Package leaflet: Information for the patient

Hydrocortisone 100 mg Powder for Solution for Injection or Infusion
hydrocortisone sodium succinate

PFIZER

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 please ask your doctor, nurse or pharmacist.
- 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.

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 or infusion contains 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 if your body cannot produce enough corticosteroid due to problems with your **adrenal glands** (e.g. adrenal insufficiency).

Corticosteroids can also help 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)

Hydrocortisone may be prescribed to treat conditions other than those listed above, such as adrenal insufficiency and other medical emergencies like treatment of shock associated with this.

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

Do not use Hydrocortisone:

- 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 other ingredients of this medicine (listed in section 6). An allergic reaction may cause a skin rash or reddening, swollen face or lips or shortness of breath.
- If you have any **fungal infection** (such as thrush) which is not being treated.
- If 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 taking 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.

- You are suffering from a **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.
- If you suffer from mood swings, sleeplessness and personality changes
- If you are under unusual **stress.**
- If you develop **adrenal insufficiency.**
- **Diabetes** (or if there is a family history of diabetes).
- **Cushing's disease** (a hormone disorder caused by high levels of cortisol in the blood).
- **Epilepsy, fits or seizure**
- **Glaucoma** (increased pressure in the eye) or if there is a family history of glaucoma.
- **Cataract**
- You have recently suffered a **heart attack**.
- **Heart problems**, including heart failure or infections.
- **Hypertension** (high blood pressure).
- **Fluid retention in the body.**
- **Hypothyroidism** (an under-active thyroid).
- **Hyperthyroidism** (an over-active thyroid gland).
- **Pancreatitis** (Inflammation of the pancreas which causes severe pain in the abdomen and back).
- **Peritonitis** (Inflammation of the thin lining (peritoneum) around the gut and stomach).
- **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** (muscle disease with muscle fatigue), or if during treatment you develop muscular disorders.

- **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.

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.

Treatment with this medicine may increase your risk of infection, may mask some signs of infections, make current infections worse, or cause old, hidden infections to come back or get worse. New infections may also appear during the treatment with this medicine. Different infections may therefore occur more easily during the treatment. Please report any signs or symptoms of infection (e.g. raised temperature) to your doctor or nurse. Your doctor will monitor you closely, for the development of infection and consider stopping treatment or reducing the dose as needed.

Tumour lysis syndrome (TLS) can occur after treatment of a fast-growing cancer, such as blood cancers or solid tumours. Symptoms of TLS include muscle cramping, muscle weakness, confusion, irregular heartbeat, visual loss or visual disturbances, and shortness of breath. Your doctor will monitor you closely, especially if you are at high risk of developing tumour lysis syndrome.

Contact your doctor immediately, if you experience any muscle pain, muscle weakness, and /or red-brown change in the colour of your urine as this might be a sign of rhabdomyolysis which is a severe condition involving breakdown of your muscles.

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

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.

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

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).

Tell your doctor if you suspect an infection has occurred, as corticosteroids can make infections more likely and may mask their signs.

This medicine is not recommended for injection via the spinal cord (intrathecal or epidural). Serious side effects have been reported with this use on occasions.

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
- **Oral anticoagulants** of the vitamin K antagonists class – medicines used to prevent blood clotting, such as acenocoumarol, fluindione, phenindione and warfarin
- **Anticholinergics** – medicines such as pancuronium, vecuronium or other muscle relaxants called neuromuscular blocking agents which are used in some surgical procedures
- **Anticholinesterases** - used to treat myasthenia gravis (a muscle condition) such as distigmine and neostigmine
- **Antibiotics** (such as erythromycin, clarithromycin, troleandomycin)
- **Antidiabetics** – medicines used to treat high blood sugar.
- **Antiemetic** – such as **Aprepitant** and **Fosaprepitant** used to prevent nausea and vomiting
- **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 heartbeat
- **Diltiazem** or **mibefradil** – used for heart problems or high blood pressure
- **Diuretics** – sometimes called water tablets
- **Isoniazid** - used to treat bacterial infections.
- **Antivirals** (such as ritonavir, indinavir) and **pharmacokinetic enhancers** (such as cobicistat) used to treat HIV infections.
- **Ethinylestradiol / Norethindrone** - oral contraceptive
- **Oestrogens containing products** - including oral contraceptives
- **Ketoconazole** or **itraconazole** – used to treat fungal infections
- Potassium depleting agents –**amphotericin B, xanthenes or beta$_2$ agonists** (e.g. medicines used to treat asthma).
- **Rifampicin** and **rifabutin** – antibiotics used to treat tuberculosis (TB)
- **Tacrolimus and cyclophosphamide** – used following an organ transplant to prevent rejection of the organ.
- **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 using this medicine. Other vaccines may be less effective.
- **Grapefruit juice.**

