

**Package leaflet: Information for the patient**  
**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 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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.

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 reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

**What is in this leaflet:**

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

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

Hydrocortisone Injection contains the active substance hydrocortisone sodium phosphate.

Hydrocortisone Injection is a glucocorticoid used to treat adults and children. This medicine 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.

### **Hydrocortisone Injection - 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 use this medicine regularly to get maximum benefit from it.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN HYDROCORTISONE INJECTION**

Do not receive **Hydrocortisone Injection**:

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

- if you just had a **vaccination** or have a vaccination planned;

- if 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.

**Warnings and precautions** Talk to your doctor, pharmacist or nurse before receiving Hydrocortisone Injection :

- 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; (or a family history of diabetes);

- epilepsy;

- an eye disease caused by a rise of pressure within the eye ( glaucoma, or a family history of glaucoma);

- osteoporosis (thinning of the bones);

- muscle problems when steroids have been taken before;

- stomach ulcers or other digestive problems;

- high blood pressure or heart failure or recently suffered a heart attack

- thyroid problems;

- a stroke or acute head injury;

- herpes infection in the eye called ocular herpes simplex;

- HIV infection;

- cerebral malaria;

- a type of muscle weakening problem called 'myasthenia gravis';

- thrombophlebitis (swelling and redness along a vein which is tender when touched);
- metastatic carcinoma (cancer that has spread from one part of the body to another);
- history of drug allergies;
  
- any liver or kidney problems.

If hydrocortisone is given to a prematurely born baby, monitoring of heart function and structure may be needed.

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

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

You should see your doctor if you develop any new infections whilst using this medication. Using Hydrocortisone for a long period of time increases your chance of getting infections, which might be worse than normal and may very rarely be fatal.

### **Children and adolescents**

If the patient is a child, it is important that the doctor monitors growth and development at intervals during treatment.

### **Elderly**

Hydrocortisone should be used with caution in the elderly as side effects can be heightened in this age group.

If you are using or have recently used (within the last 3 months) Hydrocortisone Injection and you become ill, suffer stress, get injured or are about to have a surgical procedure you must tell your doctor immediately that you are using Hydrocortisone Injection. Your dose of hydrocortisone may need to be increased (or you may have to start using it again for a short time) to prevent a sharp fall in blood pressure.

### **Long term use**

If you have been on Hydrocortisone Injection for longer than 3 weeks and wish to stop using it, do not stop suddenly as this could result in a severe drop in blood pressure which could be fatal. Your doctor will advise on how to reduce the dose you are taking.

It is important to avoid exposure to people who have chickenpox, measles or shingles, especially if you have not already had these illnesses or are not sure if you have had them. Hydrocortisone Injection increases the risk of a severe bout of chickenpox. If exposed you must contact your doctor immediately.

### **Mental health problems while using Hydrocortisone Injection**

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 using 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.

### **Other medicines and Hydrocortisone Injection**

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

- 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.

The effectiveness of Hydrocortisone Injection may be altered if other medicines are being taken at the same time.

In particular, you should not be given this medicine if you are taking any of the following:

- anticoagulants such as warfarin (medicines used to thin the blood);
- salicylates such as aspirin;
- non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, diclofenac or naproxen (medicines used to treat mild to moderate pain);
- medicines for diabetes (including insulin);
- erythromycin, telithromycin or clarithromycin (medicines used to treat bacterial infections);
- an oral contraceptive pill;
- somatropin (a type of growth hormone);
- ritonavir, efavirenz or nevirapine (medicines used in the treatment of HIV infections);
- acetazolamide (a medicine used to treat glaucoma);
- amphotericin, ketoconazole, itraconazole, posaconazole or voriconazole (used to treat fungal infections);
- mifepristone (a medicine used to assist medical termination of pregnancy);
- diuretics (water tablets);
- carbenoxolone (a medicine used to treat ulcers);
- methotrexate (a medicine used to treat rheumatoid arthritis);
- medicines used to treat epilepsy such as phenytoin, phenobarbital, carbamazepine and primidone;
- rifabutin and rifampicin (antibiotics used to treat TB);
- aminoglutethimide (a medicine used in the treatment of cancer);
- cardiac glycosides, such as digoxin (used to treat heart failure and irregular heartbeat);

- theophylline and sympathomimetics such as bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline (used to treat asthma and other breathing problems);
- cough and cold medicines that contain ephedrine (a decongestant);
- calcium supplements;
- St. John's Wort (a herbal medicine used for treating depression);
- sodium phenyl butyrate (a medicine used to treat urea cycle disorders, where you are unable to eliminate nitrogen waste from your body);
- sodium benzoate (a preservative);
- medicines used to treat myasthenia gravis;
- orally ingested chemicals used to make X-rays clearer;
- antihypertensives (medicines used to treat high blood pressure).

