

Hydrocortisone Sodium Succinate for Injection USP 100mg, 500mg, 1000mg

Hydrocortisone sodium succinate

Read all of this leaflet carefully before you are given 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 please ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. What Hydrocortisone is and what it is used for

Hydrocortisone 100 mg, powder for solution for injection/infusion contains hydrocortisone as hydrocortisone sodium succinate.

Hydrocortisone belongs to a group of medicines called corticosteroids or steroids. Corticosteroids are produced naturally in your body and are important for many body

functions.

Boosting your body with extra corticosteroid such as Hydrocortisone can help when injected by a doctor or nurse to treat **shock** following surgery, injuries, hypersensitivity (**anaphylactic**) reactions or other stressful conditions. These include inflammatory or allergic conditions affecting the:

- **bowel and gut** e.g. Crohn's disease (inflammation of the gut) or ulcerative colitis (inflammation of the lower bowel)
- **lungs** e.g. bronchial asthma or inflammation caused by breathing in (aspirating) vomit or stomach contents
- **skin** e.g. Stevens-Johnson syndrome (an autoimmune disorder in which an immune system causes the skin to blister and peel), or systemic lupus erythematosus (lupus)

You must talk to a doctor if you do not feel better or if you feel worse or are unsure why you have been given this medicine.

2. What you need to know before you are given Hydrocortisone

Hydrocortisone must not be given if:

- you think you have ever suffered an **allergic reaction**, or any other type of reaction after being given Hydrocortisone, or any other medicine containing a corticosteroid, or any of the ingredients in this medicine (listed in section 6). An allergic reaction may cause a skin rash or reddening, swollen face or lips or shortness of breath.
- you have any **fungal infection** (such as thrush) which is not being treated.
- you have recently had, or are about to have any

vaccination.

See your doctor immediately if you have any of the above.

Warnings and precautions

Talk to your doctor or nurse before you are given this medicine if you have any of the following conditions. Your doctor may also have to monitor your treatment more closely, alter your dose or give you another medicine.

- **Traumatic brain injury or stroke**
- **Chickenpox, measles, shingles** or a **herpes** eye infection. If you think you have been in contact with someone with chickenpox, measles or shingles and you have not already had these illnesses, or if you are unsure if you have had them
- Severe **depression** or **manic depression** (bipolar disorder). This includes having had depression before while taking steroid medicines like Hydrocortisone, or having a family history of these illnesses
- **Diabetes** (or if there is a family history of diabetes)
- **Epilepsy**
- **Glaucoma** (increased pressure in the eye) or if there is a family history of glaucoma.
- You have recently suffered a **heart attack**
 - **Heart problems**, including heart failure or infections
 - **Hypertension** (high blood pressure)
 - **Hypothyroidism** (an under-active thyroid)
 - **Kaposi's sarcoma** (a type of skin cancer)
 - **Kidney** or **liver** disease
 - **Muscle problems** (pain or weakness) have happened while taking steroid medicines in the past

- **Myasthenia gravis** (a condition causing tired and weak muscles)
- **Osteoporosis** (brittle bones)
- **Pheochromocytoma** (a rare tumour of adrenal gland tissue. The adrenal glands are located above the kidneys)
- **Skin abscess**
- **Stomach ulcer** or other serious stomach or intestinal problems
- **Thrombophlebitis** - vein problems due to thrombosis (clots in the veins) resulting in phlebitis (red, swollen and tender veins)
- **Tuberculosis** (TB) or if you have suffered tuberculosis in the past

Caution should be exercised with corticosteroids as they can cause an eye condition (central serous chorioretinopathy) where a collection of fluid forms under the light-sensitive layer of tissue at the back of the inner eye (retina) causing visual impairment and may lead to retinal detachment.

Long term therapy of corticosteroids in high doses can cause an abnormal amount of fat deposition on or outside the lining of the spine (epidural lipomatosis).

Other medicines and Hydrocortisone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should tell your doctor if you are taking any of the following medicines which can affect the way Hydrocortisone or the other medicine works:

- **Acetazolamide** - used to treat glaucoma and epilepsy
- **Aminoglutethimide** – used for treating cancer

- **Anticoagulants** - used to 'thin' the blood such as acenocoumarol, phenindione and warfarin
- **Anticholinesterases** - used to treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine
- **Antibiotics** (such as erythromycin)
- **Aspirin** and non-steroidal anti-inflammatory medicines (also called **NSAIDs**) such as ibuprofen used to treat mild to moderate pain
- **Barbiturates, carbamazepine, phenytoin and primidone** – used to treat epilepsy

- **Carbenoxolone** and **cimetidine** - used for heartburn and acid indigestion
- **Ciclosporin** - used to treat conditions such as severe rheumatoid arthritis, severe psoriasis or following an organ or bone marrow transplant
- **Digoxin** - used for heart failure and/or an irregular heart beat
- **Diltiazem** or **mibefradil** – used for heart problems or high blood pressure
- **Diuretics** – sometimes called water tablets
- **Ketoconazole** or **itraconazole** – used to treat fungal infections
- **Pancuronium** – or other medicines called neuromuscular blocking agents which are used in some surgical procedures
- **Rifampicin** and **rifabutin** – antibiotics used to treat tuberculosis (TB)
- **Vaccines** - tell your doctor or nurse if you have recently had, or are about to have any vaccination. You **should not** have 'live' vaccines while being treated with this

medicine. Other vaccines may be less effective.