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 operation tell your doctor, dentist or anaesthetist that you are taking 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 taking 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 taking this medicine, because it could slow the baby's growth. Corticosteroids can cross the placenta which is a risk associated with low birth weight of the baby.

Cataracts have been observed in infants born to mothers treated with long-term corticosteroids during pregnancy.

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 having treatment, 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 should not drive or operate machinery.

Hydrocortisone contains sodium

This medicine contains 10.1 mg of sodium (main component of cooking/table salt). This is equivalent to 0.5% of the recommended maximum daily dietary intake of sodium for an adult.

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 treatment (such as a doctor, nurse or dentist) while you are taking 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 taking this medicine. You can also wear a medic-alert bracelet or pendant to let medical staff know that you are taking a steroid if you have an accident or become unconscious.

Dosage information
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 mixed with another suitable fluid. No other medicines should be mixed with it.

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

Use in children and adolescents
Corticosteroids can affect growth in children so your 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 hydrocortisone, such as Hydrocortisone 100 mg powder for solution for injection or infusion, for more than 3 weeks,
- have been given high doses of corticosteroids, such as Hydrocortisone 100 mg powder for solution for injection or infusion, 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 will have given 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 taking your 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 heartbeat) or irregular beating of the heart, irregular or very fast or slow pulse.
- Increased numbers of white blood cells (leucocytosis).
- Low blood pressure.
- Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies.

Body water and salts

- Swelling and high blood pressure, caused by increased levels of water and salt content.
- Swelling of the extremities of the body e.g. ankles.
- 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.
- Bloated stomach.
- Abdominal pain.
- Diarrhoea.
- Persistent hiccups, especially when high doses are taken.

Ears

- A feeling of dizziness or spinning (vertigo).

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.

General disorders

- Feeling tired or unwell.
- Skin reactions at the site of injection.

Hormones and metabolic system

- Slowing of normal growth in infants, children and adolescents which may be permanent.
- Irregular or no periods in women.
- Round or moon-shaped face (Cushingoid facies).
- Increased appetite.
- Weight increased.
- 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.
- Blood urea increased.
- The amount of certain chemicals (enzymes) called alanine transaminase, aspartate transaminase and alkaline phosphatase that help the body digest drugs and other substances in your body 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.
- Drug withdrawal syndrome includes symptoms like runny nose, fever, headache, loss of appetite, tiredness, joint pain, peeling of skin, weight loss and low blood pressure.
- Abnormal level of fats e.g. cholesterol in the blood.
- Abnormal fat deposition in the body.

Immune system
- More likely to get infections, which can hide or change normal reactions to skin tests, such as that for tuberculosis.

Muscles and bones
- Aching muscles, muscle tenderness or weakness, not caused by exercise (myopathy).
- Muscle weakness or pain which in some cases can be associated with abnormal breakdown of muscle tissue (rhabdomyolysis).
- Change in urine colour to red-brown (rhabdomyolysis).
- Muscle wasting.
- Brittle bones (bones that break easily).
- Broken bones or fractures.
- Breakdown of bone and joint due to poor circulation of blood, this 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 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, irritability, sensation of cold, heat or numbness, tinnitus or unconsciousness.
- Headache.
- 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.
- Stretch marks (skin striae).
- Bruising.
- Small purple/red patches on the skin.
- Pale or darker patches on your skin, or raised patches which are an unusual colour.
- Excessive growth of bodily and facial hair.
- Rash, itching, hives.
- Increased sweating.

- Inflammation of the fatty tissue under the skin which can make the skin feel hard and possibly develop painful red lumps or patches (panniculitis). Panniculitis may occur following dose reduction or discontinuation of this medicine and has been more frequently reported in children.

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 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

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.
This medicine must be stored below 25°C.
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 sodium succinate (equivalent to 100 mg hydrocortisone).
The other ingredients are sodium biphosphate and sodium phosphate (see section 2 "Hydrocortisone contains sodium").

