



Hydrocortisone 100mg/1ml Solution for Injection and Hydrocortisone 500mg/5ml Solution for Injection

Read all of this leaflet carefully before you start taking this medicine. It provides a summary of the information available on your medicine. If you have any questions or are not sure about anything ask your doctor or pharmacist.

The name of your medicine is Hydrocortisone 100mg/1ml Solution for Injection and Hydrocortisone 500mg/5ml Solution for Injection; it will be called Hydrocortisone Injection for ease here after.

- Hydrocortisone Injection is a **steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor.
- You may need to reduce the dose gradually.
- Hydrocortisone Injection **can cause side effects in some people** (read section 4 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 injection, 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 section 4 for more information).
- **If you take this medicine for more than three weeks, you will get a blue 'steroid card':** always keep it with you and show it to any doctor or nurse treating you.
- **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**.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that may be especially important for you.

Hydrocortisone - benefit information

Hydrocortisone 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. 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.

In this leaflet:

1. What Hydrocortisone Injection is and what it is used for
2. Before you are given Hydrocortisone Injection
3. How Hydrocortisone Injection will be given
4. Possible side effects
5. How to store Hydrocortisone Injection
6. Further information

1. WHAT HYDROCORTISONE INJECTION IS AND WHAT IT IS USED FOR.

Hydrocortisone Injection is used to treat swollen, painful joints and tendons in conditions such as, tennis elbow and golfer's elbow.

Hydrocortisone Injection can also be used to treat conditions such as severe asthma, allergic reactions, severe shock due to injury or infection or failure of the adrenal glands.

2. BEFORE YOU ARE GIVEN HYDROCORTISONE INJECTION

Do not receive the injection if:

- You are **allergic** to hydrocortisone or any of the other ingredients of Hydrocortisone Injection (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);
- You just had a **vaccination** or have a vaccination **planned**;
- You have a viral **infection** such as **measles, chickenpox or shingles**, or any other infection. Tell your doctor **immediately** if you have come into contact with anyone suffering with measles, chickenpox or shingles in the last three months.

Take special care if you:

- have or have ever had:
 - **severe depression** or manic-depressive illness (bipolar disorder). This includes having had depression before while taking steroid medicines like hydrocortisone, or if anyone in your family has suffered from these illnesses;
 - TB (tuberculosis);
 - diabetes;
 - epilepsy;
 - an eye disease caused by a rise of pressure within the eye (glaucoma);
 - osteoporosis (thinning of the bones);
 - muscle problems when steroids have been taken before;
 - stomach ulcers;
 - high blood pressure or heart failure;
 - any liver or kidney problems.

If any of the above applies to you, or you are not sure please tell your doctor or pharmacist before you use this medicine.

Contact your doctor if you experience blurred vision or other visual disturbances.

Mental health problems while taking hydrocortisone

Mental health problems can occur while taking steroids like hydrocortisone (see also section 4 Possible Side Effects).

- These illnesses can be severe.
- 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 occur they might need treatment.

Talk to a doctor if you (or someone taking this medicine) show any signs of mental health problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental health problems have happened when doses are being lowered or the medicine stopped altogether.

Taking other medicines

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 Hydrocortisone Injection and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Hydrocortisone Injection and some other medicines can affect the way each other work. In particular, tell your doctor if you are taking any of the following:

- Medicines for **epilepsy** such as carbamazepine, phenobarbital, phenytoin or primidone;
- **Antibiotics** such as rifampicin, rifabutin;
- **Oral contraceptives**;
- Medicines for **diabetes** such as insulin, glibenclamide or metformin;
- Medicines to treat **high blood pressure**, such as diuretics (water tablets) like bendroflumethiazide and furosemide;
- **Warfarin** or other medicines used to thin the blood;
- **Aspirin** or similar medicines;
- Acetazolamide (used to treat glaucoma);
- Carbenoxolone (used to treat stomach ulcers);
- Medicines used to treat myasthenia gravis;
- Orally ingested chemicals used to make x-rays clearer.

Pregnancy and breast-feeding

Tell your doctor before being given this medicine if you are, or think you may be pregnant, or if you are breast-feeding.

Driving and using machinery

This medicine should not affect your ability to drive or use machines.

Carrying a Steroid card

Your doctor or pharmacist will have given you a **Steroid Treatment Card** with your prescription or medicine.

YOU SHOULD ALWAYS CARRY THIS CARD WITH YOU as it must be shown to any of the following persons:

Doctor or Nurse

- before having any surgery or emergency treatment or if any new treatment is prescribed.

Dentist

- before having any dental surgery.

Pharmacist

- before buying any medicine.

Optician

- it is advisable to have regular eye tests.