If you are taking long term medication(s)

If you are being treated for diabetes, high blood pressure or water retention (oedema), tell your doctor as he/she may need to adjust the dose of the medicines used to treat these conditions.

Before you have any operations, tell your doctor, dentist or anesthetist that you are being treated with this medicine.

If you require a test to be carried out by your doctor or in hospital, it is important that you tell the doctor or nurse that you are being treated with

Hydrocortisone. This medicine can affect the results of some tests.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine, because it could slow the baby's growth. Tell your doctor if you are breast-feeding as small amounts of corticosteroid medicines may get into breast milk.

If you continue breast-feeding while you are being treated with this medicine, your baby will need extra checks to make sure he or she is not being affected by your medicine.

Driving and using machines

The effect of this class of medicines on the ability to drive or use machinery has not been studied. There are undesirable effects observed with the use of this medicine

such as syncope (fainting), vertigo (sensation of rotation or movement of oneself or the surrounding), and convulsions (seizures). If you are affected by any of them, you do not drive nor operate machinery.

Hydrocortisone contains sodium

This medicinal product contains 0.3 mmol (6.2 mg) of sodium per vial of 100 mg hydrocortisone. This means that sodium content has to be taken into consideration by patients on a controlled sodium diet for dose above 370 mg of hydrocortisone.

3. How Hydrocortisone is given to you

Steroid Cards

Remember to always carry a Steroid Treatment Card. Make sure your doctor or pharmacist has filled out the details of your medicine, including the dose and how long you will require steroid treatment.

You should show your steroid card to **anyone** who gives you any medical treatment (such as a doctor, nurse or dentist) while you are receiving this medicine, and for 3 months after your last injection.

If you are admitted to hospital for any reason always tell your doctor or nurse that you are being treated with this medicine. You can also wear a medic-alert bracelet or pendant to let medical staff know that you are treated with a steroid if you have an accident or become unconscious.

The recommended dose

Your doctor will decide on the site of injection, how much of the medicine and how many injections you will receive

depending on the condition being treated and its severity. Your doctor will inject you with the lowest dose for the shortest possible time to get effective relief of your symptoms.

Adults

Hydrocortisone will be given as an injection by your doctor or nurse, either into a vein (intravenous) or into a muscle (intramuscular). Usually the first dose is given into a vein, especially in an emergency.

It will be given slowly over a period of between 1 – 10 minutes. Depending on your condition a repeat dose may be injected at intervals of between 2 to 6 hours. Large doses should normally be used for only two to three days. The medicine is first dissolved in sterile water for injections. If the medicine is to be given by infusion (using a pump or drip) it is then also mixed with another suitable fluid. No other medicines should be mixed with this medicine.

Elderly patients

Treatment will normally be the same as for younger adults. However your doctor may want to see you more frequently to check how you are getting on with this medicine.

Use in children and adolescents

Corticosteroids can affect growth in children so the doctor will prescribe the lowest dose (should not be less than 25 mg a day) that will be effective for your child.

If you are given more Hydrocortisone than you should have

If you think you have been given too many injections of this

medicine please speak to your doctor immediately.

Stopping/reducing the dose of your Hydrocortisone Your doctor will decide when it is time to stop your treatment.

You will need to come off this treatment slowly if you:

- have been given more than 160 mg of corticosteroids, such as Hydrocortisone, for more than 3 weeks,
- have been given high doses of corticosteroids, such as Hydrocortisone, over 32 mg (0.8 ml) daily, even if it was only for 3 weeks or less,
- have already had a course of corticosteroid tablets or injections in the last year,
- already have problems with your adrenal glands (adrenocortical insufficiency) before you started this treatment.

You will need to come off this medicine slowly to avoid **withdrawal symptoms**. These symptoms may include itchy skin, fever, muscle and joint pains, runny nose, sticky eyes, sweating and weight loss.

If your symptoms seem to return or get worse as your dose of this medicine is reduced tell your doctor immediately.

Mental problems while taking Hydrocortisone Mental health problems can happen while taking steroids like Hydrocortisone (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 the problems do

happen they might need treatment.

Talk to a doctor if you (or someone using 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.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor prescribed you this medicine for a condition which if not treated properly could become serious.

In certain medical conditions, medicines like Hydrocortisone (steroids) should not be stopped abruptly. If you suffer from any of the following symptoms seek IMMEDIATE medical attention. Your doctor will then decide whether you should continue receiving this medicine:

- **Allergic reactions**, such as skin rash, swelling of the face or wheezing and difficulty breathing. This type of side effect is rare, but can be serious.
- **Acute pancreatitis**, stomach pain which may spread through to your back, possibly accompanied by vomiting, shock and loss of consciousness.
- **Ulcers or bleeding ulcers**, symptoms of which are severe stomach pain which may go through to the back and could be associated with bleeding from the back passage, black

or bloodstained stools and/ or vomiting blood.

