical insufficiency is

The adrenal cortex, part of the adrenal glands situated near the kidneys, produces hormones called corticosteroids. Your adrenal cortex is not producing sufficient amounts of these corticosteroids to keep your body working properly. The hydrocortisone in your tablets replaces the natural steroids that you lack and helps to keep you healthy.

2. What you need to know before you take Hydrocortisone Hualan tablets

Do not take Hydrocortisone Hualan tablets if:

- you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6);
- you have a gastric or duodenal ulcer;
- you have a viral or systemic fungal infections (e.g. thrush). See also section “Warnings and precautions”;
- you have tropical worm infections;
- you are vaccinated with live attenuated virus (see also section “Warnings and precautions”)
- you have had a bad reaction to this or similar medicines in the past;
- you are or think you may be pregnant or if you are planning to become pregnant (see also “Pregnancy and breast-feeding”);
- you are breast-feeding (see also “Pregnancy and breast-feeding”).

If you are not sure, talk to your doctor or pharmacist before taking Hydrocortisone Hualan tablets.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hydrocortisone Hualan tablets if:

- you have recently suffered from a heart attack;
- you suffer from a disease called tuberculosis;
- you suffer from kidney or liver problems, high blood pressure, diabetes, heart problems, osteoporosis (thinning of the bone), myasthenia gravis (a disease causing weak muscles), digestive system or stomach problems or have an under active thyroid;
- you suffer from glaucoma; regular ophthalmic monitoring (eye tests) is recommended;
- you have suffered from muscle weakness with this or other steroids in the past;
- you have an eye infection with the herpes virus;

- you have ever had severe depression or manic-depression (bipolar disorder) or if any of your close family has had these illnesses. This includes having had depression before while taking steroid medicines like hydrocortisone (see also “Mental problems”);
- you are immunocompromised (where your immune system does not work properly);
- you experience blurred vision or other visual disturbances.

You should see your doctor if you develop any new infections while taking these tablets. The microorganism responsible for the infections should be determined and the infection treated before the administration of this medicine.

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.

Mental problems while taking hydrocortisone tablets

Mental health problems can happen while taking steroids like hydrocortisone (see also section 4).

You should be aware that:

- 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 **straight away** if you (or someone taking this medicine), show 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.

Vaccinations

Tell your doctor that you are taking hydrocortisone tablets if you are to receive any vaccinations. This is because steroids can reduce the effectiveness of vaccines. Live virus vaccines should **NOT** be used if you are taking Hydrocortisone Hualan tablets.

Surgery

If you have an accident, fall ill, require any surgery (including at the dentist), during or after treatment with hydrocortisone, you **MUST** tell the doctor or dentist treating you that you are taking or have taken steroids.

Children and adolescents

Hydrocortisone Hualan tablets can be used in children and adolescents, but it is important that the doctor monitors growth and development at intervals during treatment. If hydrocortisone is given to a prematurely born baby, monitoring of heart function and structure may be needed.

Elderly

Treatment of elderly patients, particularly if long term, should be planned to bear in mind the more serious consequences of the common side effects of corticosteroids in old age, especially osteoporosis, diabetes, hypertension, susceptibility to infection and thinning of the skin.

Other medicines and Hydrocortisone Hualan tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicine obtained without prescription and herbal medicines. This is because Hydrocortisone Hualan tablets can affect the way some medicines work. Also, some other medicines can affect the way Hydrocortisone Hualan tablets work.

If you are taking any of the following medicines you should talk to your doctor before taking Hydrocortisone Hualan tablets:

- phenytoin (used to treat epilepsy);
- carbamazepine (used to treat epilepsy);
- ephedrine (a nasal decongestant);
- barbiturates (used to treat epilepsy);
- antibiotics called rifampicin and rifabutin, used to treat tuberculosis;
- an anticancer medicine called aminoglutethimide.

The use of any of the above listed medicines may require adjustment in corticosteroid dosage.

- anticoagulant medicines which thin the blood;
- certain diuretics (water tablets); the combination of these medicines and hydrocortisone increases the risk of hypokalemia;
- amphotericin (used to treat fungal infections);
- ketoconazole (used to treat fungal infections);
- aspirin;
- ulcerogenic agents (e.g. NSAIDs);
- CYP3A inhibitors; the combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid effects.

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

Pregnancy and breast-feeding

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.

Pregnancy

Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

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 Hualan may affect your ability to drive or use machines. If you experience the occurrence of muscle weakness, problems with eyesight and mood changes (euphoria, depression), do not drive or use machines.

Hydrocortisone Hualan 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 Hualan 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.

