**Hydrocortisone Powder for Injection Solution 100 mg**

**Hydrocortisone**

**What is Hydrocortisone Powder for Injection**

**and what is it used for?**The active ingredient in hydrocortisone, is a glucocorticoid (a natural hormone) produced in the adrenal cortex in humans. The main effect of hydrocortisone is to suppress inflammatory and immune responses (the body's defense reactions against foreign substances). Additionally, it has effects on sugar and protein metabolism, among other things.

hydrocortisone can be used in combination with another adrenal cortex hormone when your adrenal cortex is not functioning adequately, for example, in Addison's disease or adrenogenital syndrome. It can also be used when the adrenal cortex is not functioning due to another condition.

Furthermore, hydrocortisone can be used briefly when other treatments are ineffective or insufficient:

* In severe exacerbations of asthma, chronic bronchitis, or emphysema;
* In status asthmaticus (a persistent asthma attack);
* In combination with other medications for severe allergic reactions.

**When should you not use this medicine or use it with caution?**

**When should you not use this medicine?**

* If you are allergic to any of the ingredients in this medicine.
* If you have acute viral, fungal, or tropical worm infections. Bacterial infections must be treated before starting hydrocortisone treatment.
* When you have a stomach or intestinal ulcer.
* If you have been vaccinated or need to be with a live or weakened virus, you should not use hydrocortisone in a dosage that weakens your immune system.
* hydrocortisone should not be administered within the membranes of the brain or spinal cord (intrathecally).
* hydrocortisone should not be administered via a spinal tap (epidurally).
* The general conditions for not using adrenal cortex hormones (glucocorticosteroids) and the precautions that apply to the use of systemic glucocorticosteroid therapy also apply to hydrocortisone.

**When should you be extra cautious with this medicine?**Because the risk of side effects increases with higher doses and longer treatment duration when using glucocorticosteroids, the benefits and drawbacks of treatment will be carefully weighed against each other when determining the dosage and treatment duration.

The use of hydrocortisone should not be abruptly discontinued but should be gradually tapered. Contact your doctor or pharmacist before using this medicine.

* Patients who undergo surgery, have an accident, or contract an infection during or after treatment with hydrocortisone may sometimes need rapid-acting glucocorticoids.
* Glucocorticoids can suppress the symptoms of an infection, and new infections may occur during their use because your immunity can decrease. In the case of a bacterial infection, your doctor will first identify the type of bacteria and treat the infection before administering glucocorticoids.
* If you are using medications that suppress the immune system, you may be more susceptible to infections than healthy individuals.
* If you already have a pre-existing risk factor for cardiovascular disease, you may have an increased risk of additional cardiovascular conditions with high doses and long-term use of hydrocortisone. Examples include high blood pressure and an increase and/or decrease in one or more blood lipids (lipids, cholesterol, triglycerides).
* If you suffer from reduced heart pumping capacity (congestive heart failure).
* Hydrocortisone can lead to an increase in your blood pressure due to the retention of salt and fluid. Your doctor may prescribe a low-salt diet with additional potassium for this.
* When you experience septic shock. This is a condition caused by an infection, characterized by a significant drop in blood pressure, pallor, restlessness, a weak rapid pulse, clammy skin, and reduced consciousness. Routine use of hydrocortisone is not recommended in such cases.
* During treatment with a high dose of hydrocortisone, you should not be vaccinated with a live virus vaccine.
* If you have active tuberculosis or are being treated for tuberculosis, your doctor will closely monitor you during treatment with hydrocortisone.
* If you have had hypersensitivity reactions from using medications before treatment, your doctor will take the necessary precautions before starting treatment.
* If you have a herpes eye infection, you should be regularly monitored by an eye doctor during treatment.
* Treatment with corticosteroids can cause retinal detachment and cataracts. Contact your doctor if you experience blurred vision or other visual disturbances.
* During treatment, there may be psychological changes, such as excessive cheerfulness, insomnia, irritability, personality changes, and depression.
* Prolonged use of corticosteroids in high doses has been reported to lead to the accumulation of fat in the spinal canal.
* If you have inflammation in the stomach or intestines, high blood pressure, an active or dormant stomach ulcer, impaired kidney function, a tumor in the adrenal medulla, Kaposi's sarcoma (a specific form of skin cancer), osteoporosis, myasthenia gravis (a specific muscle disease), or suffer from or have an increased risk of thrombosis, your doctor will be extra cautious when prescribing hydrocortisone.
* If you have a liver condition, your doctor may prescribe a lower dosage, as hydrocortisone may have an enhanced effect on you.
* When you have Cushing's disease (a disease caused by an excess of the hormone cortisol in the blood).
* When you have reduced thyroid function (hypothyroidism).
* When you have diabetes.
* When you have a disease accompanied by seizures (e.g., epilepsy).
* When you use certain pain relievers with anti-inflammatory and fever-reducing effects (NSAIDs).
* When you have pancreatitis (inflammation of the pancreas) accompanied by severe pain in the upper abdomen radiating to the back, and nausea and vomiting.
* Children and adolescents up to 18 years
* Long-term treatment with glucocorticoids can lead to growth inhibition in children. Therefore, doctors usually treat children with alternating dosages.
* Babies and children who are treated with corticosteroids for an extended period are at risk of increased pressure within the skull.
* High doses of corticosteroids can cause pancreatitis in children.
* If hydrocortisone is given to a prematurely born baby, monitoring of heart function and structure may be necessary.