- **Infections.** This medicine can hide or change the signs and symptoms of some infections, or reduce your resistance to the infection, so that they are hard to diagnose at an early stage. Symptoms might include a raised temperature and feeling unwell. Symptoms of a flare up of a previous TB infection could be coughing up blood or pain in the chest. This medicine may also make you more likely to develop a severe infection.
- **Pulmonary embolus** (blood clot in the lung) symptoms include sudden sharp chest pain, breathlessness and coughing up blood.
- **Raised pressure within the skull** of children (pseudotumour cerebri) symptoms of which are headaches with vomiting, lack of energy and drowsiness. This side effect usually occurs after treatment is stopped.
- **Thrombophlebitis** (blood clots or thrombosis in a leg vein), symptoms of which include painful swollen, red and tender veins.

If you experience any of the following side effects, or notice any other unusual effects not mentioned in this leaflet, tell your doctor straight away.

The frequency of the side effects is not known. The frequency cannot not be estimated from the available data.

Blood, heart and circulation

- Problems with the pumping of your heart (heart failure) symptoms of which are swollen ankles, difficulty in breathing and palpitations (awareness of heart beat) or

irregular beating of the heart, irregular or very fast or slow pulse.

- Increased numbers of white blood cells (leucocytosis).

Body water and salts

- Swelling and high blood pressure, caused by increased levels of water and salt content.
- Cramps and spasms, due to the loss of potassium from your body. In rare cases this can lead to congestive heart failure (when the heart cannot pump properly).

Digestive system

- Nausea (feeling sick) or vomiting (being sick).
- Ulcers or thrush in the gullet (discomfort on swallowing).
- Indigestion.
- Bloating stomach.
- Persistent hiccups, especially when high doses are given.

Eyes

- Glaucoma (raised pressure within the eye, causing pain in the eyes and headaches).
- Swollen optic nerve (causing a condition called papilloedema, and which may cause sight disturbance).
- Damage to the optic nerve or cataracts (indicated by failing eyesight).
- Thinning of the clear part at the front of the eye (cornea) or of the white part of the eye (sclera).
- Worsening of viral or fungal eye infections.
- Protruding of the eyeballs (exophthalmos).
- Blurred or double vision.
- Eye condition (central serous chorioretinopathy) where a

collection of fluid forms under the light- sensitive layer of tissue at the back of the inner eye (retina) causing visual impairment and may lead to retinal detachment.

Hormones and metabolic system

- Slowing of normal growth in infants, children and adolescents which may be permanent.
- Irregular or no periods in women.
- Increased hair on the body and face in women (hirsutism).
- Round or moon-shaped face (Cushingoid facies).
- Increased appetite.
- Weight increase.
- Diabetes or worsening of existing diabetes.
- Prolonged therapy can lead to lower levels of some hormones which in turn can cause low blood pressure and dizziness. This effect may persist for months.
- The amount of certain chemicals (enzymes) called alanine transaminase, aspartate transaminase and alkaline phosphatase that help the body digest medicines and other substances may be raised after treatment with a corticosteroid. The change is usually small and the enzyme levels return to normal after your medicine has cleared naturally from your system. You will not notice any symptoms if this happens, but it will show up if you have a blood test.

Immune system

- Increased susceptibility to infections which can hide or change normal reactions to skin tests, such as that for tuberculosis.

Muscles and bones

- Muscle weakness or wasting.
- Brittle bones (bones that break easily).
- Broken bones or fractures.
- Breakdown of bone due to poor circulation of blood, which causes pain in the hip.
- Torn muscle tendons causing pain and/or swelling.
- Muscle cramps or spasms.

Nerves and mood issues

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 taking medicines like Hydrocortisone.

- Feeling depressed, including thinking about suicide.
- Feeling high (mania) or having 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.
- Other nervous system side effects may include breathing problems, convulsions, dizziness, drowsiness, difficulty breathing, sensation of cold, heat or numbness, tinnitus or unconsciousness.
- Abnormal amount of fat deposition on or outside the lining of the spine (epidural lipomatosis).

Skin

- Abscess, especially near injection sites.
- Acne.
- Poor wound healing.



- Thinning of skin with stretch marks.
- Bruising.
- Small purple/red patches on the skin.
- Pale or darker patches on your skin, or raised patches of unusual colour.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hydrocortisone

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 label and carton after EXP. The expiry date refers to the last day of that month.

Once the medicine has been mixed with sterile water for injections the solution should be used straight away. Any unused liquid should be disposed of safely.

Your doctor will check that the solution contains no particles and is not discoloured before using it.

6. Contents of the pack and other information

What Hydrocortisone contains

The active substance is hydrocortisone as hydrocortisone sodium succinate.

The other excipient is sodium hydrogen phosphate buffer.

What Hydrocortisone looks like and contents of the pack

Hydrocortisone is a white to almost white powder for parenteral use stored in colourless glass vials with a rubber closure and an aluminum flip cap with plastic disk.

Hydrocortisone is available in packs containing 10 vials.

7. Manufactured in India by:

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