

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.

What is in this leaflet

1. What Hydrocortisone Hualan is and what it is used for
2. What you need to know before you take Hydrocortisone Hualan
3. How to take Hydrocortisone Hualan
4. Possible side effects
5. How to store Hydrocortisone Hualan
6. Contents of the pack and other information

1. What Hydrocortisone Hualan is and what it is used for

Hydrocortisone Hualan 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 is used when the body is not making enough cortisol, because part of the adrenal gland is not working (adrenal insufficiency).

Hydrocortisone Hualan is for use in adults, children and adolescents (from birth to < 18 years of age).

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

What adrenal 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

Do not take Hydrocortisone Hualan if:

- you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6).

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

Warnings and precautions

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

- you have an adrenal crisis. If you are vomiting or seriously unwell, you may need an injection of hydrocortisone.
- you have short-term or temporary illness such as infections, fever, or situations causing a great amount of physical stress, such as an operation: the dose of hydrocortisone must be temporarily increased. Ask your doctor promptly for information on how you should handle these situations.
- you are due to be vaccinated. Usually, taking Hydrocortisone Tablets should not stop you receiving vaccination.
- you are due for an operation, tell the surgeon or anaesthetist that you are receiving Hydrocortisone Tablets before your operation.
- you experience blurred vision or other visual disturbances.
- you suffer from kidney or liver problems, high blood pressure, diabetes, heart problems, osteoporosis (thinning of the bone) or have an under active thyroid.
- you suffer from glaucoma; regular ophthalmic monitoring (eye tests) is recommended.
- you have pheochromocytoma (a rare tumour of the adrenal glands).
- you have an over-active thyroid gland (hyperthyroidism).

If you have an infection before you start taking this medicine, you should talk to your doctor. The microorganism responsible for the infections should be determined and the infection treated before the administration of this medicine. If you develop any new infections while taking these tablets speak to your doctor who will decide how to continue your treatment.

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using hydrocortisone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis, which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with hydrocortisone. You may need additional treatment to alleviate this condition.

Mental problems while taking Hydrocortisone Hualan

Serious mental health problems can happen while taking steroids like hydrocortisone, which commonly start within a few days or weeks of starting the medicine.

- This is more likely to happen at higher doses
- These usually go away if the dose is lowered or the treatment is stopped.

If mental health problems do happen, they may need treatment. Talk to a doctor 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 and when doses are being lowered or stopped.

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

This medicinal product 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

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 it can affect the way some medicines work. Also, some other medicines can affect the way this medicine works.

If you are taking any of the following medicines, you should talk to your doctor before taking Hydrocortisone Hualan as these may require adjustment in corticosteroid dosage:

- Medicines used to treat epilepsy: phenytoin, carbamazepine and oxcarbazepine.
- Medicines called barbiturates, which can be used to treat convulsions (including phenobarbital and primidone).
- St. John's wort (Herbal medicine used to treat anxiety).
- Medicines used to treat human immunodeficiency virus (HIV) infection and AIDS: efavirenz and nevirapine, ritonavir.
- Medicines used to treat infections (antibiotics): rifampicin and rifabutin.
- Medicines used to treat fungal diseases: ketoconazole, posaconazole, itraconazole and voriconazole.
- Medicines used to treat infections: erythromycin, telithromycin, clarithromycin.

You should also tell your doctor or pharmacist if you are taking:

- Medicines used to thin the blood such as warfarin.
- Water tablets (diuretics).
- Medicines used for pain and inflammation called NSAIDs such as ibuprofen, diclofenac or naproxen.
- Acetylsalicylic acid (aspirin).
- Medicines used to treat diabetes.

If you are taking medicines that can lower your potassium levels (such as diuretics), your risk of developing hypokalaemia (low potassium) will be higher than when taking Hydrocortisone Hualan alone. Your potassium levels will be monitored by your doctor and your doctor will adjust the dose of these medicines accordingly or may prescribe potassium supplements or potassium-sparing diuretics (such as spironolactone).

If Hydrocortisone Hualan is used with mifepristone, a treatment used to end a pregnancy, the effect of Hydrocortisone Hualan may be reduced.

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

Hydrocortisone Hualan with food and drink

Hydrocortisone can be taken with or without food. Some foods and drinks can affect how Hydrocortisone Hualan works, and this may require your doctor to reduce your dose:

- Grapefruit juice
- Liquorice

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

It is important that you continue treatment with Hydrocortisone Hualan during pregnancy. Treatment in pregnant women with adrenal insufficiency is unlikely to cause any harmful effects on the mother and/or the baby. You should tell your doctor if you become pregnant as the dose of Hydrocortisone Hualan may have to be adjusted.