3. HOW HYDROCORTISONE INJECTION WILL BE GIVEN

Hydrocortisone Injection will be given by a doctor or nurse. Your doctor will decide upon the most suitable dose for your condition. The injection can be given in the following ways:

Adults:

For soft tissue conditions: 100 mg to 200 mg injected into or around the soft tissue daily. This daily dose may be repeated on up to three occasions.

For other conditions: 100 mg to 500 mg injected into a muscle, or injected slowly into a vein over at least 30 seconds (through a 'drip' into the vein), up to four times a day.

Children: 25 mg to 100 mg injected into a vein. This may be repeated up to four times a day depending on the patient response.

If you receive more Hydrocortisone Injection than you should

Overdosing is unlikely. If it does happen the doctor will treat any symptoms that follow.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Hydrocortisone Injection can cause side effects although not everybody gets them.

Steroids including hydrocortisone can cause severe mental health problems.

These are common in both adults and children. They can affect about five 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, having 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 immediately.**

If you notice:

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

Tell your doctor immediately. These may be signs of an allergic reaction.

If you are given the injection into a vein, you may experience a 'pins and needles' type sensation. This reaction is unpleasant but harmless. It can occur in the genital area, or over the whole body.

If this happens, tell your doctor or nurse.

High doses of steroids taken for a long time, or repeated in short courses, can lead to side effects. The doctor will always give you the lowest dose possible to prevent these.

The side effects which can occur if steroids are given in high doses for a long time are:

- generally feeling unwell;
- feeling sick (nausea);
- flushing;
- indigestion;
- stomach ulcer (which can rupture and bleed);
- thrush;
- inflammation of the pancreas causing abdominal pain (pancreatitis);
- muscle weakness;
- thinning of bones which makes fractures more likely (osteoporosis);
- damage to tendons;
- joint stiffness causing limited motion, pain and muscle spasms;
- fluid retention causing swelling;
- feeling dehydrated;
- high blood pressure;
- slow healing of wounds, thinning of the skin, bruising, marks which look like stretch marks and acne;
- small red, purple or blue spots found along the surface of the skin (caused by blood vessels under the skin);
- low adrenal gland function;
- slowed growth in infants, children and teenagers;
- irregular or stopped menstrual periods;

- swollen, round face (Cushingoid faces);
- excess hair growth;
- increased appetite and weight gain;
- intolerance to carbohydrates;
- mood changes, dependence, depression, difficulty sleeping, worsening of schizophrenia;
- worsening of epilepsy;
- raised pressure in the eyes (glaucoma), cataracts, thinning and inflammation of the cornea (part of the eye), worsening of viral or fungal eye diseases, Not known: (frequency cannot be estimated from the available data)- Blurred vision;
- changes in body chemistry;
- an increase in the number of white blood cells;
- formation of blood clots.

Injections like these can make it easier for you to pick up infections. Infections such as chicken-pox and measles can be made worse, or TB (tuberculosis) may recur.

In the **elderly**, the side effects caused by corticosteroids may be more serious. This is especially in cases of osteoporosis (thinning of the bones), high blood pressure, low potassium levels in the blood, diabetes, higher risk of infections and thinning of the skin.

Older people being given Hydrocortisone Injection will be monitored closely by their doctor in order to avoid any serious side effects.

If any of the side effects becomes severe, or if you notice any side effects not listed in this leaflet, please **tell your doctor or pharmacist immediately.**

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. HOW TO STORE HYDROCORTISONE INJECTION

Hydrocortisone Injection ampoules will be stored at the healthcare centre.

They should be stored at room temperature not above 25°C and kept in the carton to protect them from light.

The doctor or nurse will check that the expiry date on the label has not passed before you are given the injection.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN**6. FURTHER INFORMATION****What Hydrocortisone Injection contains**

Each 1 ml Hydrocortisone Injection ampoule contains 100 mg of the active ingredient hydrocortisone (as hydrocortisone sodium phosphate)

Each 5 ml Hydrocortisone Injection ampoule contains 500 mg of the active ingredient hydrocortisone (as hydrocortisone sodium phosphate)

The other ingredients are: disodium edetate, sodium formaldehyde bisulphite monohydrate, disodium hydrogen phosphate anhydrous, sodium acid phosphate, phosphoric acid and water for injections.

What Hydrocortisone Injection looks like and the contents of the pack:

Hydrocortisone Injection is a clear, colourless to pale yellow solution, which is available in 1 ml or 5 ml clear glass ampoules.

It is available in packs containing 5 x 1 ml (100 mg) or 5 x 5 ml (500 mg) ampoules.

Marketing Authorisation Holder and Manufacturer responsible for release:

Amdipharm UK Limited,
Capital House,
85 King William Street,
London EC4N 7BL,
UK

Date of preparation of leaflet: April 2017



AMDIPHARM