**Are you using any other medications?**If you are using other medicines besides hydrocortisone, have done so recently, or may use other medicines in the near future, please tell your doctor or pharmacist. This also applies to medicines for which you do not need a prescription.

You should inform your doctor of any other medication use, such as:

* Isoniazid: used in the treatment of bacterial infections.
* Rifampin: an antibiotic used in the treatment of tuberculosis.
* Medications that counteract blood clotting (oral anticoagulants).
* Barbiturates, carbamazepine, and/or phenytoin used in the treatment of epilepsy.
* Medications used in the treatment of certain diseases of the nervous system (anticholinergics).
* Medications used in the muscle disease myasthenia gravis (anticholinesterases).
* Medications used in the treatment of diabetes (antidiabetics).
* Aprepitant and fosaprepitant: used to prevent nausea and vomiting.
* Itraconazole or ketoconazole: used in the treatment of fungal infections.
* Some medications can enhance the effects of hydrocortisone, and your doctor may want to monitor you closely if you use these medications (including some HIV medications: indinavir, ritonavir, cobicistat).
* Aminoglutethimide and/or cyclophosphamide: used in the treatment of cancer.
* Tacrolimus: a drug used after organ transplantation to prevent rejection.
* Diltiazem: used in the treatment of heart conditions or high blood pressure.
* Digoxin: medications for the heart belonging to the group of cardiac glycosides.
* Estrogens (including oral contraceptives containing estrogens).
* Ciclosporine; used in the treatment of conditions such as severe joint inflammation (rheumatoid arthritis), severe skin conditions accompanied by scaly, dry skin rash (psoriasis), and for the prevention of organ transplant rejection.
* Clarithromycin, erythromycin, and/or troleandomycin: medications used for the prevention/treatment of certain infections.
* Aspirin (acetylsalicylic acid) and/or a certain group of pain relievers with anti-inflammatory and fever-reducing properties (NSAIDs).
* Potassium-lowering agents, such as diuretics.
* What to consider with food and drink?
* Grapefruit juice can alter the effects of hydrocortisone. Always consult your doctor or pharmacist regarding the consumption of grapefruit juice along with this medication.

**Pregnancy, breastfeeding, and fertility**

Are you pregnant, think you might be pregnant, planning to become pregnant, or breastfeeding? Contact your doctor or pharmacist before using this medication.

**Pregnancy:** hydrocortisone can be used in accordance with approved indications. Chronic use of higher doses should be avoided as much as possible.

Breastfeeding Adrenal cortex hormones are excreted in breast milk. Therefore, breastfeeding is discouraged during corticosteroid therapy unless done in consultation with your doctor.