Contact your doctor if you are pregnant and have any of the following symptoms, your doctor will have to monitor your treatment with hydrocortisone:

- fluid retention or

- high blood pressure and protein in urine (pre-eclampsia).

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

This medicine has minor influence on your ability to drive, to perform skilled tasks (e.g., riding bicycle) and 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 and sodium

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.

Sodium: this medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take Hydrocortisone Hualan

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 with a glass of water, preferably in an upright position and on an empty stomach. 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. The daily dose should be split into two to three doses. The first dose in the morning should be higher than the last dose, to simulate the normal diurnal rhythm of cortisol secretion.

If you are unsure about the dose you should take, you must talk to your doctor or pharmacist.

The recommended doses are:

Adults

- 15 to 30 mg a day, divided in 2-3 doses.
- Your doctor may want to prescribe more. The exact dose depends on your condition.

Use in children

- 8-10 mg/m²/day, given as three divided 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 have a score on one side. The tablet can be divided into equal doses.

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 have a score on one side. The tablet can be divided into equal doses.

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').

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 than you should

If you take too many tablets by mistake, contact your doctor as soon as possible. A too high dose of this medicine for more than a few days may be harmful to your health. Your blood pressure may increase, you may gain extra weight and your blood sugar may become too high. An increased dose is necessary occasionally in order for the body to cope with increased stress such as fever. If extra doses are needed frequently and regularly, you should contact your doctor for re-evaluation of your maintenance dose.

If you forget to take Hydrocortisone Hualan

If you forget to take a dose, take the missed dose as soon as you remember and take the next dose at the usual time, even if this means taking two doses at the same time.

If you stop taking Hydrocortisone Hualan

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.

Other side effects:

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

Heart

- thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies.

Mental Health Problems

- feeling high (mania) or moods that go up and down
- having problems sleeping
- feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

Eyes

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

Gastrointestinal problems

- feeling sick (nausea)
- stomach pain (dyspepsia) or stomach inflammation (gastritis)
- worsening of existing ulcers.

Infections

- taking hydrocortisone can make it easier for you to pick up infections which may very rarely be fatal
- tuberculosis, fungal and viral infections may recur.

Bones, muscles and joints

- osteoporosis (thinner or brittle bones with a higher risk of breaking them, especially in older women)
- broken bones or fractures.

Endocrine system

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

Metabolism and nutrition

- sodium and fluid retention
- high blood pressure (hypertension)
- lack of potassium in the body (potassium decrease with hypokalemic alkalosis).

Skin and tissues problems

- development of 'Cushingoid' state (round or moon-shaped face, cheeks and stomach increase in size, limbs become thin with flushed face and increased appetite)
- slow healing of cuts or wounds
- redness
- bruising easily, red or purple spots, acne
- growth of body hair on face and abdomen in women.

Investigations

- weight increased.

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 HPRAs Pharmacovigilance Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Hydrocortisone Hualan

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.

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:

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:

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:

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:

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:

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 Pharmaservices Europe Limited

239 Blanchardstown Corporate Park, Ballycoolin, Dublin,

D15 KV21, Ireland

Elara Pharmaservices 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

Austria/Germany 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

Belgium Hydrocortisone Hualan 2,5 mg comprimés
Hydrocortisone Hualan 5 mg comprimés
Hydrocortisone Hualan 10 mg comprimés

Hydrocortisone Hualan 15 mg comprimés
Hydrocortisone Hualan 20 mg comprimés

Denmark
Cortiren 2,5 mg tablett
Cortiren 5 mg tablett
Cortiren 10 mg tablett
Cortiren 15 mg tablett
Cortiren 2 mg tablett

Finland
Petacort 2.5 mg tablet
Petacort 5 mg tablet
Petacort 10 mg tablet
Petacort 15 mg tablet
Petacort 20 mg tablet

Spain
Hidrocortisona Hualan 2,5 mg comprimidos
Hidrocortisona Hualan 5 mg comprimidos
Hidrocortisona Hualan 10 mg comprimidos
Hidrocortisona Hualan 15 mg comprimidos

Sweden
Cortiren 2,5 mg tablett
Cortiren 5 mg tablett
Cortiren 10 mg tablett
Cortiren 15 mg tablett
Cortiren 2 mg tablett

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