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 recommended doses are:

Adults

- 20 to 30 mg a day
- Sometimes it is taken twice a day with 4 to 6 g of salt (sodium chloride) or 50 to 300 micrograms of fludrocortisone.
- Your doctor may want to prescribe more. The exact dose depends on your condition.

Use in children

- 0.4 to 0.8 mg a day, for every kilogram of your child's weight given as 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 Hualan 5 mg tablets:

Hydrocortisone Hualan 5 mg tablets have a score on one side. The tablet can be divided into equal doses.

Hydrocortisone Hualan 10 mg tablets:

Hydrocortisone Hualan 10 mg tablets have a quarter score in the middle of one side. The tablet can be divided into equal doses.

Hydrocortisone Hualan 15 mg tablets:

Hydrocortisone Hualan 15 mg tablets have a score on one side. The tablet can be divided into equal doses

Hydrocortisone Hualan 20 mg tablets:

Hydrocortisone Hualan 20 mg tablets have a score on one side. The tablet can be divided into equal doses

Discontinuing treatment

When long term treatment is to be discontinued, the dose should be gradually reduced over a period of weeks or months, depending on dosage and duration of treatment (see below: 'If you stop taking Hydrocortisone Hualan tablets').

It is dangerous to reduce the dose of Hydrocortisone Hualan too quickly (e.g. post illness) as this may leave you without sufficient quantities of vital hormones. It may also cause withdrawal symptoms, including pains in muscles or joints, fever, and general discomfort. Your doctor will give you advice on reducing the amount of Hydrocortisone Hualan tablets gradually if necessary.

If you take more Hydrocortisone Hualan 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 Hualan tablets

If you miss a dose, just carry on with the next one as normal. Do not take a double dose to make up for a forgotten one.

If you stop taking Hydrocortisone Hualan tablets

Do NOT stop taking this medicine without talking to your doctor first – you may need to reduce the dose gradually.

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 **straight away** if you notice any of these side effects; they may be signs of an allergic reaction:

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

Steroids including hydrocortisone can cause **serious mental health problems**. These are common in both adults and children (they can affect about 5 in every 100 people).

- 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.

If you notice any of these problems **talk to a doctor straight away**.

Other side effects:

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

Heart problems

- heart failure (indicated by swollen ankles, chest pain, difficulty in breathing and palpitations and irregular beating of the heart, irregular or very fast or very slow pulse, high blood pressure);
- high blood pressure (hypertension) indicated by headaches or feeling unwell;
- thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies.

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

- high number of red blood cells in your blood (erythrocytosis);
- high number of white blood cells in your blood (granulocytosis);
- low number of white blood cells in your blood (eosinopenia);
- cancer of the lymphatic system (lymphoma)

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 indicated by abdominal pain, stomach pain and discomfort;
- infection or ulceration of the gullet (indicated by discomfort on swallowing, which can cause chest pain).

Nervous system

- raised pressure within the skull (pseudotumor cerebri, indicated by headaches with vomiting, listlessness and drowsiness) has been reported in children; this usually occurs after treatment has stopped.

Bones, muscles and joints

- muscle weakness or wasting;
- osteoporosis (thinner or brittle bones with a higher risk of breaking them, especially in older women);
- broken bones or fractures;
- joint inflammation in the knee and groin (aseptic necrosis).

Eyes

- changes in vision as a result of,
 - cataract;
 - blurred vision;
 - glaucoma (increased pressure inside the eye).

Reproductive system

- in women: irregular or lack of periods.

Endocrine system

- development of 'Cushingoid' state (round or moon-shaped face, 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;
- growth of body hair on face and abdomen in women.

Metabolism and nutrition

- sodium and fluid retention;
- lack of potassium in the body (potassium decrease with hypokalemic alkalosis);
- weight gain;
- increased appetite.

Skin

- slow healing of cuts or wounds;
- redness;
- bruising easily, red or purple spots, acne;
- wrong results from skin tests.

Investigations

- intolerance to carbohydrates, high blood glucose levels (may be indicated by an excessive thirst and increased passing of urine);
- breakdown of body protein stores (may be indicated by 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.

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 national reporting system listed in Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine

5. How to store Hydrocortisone Hualan 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 or bottle (*only 10 mg and 20 mg tablets*) after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Hydrocortisone Hualan 10 mg tablets: Bottles: discard contents 50 days after first opening.

Hydrocortisone Hualan 20 mg tablets: Bottles: discard contents 50 days after first opening.

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 Hualan contains

Hydrocortisone Hualan 2.5 mg tablets:

The active substance is hydrocortisone. Each tablet contains 2.5 mg hydrocortisone. The other ingredients are lactose monohydrate (see section 2 “Hydrocortisone Hualan contains lactose), magnesium stearate and maize starch.