### **Test results while using Hydrocortisone Injection**

Hydrocortisone could affect the results of some tests performed by your doctor or in hospital, so tell your doctor or nurse that you are using this medicine before any tests are carried out.

### **Hydrocortisone Injection with food and drink**

Do not use this medicine with grapefruit juice as the juice will conflict with the action of this medicine.

### **Pregnancy, breast-feeding and fertility**

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.

### **Driving and using machines**

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.

**Information about ingredients**

This medicine contains less than 1 mmol sodium (23 mg) per dosage, that is to say essentially 'sodium-free'.

**3. HOW HYDROCORTISONE INJECTION WILL BE GIVEN**

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

Hydrocortisone Injection will be given by a doctor or nurse.

The recommended dose is:

**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 to 1 minute (through a 'drip' into the vein), up to four times a day.

**Use in 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.

**If you stop using Hydrocortisone Injection**

If you have been on hydrocortisone for longer than 3 weeks and wish to stop using it, do not stop suddenly as this could result in a severe drop in blood pressure which could be fatal. Your doctor will advise on how to reduce the dose you are taking.

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.

Steroids including Hydrocortisone Injection 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. Symptoms may include:

- 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.**

Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies (Frequency 'Not known').

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 listed below:

**Not known: frequency cannot be estimated from the available data**

- generally feeling unwell;
  - tiredness
  - feeling sick (nausea);
  - flushing;
  - indigestion;
  - stomach discomfort
  - stomach ulcer (which can rupture and bleed);
  - ulcer in the oesophagus (gullet);
  - thrush;
  - tooth decay;
  - inflammation of the pancreas causing abdominal pain (pancreatitis);
  - muscle weakness or wasting;
  - thinning of bones which makes fractures more likely (osteoporosis);
- broken bones or fractures;
  - hip or shoulder pain due to poor blood circulation;
  - risk of torn tendons;

- joint inflammation in the knee and groin (aseptic necrosis);
  - joint stiffness causing limited motion, pain and muscle spasms;
  - fluid retention causing swelling;
  - feeling dehydrated;
  - high blood pressure;
  - headache;
  - sedation;
  - dizziness/spinning sensation;
  - slow healing of wounds
  - thinning of the skin, bruising, marks which look like stretch marks and acne, redness, increased sweating, itchy rash;
  - small red, purple or blue spots found along the surface of the skin (caused by blood vessels under the skin);
  - low adrenal gland function;
  - irregular or stopped menstrual periods ( in women);
  - change in number and motility of sperm (in men);
  - increased hair on the body and face in women;
  - increase in blood sugar levels/diabetes;
  - breakdown of body protein stores (loss of weight and muscle loss);
  - loss of calcium and nitrogen;
  - salt retention;
  - swollen, round face (Cushingoid faces);
  - excess hair growth;
  - cramps and spasms due to the loss of potassium salts from your body;
  - increased appetite and weight increase ;
  - intolerance to carbohydrates;
  - suppression of reaction to skin tests;
  - decrease in good cholesterol in the blood;
  - mood changes, dependence, depression, difficulty sleeping, worsening of schizophrenia;
  - worsening of epilepsy;
  - severe headaches with blurred vision or temporary visual problems in children (usually after stopping treatment);
  - blurred vision;
  - worsening of sight;
  - bulging eyes;
  - dry eyes;
  - raised pressure in the eyes (glaucoma), cataracts, thinning and inflammation of the cornea (part of the eye), worsening of viral or fungal eye diseases, blurred vision;
  - heart attack;
  - increased damage to the heart in the event of a heart attack;
  - heart failure;
  - changes in body chemistry;
  - an increase in the number of white blood cells;



- formation of blood clots.

#### **Additional side effects in children and adolescents**

- slowed growth in infants, children and teenagers.

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.

Kaposi's sarcoma (a type of cancer) has also been reported to occur in patients receiving corticosteroids. However, once the treatment is stopped, this may go away.

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.

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

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#### **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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

### **5. HOW TO STORE HYDROCORTISONE INJECTION**

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

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.

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

### **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Hydrocortisone Injection contains**

The active substance is hydrocortisone (as hydrocortisone sodium phosphate).

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, , formaldehyde sodium 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**

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