**Fertility:**There is no evidence that corticosteroids disrupt fertility.

**Driving and using machines:** Several potential side effects of hydrocortisone, such as blurred vision, mood changes, muscle weakness, and involuntary muscle contractions, can negatively affect your ability to drive and operate machinery.

hydrocortisone contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per vial or Act-O-Vial, which essentially makes it "sodium-free."

**How to use this medicine?**

hydrocortisone will be administered to you by your doctor or a nurse. It can be given into a vein (with a syringe or infusion) or into a muscle (with a syringe). Different dosing schedules will be applied depending on your response and clinical condition. The duration of treatment will be as short as possible, and the frequency of administration should be minimized.

Your doctor will determine the appropriate dosage for you depending on your illness and situation.

**Have you used too much of this medicine?**

There is no information available about acute overdosage of hydrocortisone. Hydrocortisone is dialyzable, which means that in case of overdose, excess hydrocortisone can be removed from the blood using a dialysis machine. Prolonged, repeated use (daily or multiple times per week) may lead to Cushing's syndrome (including a moon-shaped face).

**Did you forget to use this medicine?**

Your doctor will typically ensure that you receive the next dose on time. Do not take a double dose to make up for a missed dose.

**If you stop using this medicine**

When treatment with hydrocortisone is abruptly discontinued or if you need surgery, have an accident, or contract a severe infection during treatment, your adrenal cortex may function less effectively. This could lead to a recurrence of the symptoms of the disease you are being treated for. Especially in children, epileptic seizures, dizziness, and headaches can occur if treatment is discontinued too rapidly.

Therefore, your doctor will typically taper the hydrocortisone treatment gradually.

If you have any other questions about using this medicine, please contact your doctor or pharmacist.

**Possible side effects**

Like all medicines, this medicine can cause side effects, although not everyone gets them.

The following side effects have been reported at an unknown frequency, meaning that the frequency cannot be determined with the available data:

* hydrocortisone suppresses the symptoms of an inflammatory reaction, which can lead to a poor recognition of infections, activation of dormant infections, and the occurrence of new infections.
* Infection that rarely occurs under normal circumstances (opportunistic infection)
* A form of skin cancer (Kaposi's sarcoma)
* Severe increase in blood pressure due to a tumor of the adrenal medulla (pheochromocytoma)
* More white blood cells in the blood than normal (leukocytosis).
* Severe allergic reaction to certain substances, resulting in a sudden, severe vasodilation (anaphylactic reaction) with a sharp drop in blood pressure, pallor, restlessness, weak rapid pulse, clammy skin, and reduced consciousness.
* Severe drop in blood pressure, pallor, restlessness, weak rapid pulse, clammy skin, and reduced consciousness due to a sudden, severe vasodilation without an existing allergy (anaphylactoid reaction)
* Drug hypersensitivity
* Development of obesity (head, trunk), moon-shaped face, and high blood pressure (Cushing's syndrome)
* Deficiency of one or more hormones produced by the pituitary gland (hypothalamus-pituitary-adrenal axis suppression)
* A syndrome associated with withdrawal symptoms that may occur after discontinuing corticosteroid treatment (steroid withdrawal syndrome)
* Acidification of the blood (metabolic acidosis)
* Retention of sodium salt by the kidney (sodium retention)
* Retention of excess fluid in the body (fluid retention)
* Disruption of lipid metabolism (dyslipidemia)
* Disturbed acid-base balance in the blood due to excessive potassium loss (hypokalemic alkalosis)
* Decreased ability to tolerate glucose (reduced glucose tolerance)
* Disrupted glucose metabolism that may lead to the detection of dormant diabetes or require diabetes patients to use more insulin or other blood sugar-lowering medications
* Increased appetite
* Accumulation of fat tissue in various parts of the body (lipomatosis)
* Mental disorders, such as excessive elation accompanied by high energy (mania), delusions, perceptions of things that are not there (hallucinations), and a severe mental illness (schizophrenia) characterized by a gradual change in personality.
* Mood disorders like depressive mood, extreme feelings of joy (euphoria), emotional instability, drug dependency, suicidal thoughts.
* Mental disorder
* Confusion
* Anxiety
* Personality changes
* Mood swings
* Abnormal behavior
* Insomnia
* Irritability
* Exacerbation of pre-existing psychotic behavior
* Accumulation of fat in the spinal canal (epidural lipomatosis)
* Increased skull pressure
* Increased brain pressure with swollen mucous membranes (benign intracranial hypertension)
* Episode of unconsciousness with muscle spasms (convulsion)
* Memory loss (amnesia)
* Disruption in cognitive functions such as perception, attention, concentration, memory, orientation, language use, and skills (cognitive disorder)
* Dizziness
* Headache
* Disorder of the retina and choroid (chorioretinopathy)
* Blurred vision
* Lens opacity (cataract).
* Increased eye pressure (glaucoma)
* Abnormal protrusion of the eye (exophthalmos)
* Dizziness with balance disturbance (vertigo)
* Heart function may decrease in susceptible patients (congestive heart failure)
* Increased blood clotting (thrombosis)
* Decreased blood pressure (hypotension)
* Increased blood pressure (hypertension)
* Pulmonary embolism
* Gasping for breath (gasping syndrome)
* Hiccup
* Stomach/intestinal ulcers with potential complications such as perforation and bleeding
* Bleeding and injury to the intestinal wall (intestinal perforation)
* Gastric bleeding
* Inflammation of the pancreas with symptoms of severe pain in the upper abdomen radiating to the back, nausea, and vomiting (pancreatitis)
* Esophagus inflammation with or without ulcers (esophagitis)
* Abdominal pain
* Abdominal distension
* Diarrhea
* Fullness or pain in the stomach area, burping, nausea, vomiting, and/or heartburn (dyspepsia)
* Nausea
* Sudden swelling of the skin and mucous membranes (e.g., throat or tongue), resulting in breathing difficulties and/or itching and rash, often as an allergic reaction (angioedema)
* Excessive hair growth in women (hirsutism)
* Small pinpoint bruises under the skin (petechiae)
* Small pinpoint bruises on a mucous membrane (ecchymoses)
* Thin, fragile, and wrinkled skin (skin atrophy)
* Skin redness (erythema)
* Excessive sweating (hyperhidrosis)
* Stretch marks on the skin (striae)
* Skin rash
* Itching (pruritus)
* Skin rash with intense itching and hives (urticaria, hives)
* (Youth) Acne
* Muscle weakness
* Muscle pain (myalgia)
* Muscle disease (myopathy)
* Reduction of muscle tissue due to disuse of the muscle or inability to use a muscle due to a nervous system disease (muscle atrophy)
* Bone decay (osteonecrosis)
* Bone loss (osteoporosis)
* Bone fracture (pathological fracture)
* Joint disease due to a nerve disorder (neuropathic arthropathy)
* Joint pain (arthralgia)
* Growth delay
* Collapsed vertebra (spinal compression fracture)
* Tendon rupture
* Irregular menstruation
* Impaired wound healing
* Accumulation of fluid in the arms and legs (peripheral edema)
* Fatigue
* Feeling generally unwell (malaise)
* Injection site reaction after administration of the injection
* Increased eye pressure
* Impaired ability to process sugars (carbohydrates), leading to an increased need for insulin or another medication to reduce blood sugar levels (impaired carbohydrate tolerance)
* Low potassium levels in the blood, severe cases recognized by muscle cramps or weakness and fatigue (hypokalemia)
* Increased calcium levels in the urine
* Abnormalities in blood tests (elevated alanine aminotransferase, elevated aspartate aminotransferase, elevated blood alkaline phosphatase)
* Increased levels of waste products in the blood due to protein breakdown (elevated blood urea)
* Suppression of the response to skin allergy tests
* Increased weight
* Additional side effects that may occur in children and adolescents up to 18 years old:
* Growth inhibition in children
* Thickening of the heart muscle (hypertrophic cardiomyopathy) in preterm infants (frequency not known).

**How to store this medicine:**

Keep this medicine out of sight and reach of children.

Store below 25°C. Do not store in the freezer. Store in the original packaging.

Do not use this medicine after the expiry date which is stated on the label on the vial and the box after 'EXP:'. The last day of that month is the expiry date. Do not dispose of medicines in the sink or in the toilet, and do not throw them in the trash. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.