Hydrocortisone Hualan 5 mg tablets:

The active substance is hydrocortisone. Each tablet contains 5 mg hydrocortisone. The other ingredients are lactose monohydrate (see section 2 “Hydrocortisone Hualan contains lactose), magnesium stearate and maize starch.

Hydrocortisone Hualan 10 mg tablets:

The active substance is hydrocortisone. Each tablet contains 10 mg hydrocortisone. The other ingredients are lactose monohydrate (see section 2 “Hydrocortisone Hualan contains lactose), magnesium stearate and maize starch.

Hydrocortisone Hualan 15 mg tablets:

The active substance is hydrocortisone. Each tablet contains 15 mg hydrocortisone. The other ingredients are lactose monohydrate (see section 2 “Hydrocortisone Hualan contains lactose), magnesium stearate and maize starch.

Hydrocortisone Hualan 20 mg tablets:

The active substance is hydrocortisone. Each tablet contains 20 mg hydrocortisone. The other ingredients are lactose monohydrate (see section 2 “Hydrocortisone Hualan contains lactose), magnesium stearate and maize starch.

What Hydrocortisone Hualan looks like and contents of the pack

Hydrocortisone Hualan 2.5 mg tablets:

Hydrocortisone Hualan 2.5 mg tablets are white round, flat bevelled tablets of about 5.1 – 5.5 mm in diameter, engraved “2.5” on one side.

Hydrocortisone Hualan 5 mg tablets:

Hydrocortisone Hualan 5 mg tablets are white, oval shaped tablets of about 9.8 – 10.2 mm in length and 4.2 - 4.6 mm in width, engraved “H5” on one side and a score in the middle of the other side. The tablet can be divided into equal doses.

Hydrocortisone Hualan 10 mg tablets:

Hydrocortisone Hualan 10 mg tablets are white oval shaped tablet of about 10.6 – 11.0 mm in length and 6.8 - 7.2 mm in width, engraved “HC10” on one side and a quarter score in the middle of the other side. The tablet can be divided into equal doses.

Hydrocortisone Hualan 15 mg tablets:

Hydrocortisone Hualan 15 mg tablets are white, oval shaped tablets of about 11.3 – 11.7 mm in length and 4.8 – 5.2 mm in width, engraved “HC15” on one side and a score in the middle of the other side. The tablet can be divided into equal doses

Hydrocortisone Hualan 20 mg tablets:

Hydrocortisone Hualan 20 mg tablets are white oval shaped tablet of about 10.6 – 11.00 mm in length and 6.8 - 7.2 mm in width, engraved “HC20” on one side and a score in the middle of the other side. The tablet can be divided into equal doses.

Hydrocortisone Hualan 2.5 mg, 5 mg and 15 mg tablets are available in PVC/aluminium blister packs containing 28, 30, 50, 56, 60, 84, 90, 100 and 112 tablets per carton.

Hydrocortisone Hualan 10 mg and 20 mg tablets are available in PVC/aluminium blister packs containing 28, 30, 50, 56, 60, 84, 90, 100 and 112 tablets per carton and HDPE bottles containing 30, 50, 56, 60, 84, 90 and 100 tablets per bottle.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Hualan Pharmaceuticals Limited 16/17 College Green
Dublin D02 V078
Ireland

Manufacturer:

Elara Pharmservices Europe Limited
239 Blanchardstown Corporate Park, Ballycoolin, Dublin,
D15 KV21, Ireland

Elara Pharmservices Europe Limited
Regus Block 1, Blanchardstown Corporate Park 1,
Ballycoolin Road, Blanchardstown,
Dublin 15, D15 AKK1
Ireland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria: Hydrocortison Hualan 2,5 mg Tabletten
Hydrocortison Hualan 5 mg Tabletten
Hydrocortison Hualan 10 mg Tabletten
Hydrocortison Hualan 15 mg Tabletten
Hydrocortison Hualan 20 mg Tabletten

Ireland: Hydrocortisone Hualan 2.5 mg tablets
Hydrocortisone Hualan 5 mg tablets
Hydrocortisone Hualan 10 mg tablets
Hydrocortisone Hualan 15 mg tablets

Hydrocortisone Hualan 20 mg tablets

Netherland: Hydrocortison Hualan 2,5 mg, tabletten
Hydrocortison Hualan 5 mg, tabletten
Hydrocortison Hualan 10 mg, tabletten
Hydrocortison Hualan 15 mg, tabletten
Hydrocortison Hualan 20 mg, tabletten

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