

Package leaflet: Information for the user

Hydrocortone® 10 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 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).

• **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**.

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

1. What Hydrocortone is and what it is used for

Hydrocortisone belongs to a group of medicines called steroids. Their full name is corticosteroids. These corticosteroids occur naturally in the body and help 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.

Hydrocortone is used:

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

Corticosteroid therapy should be used only when simpler proven diagnosis and therapy is not feasible or has failed (unless there is a life-threatening situation).

What is Adrenocortical insufficiency

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 Hydrocortone

Do not take Hydrocortone 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 Warnings and precautions)
- you have tropical worm infections
- you are after vaccination with live attenuated virus (see also 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 think any of these apply to you, do not take the tablets; go and talk to your doctor first and follow the advice given.

Warnings and precautions

Talk to your doctor before taking Hydrocortisone 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, an under active thyroid
- you suffer from glaucoma; regular ophthalmic monitoring 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 Hydrocortone (see also “Mental problems”).
- you are immunocompromised (where your immune system does not work properly)
- if you experience blurred vision or other visual disturbances
- If you have an over-active thyroid gland (hyperthyroidism)

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.

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

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

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 Hydrocortone 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 Hydrocortone.

Surgery

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

Children and adolescents

Hydrocortone 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 bearing 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 Hydrocortone

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of Hydrocortone 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 taking any of the following medicines you should talk to your doctor before taking Hydrocortone:

- 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 Hydrocortone 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.

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

Do NOT take this medicine during pregnancy as hydrocortisone crosses the placenta and may be harmful to the mother, embryo or foetus.

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

Breast-feeding

Do NOT take this medicine during breast-feeding. Corticosteroids appear in breast milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other unwanted effects.

Mothers taking pharmacological doses of corticosteroids should be advised not to breast-feed.

Driving and using machines

There are some side effects with Hydrocortone that may affect your ability to drive or operate machinery. You should take into account the possibility of the occurrence of muscle weakness, muscle atrophy, and mood changes (euphoria, depression) when driving vehicles or operating machinery.

Hydrocortone contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine as lactose may produce symptoms in lactose-intolerant individuals.

3. How to take Hydrocortone

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual adult dose is: 20 to 30 mg a day, sometimes taken together with 4 to 6 g of 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

The dosage should be approximately 0.4 to 0.8 mg/kg given as two or three doses per day, adjusted to the needs of the individual child. Treatment should be limited to the minimum dosage for the shortest possible time.

Take the tablets by mouth exactly as the doctor, pharmacist or medicine label tells you to. Do not take more or less than your doctor has advised.

It is dangerous to reduce the dose of Hydrocortone 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 Hydrocortone tablets gradually if necessary.

If you take more Hydrocortone than you should

If you take too much Hydrocortone by mistake, contact your doctor as soon as possible.

If you forget to take Hydrocortone

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 Hydrocortone

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

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.

Steroids including Hydrocortone 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)

- reduced resistance, which increases the risk of infections (opportunistic), an unfavourable course of infections (sepsis and reactivation of latent tuberculosis and parasitic infections such as amoebiasis and strongyloidiasis). Masking of warning symptoms of sepsis and perforation
- erythrocytosis and granulocytosis, lymphoma and eosinopenia
- hypersensitivity or anaphylactic reactions
- inhibition of hypothalamic-pituitary-adrenal axis function (due to negative feedback by exogenous steroid) with risk of adrenal insufficiency when the patient is exposed to stress (trauma, surgery, infection). Development of Cushing's syndrome
- sodium and fluid retention, potassium decrease with hypokalemic alkalosis
- centripetal obesity (face, trunk) enhanced by increased appetite
- increased intracranial pressure with papilledema (pseudotumor cerebri), particularly in children during or shortly after rapid withdrawal
- insomnia
- eye problems such as posterior subcapsular cataract or glaucoma
- congestive heart failure in predisposed patients
- high blood pressure (hypertension), blood clots (thromboembolism)
- inflammation of the oesophagus (oesophagitis)
- peptic ulcer with increased risk of bleeding and (masked) perforation,
- inflammation of the pancreas (pancreatitis)
- skin atrophy with large bruising ("easy bruising")
- reddening of the face, acne
- excessive hair growth
- impaired wound healing
- suppressed skin reactions to skin tests
- allergic reactions such as rash or hives (urticarial)
- muscle weakness and muscle atrophy (steroid myopathy), risk of osteoporosis with compression fractures of vertebrae, aseptic bone necrosis, especially of the femoral head
- growth retardation in children
- decreased glucose tolerance, resulting in latent diabetes, increased need for oral hypoglycaemic agents or insulin in diabetics
- negative nitrogen balance due to protein degradation
- abnormal menstrual cycle
- blurred vision
- thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies.
- 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 HPRA 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 Hydrocortone

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

Store below 25°C. Store in original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Do not transfer your medicine into another container, as it might get mixed up.

Remember, this medicine is for you. Do not share it with anyone else. It may not suit them.

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 Hydrocortone contains

- The active substance is hydrocortisone. Each tablet contains 10 mg of hydrocortisone.
- The other ingredients are: lactose monohydrate, magnesium stearate and maize starch.

What Hydrocortone looks like and contents of the pack

White, oval-shaped tablets quarter sectioned on one side and imprinted with 'HYD 10' on the other side. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Hydrocortone Tablets are available in blister packs of opaque PVC lidded with aluminium foil containing 30 tablets, presented in an outer carton.

Marketing Authorisation Holder

Teva B.V., Swensweg 5, 2031GA Haarlem, Netherlands.

Manufacturer

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