What Hydrocortisone looks like and contents of the pack
Hydrocortisone is a white freeze dried powder in a clear glass vial fitted with a rubber cap and metal seal.

Hydrocortisone is available in packs containing 1 or 10 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:
Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, UK.

Manufacturer:
Pharmacia NV/SA, Rijksweg 12, B-2870, Puurs, Belgium, and Laboratoires Pharmacia SAS, Parc Industriel d'Incarville, BP 606, 27106 Val De Reuil, Cedex, France

Company contact address:
For further information on your medicine contact Medical Information at the following address:
Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.
Tel: 01304 616161.

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The following information is intended for healthcare professionals only:

Hydrocortisone 100 mg Powder for Solution for Injection or Infusion
hydrocortisone sodium succinate

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For further information, consult the Summary of Product Characteristics (SPC).

Posology and method of administration.
Hydrocortisone may be administered by intravenous injection, by intravenous infusion, or by intramuscular injection, the preferred method for initial emergency use being intravenous injection. Following the initial emergency period, consideration should be given to employing a longer-acting injectable preparation or an oral preparation.

Dosage usually ranges from 100 mg to 500 mg depending on the severity of the condition, administered by intravenous injection over a period of one to ten minutes.
This dose may be repeated at intervals of 2, 4 or 6 hours as indicated by the patient's response and clinical condition.

Dosage requirements are variable and must be individualized on the basis of the disease under treatment, its severity and the response of the patient over the entire duration of treatment. A risk/benefit decision must be made in each individual case on an ongoing basis.

The lowest possible dose of corticosteroid should be used to control the condition under treatment for the minimum period. The proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage, which will maintain an adequate clinical response, is reached.

In general high-dose corticosteroid therapy should be continued only until the patient's condition has stabilised - usually not beyond 48 to 72 hours. If hydrocortisone therapy must be continued beyond 48 to 72 hours hypernatraemia may occur, therefore it may be preferable to replace Hydrocortisone with a corticosteroid such as methylprednisolone sodium succinate as little or no sodium retention occurs. Although adverse effects associated with high dose, short-term corticoid therapy are uncommon, peptic ulceration may occur. Prophylactic antacid therapy may be indicated.

If after long-term therapy the drug is to be stopped, it needs to be withdrawn gradually rather than abruptly (see section 4.4 of the SPC).

Patients subjected to severe stress following corticoid therapy should be observed closely for signs and symptoms of adrenocortical insufficiency.

Corticosteroid therapy is an adjunct to, and not a replacement for, conventional therapy.

In patients with liver disease, there may be an increased effect (see section 4.4 of the SPC) and reduced dosing may be considered.

Elderly patients:
Hydrocortisone is primarily used in acute short-term conditions. There is no information to suggest that a change in dosage is warranted in the elderly. However, treatment of elderly patients should be planned bearing in mind the more serious consequences of the common side effects of corticosteroids in old age and close clinical supervision is required (see section 4.4 of the SPC).

Paediatric population:
While the dose may be reduced for infants and children, it is governed more by the severity of the condition and response of the patient than by age or body weight, but should not be less than 25 mg daily (see section 4.4 of the SPC).

Hypertrophic cardiomyopathy was reported after administration of hydrocortisone to prematurely born infants, therefore appropriate diagnostic evaluation and monitoring of cardiac function and structure should be performed.

This medicine is not recommended for intrathecal or epidural use.

Preparation of solutions:
For intravenous or intramuscular injection prepare the solution aseptically by adding not more than 2 ml of sterile water for injections to the contents of one vial of Hydrocortisone 100 mg, shake and withdraw for use.
For intravenous infusion, first prepare the solution by adding not more than 2 ml of sterile water for injections to the vial; this solution may then be added to 100 ml - 1000 ml (but not less than 100 ml) of 5% dextrose in water (or isotonic saline solution or 5% dextrose in isotonic saline solution if patient is not on sodium restriction).
When reconstituted as directed the pH of the solution will range from 7.0 to 8.0.

Shelf life
The shelf life is printed on labels and cartons. Do not use Hydrocortisone after this date.
After reconstitution with sterile water for injections, use immediately, discard any remainder.

Storage of the product
Store below 25°C.
Refer to Posology and method of administration section above.
Reconstituted solutions should be used immediately. No diluents other than those referred to are recommended. Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration.