

## Package leaflet: Information for the user

### Dexamethasone 3.3 mg/ml Solution for Injection (6.6 mg/2 ml vials)

dexamethasone

- **Dexamethasone 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.
- **Dexamethasone 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 medicine, 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 it for more than 3 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, shingles or measles**, if you have never had them. They could affect you severely. If you do come into contact with chicken pox, shingles, or measles, **see your doctor straight away**.

**Read all of this leaflet carefully before you start using 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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

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

#### 1. What Dexamethasone Solution for Injection is and what it is used for

Dexamethasone belongs to a group of medicines called steroids. Their full name is corticosteroids. Corticosteroids occur naturally in the body, and help to maintain health and well-being.

Boosting your body with extra corticosteroid (such as Dexamethasone) is an effective way to treat various illnesses involving inflammation in the body. Dexamethasone reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

It is used in acute conditions in which oral steroid treatment is not possible, such as:

- Shock (e.g. after an accident, after surgery or due to blood poisoning).
- Swelling of the brain because of a brain tumour.

- Diseases of joints and soft tissues, such as rheumatoid arthritis.
- Allergic reactions.

These conditions often require the use of other medicines in addition to corticosteroids.

## 2. What you need to know before you use Dexamethasone Solution for Injection

### Do not use Dexamethasone Solution for Injection:

- **If you are allergic to dexamethasone** or any of the other ingredients of this medicine including sulfites, (listed in section 6).
- **If you have an infection affecting the whole body** which is not being treated with antibiotics (dexamethasone treatment may still be used if it is considered to be life saving).
- If you have an infection at the injection site, particularly in the joint, where Dexamethasone Solution for Injection will be injected.
- If you have unstable joints (this is a condition where joints, such as knee, can suddenly give way), where Dexamethasone Solution for Injection will be injected.

Tell your doctor or pharmacist if either of the above applies to you before this medicine is used.

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

### Warnings and precautions

Talk to your doctor or pharmacist before using Dexamethasone Solution for Injection

- **If you have ever had severe depression** or manic depression (bipolar disorder). This includes having had depression before while taking steroid medicines like dexamethasone.
- **If any of your close family** has had these illnesses.
- If you have symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath, in case you suffer from haematological malignancy.
- If you have suffered a head injury or stroke.

### Take special care with Dexamethasone Solution for Injection and check with your doctor first if you have:

- A cancer of the blood because you may be at risk of a very rare, potentially life-threatening condition resulting from a sudden breakdown of tumour cells
- Liver, kidney or heart problems
- High blood pressure
- Epilepsy
- A history of migraines
- If you suffer or have suffered from, or have a family history of schizophrenia or psychiatric disorders (especially previous steroid psychosis), affective disorders; depressive, manic-depressive or psychotic illness
- Osteoporosis (thinning of the bones)
- Had tuberculosis in the past
- Had exposure to chicken pox, shingles or measles
- An under-active thyroid
- Had amoebiasis in the past (infection specific to tropical countries which causes diarrhoea)
- A herpes or fungal infection of the eye
- Diabetes (or a family history of diabetes)
- An eye disease called glaucoma (or a family history of glaucoma)
- Stomach ulcers
- Experienced muscle weakness caused by previous steroid treatment.
- Stunted growth

- Been diagnosed with Acute Respiratory Distress Syndrome (ARDS, a serious lung disease) for over 2 weeks
- An inflammation of a tendon or of the fluid-filled sheath that surrounds the tendon

### **Children**

Special care should be taken if Dexamethasone Solution for Injection is to be given to babies or children.

### **Dexamethasone should not be used routinely in pre-term neonates with respiratory problems.**

Thickening of the heart muscle (hypertrophic cardiomyopathy) may develop if dexamethasone is given to a prematurely born baby, monitoring of heart function and structure is needed. The effect is temporary and can reverse on withdrawal of treatment.

Special care will be taken if Dexamethasone Solution for Injection is to be given to elderly patients.

### **Other medicines and Dexamethasone Solution for Injection**

**Tell your doctor or pharmacist if you are taking or have recently taken any other medicines**, including medicines obtained without a prescription.

You should not be vaccinated with a live vaccine while having steroid therapy. **Tell your doctor or pharmacist if you are planning to have a vaccination.**

Special care is needed if you are taking/using other medicines as some could interact with dexamethasone, for example:

- Barbiturates such as phenobarbital (medicines for treating sleep disorders and epilepsy)
- Ephedrine (a medicine that is used as a nasal decongestant or for respiratory conditions)
- Rifampicin and rifabutin (antibiotics that are used for treating tuberculosis)
- Primidone, phenytoin, carbamazepine (medicines to treat epilepsy)
- Aminoglutethimide (an anti-cancer medicine)
- Anticoagulants (medicines used to thin the blood)
- Insulin and other medicines used to treat diabetes
- Salicylates including aspirin
- Phenylbutazone and other non-steroidal anti-inflammatory drugs (medicines for treating pain and inflammation)
- Acetazolamide (a medicine for treatment of the eye disorder glaucoma)
- Diuretics (water tablets)
- Carbenoxolone (a medicine for treating stomach ulcers)
- Digoxin and other medicines which regulate heart beat
- Antihypertensives (medicines used to treat high blood pressure)
- Anticholinesterases (medicines used to treat myasthenia gravis)
- Some medicines may increase the effects of Dexamethasone Phosphate Solution and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

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

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Newborn babies of mothers who received Dexamethasone near the end of pregnancy may have low blood sugar levels after birth.

If you receive dexamethasone often or over a long period of time during pregnancy there may be a risk that the baby's growth slows down. The baby may need careful observation for a short time after being born.

If you are being given dexamethasone for a long time during breast-feeding then the baby's growth may slow down and it may have other side effects (see Section 4 Possible side effects). Your doctor will discuss this with you and decide whether you should receive dexamethasone.

### **Driving and using machines**

Do not drive or use machines if you experience any side effect which may lessen your ability to do so.

### **Information on sodium content and sulfites**

This medicine contains less than 1 mmol sodium (23 mg) per 20 mg dose, that is to say essentially "sodium-free".

This medicine contains an ingredient called sodium sulfite which may rarely cause severe allergy (hypersensitivity) and difficulty breathing.

The vial stopper contains dry natural rubber (a derivative of latex), which may cause severe allergic reactions.

## **3. How to use Dexamethasone Solution For Injection**

This medicine may be given intravenously (injection into a vein), intramuscularly (injection into a muscle) or directly into a joint or soft tissue. This medicine may also be diluted with glucose or sodium chloride solution and given as a slow injection via a drip into a vein (infusion).

This medicine must not be given intrathecally (injection into the spine), as it contains sulfites.

### **Dose**

The dose of medicine given to you will depend on your age and medical condition and will be carefully adjusted by your doctor.

You are unlikely to need Dexamethasone Solution for Injection for more than a week or two, unless you receive it for treatment of arthritic joints when treatment may carry on for longer. If dexamethasone treatment needs to continue you may be given tablets, rather than an injection.

This medicine suppresses your body's natural ability to make its own corticosteroids. As a result, during prolonged treatment, any new illness, trauma or surgical procedure will require a temporary increase in dosage; if corticosteroids have been recently stopped they may need to be started again.

### **Mental problems while taking dexamethasone**

Mental health problems can happen while taking steroids like dexamethasone (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 problems do happen they might need treatment.

Talk to a doctor if you (or someone taking 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 are given too much or too little Dexamethasone Solution for Injection**

This medicine will be given to you by a doctor or nurse. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

#### **When you stop using Dexamethasone Solution for Injection**

Do not stop taking this medicine suddenly as this might be dangerous. Your doctor will tell you how the treatment will be gradually reduced. When treatment is stopped, a “withdrawal syndrome” can happen, which includes fever, muscle pain, joint pain, inflammation of the lining of the nose, eye discomfort (conjunctivitis), painful itchy skin lumps and loss of weight. Stopping too quickly may lead to insufficient adrenal hormones, low blood pressure and death. In children raised pressure in the skull may occur: if they complain of a headache, have a fit or are sick then **tell a doctor immediately**.

In a few cases, mental problems (see section 4 Possible side effects) have happened when doses are being lowered or stopped.

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

#### **4. Possible side effects**

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

##### **If any the following happen, tell your doctor straight away:**

- **Severe allergic reaction** – you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint.
- **Severe infection and/or fever which makes you feel very ill.**
- **Blood clots causing loss of blood supply to a part of the body – these can include conditions such as DVT (Deep vein thrombosis) causing symptoms such as swelling of the leg; Pulmonary embolism (causing shortness of breath and chest pain).**

These are very serious side effects. You may need urgent medical attention. All of these very serious side effects are rare.

##### **Serious effects: tell a doctor straight away**

Steroids including dexamethasone 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 dexamethasone.

- 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.

If you notice any of these problems **talk to a doctor straight away**.

Carers of patients taking/using dexamethasone should talk to the doctor straight away if the patient shows any signs of mental problems. This is particularly important if the patient appears to be depressed, or mentions thoughts of suicide.

##### **If any of the following happen, tell your doctor as soon as possible:**

- Fits
- Epilepsy or schizophrenia made worse
- Breathlessness
- Severe thirst or passing urine more than usual (may indicate raised blood sugar levels)

- Water retention (swelling) and high blood pressure
- Lowered response to stress (such as surgery or trauma) showing as weakness, fatigue, muscle pain, light-headedness
- Muscle weakness, wasting and pain
- Breakdown of weight-bearing joints (Charcot-like arthropathy)
- You feel that you or your surroundings are spinning
- Eye disorders including cataracts and glaucoma, infections of the eye may become worse
- Blindness associated with injecting the product directly into lesions around the face and neck
- Swelling of the face and body and weight gain, excess body hair
- Osteoporosis (thinning of the bones) – the doctor may ask you to have a bone scan to check for this
- Increased likelihood of bone fractures
- Tendon rupture
- Slow growth in children or teenagers (the doctor will check for this)
- You feel you are picking up minor infections too easily and mild infections may be more severe with the symptoms being less obvious
- Recurrence of previous tuberculosis
- Yeast infections
- Irregular periods or absence of periods in women
- Burning or tingling sensation around genitals and anus (after large doses)
- Indigestion, stomach ulcers, ulcers in the food pipe and pain in stomach and back
- Skin disorders such as thinning of the skin, slow healing of wounds, increased bruising, broken veins or stretch marks on the skin, increased sweating, rashes, or changes in skin pigmentation, raised itchy coloured lumps on the skin, itchy red rash with flaky white patches (thrush), acne, abscesses that are not due to infection
- Reduced reaction to skin tests
- Increased pressure in the brain with specific eye signs (papilloedema) in children
- Headache
- Pain, redness or swelling at the injection site (if the injection is into a joint)
- Increased appetite
- Visual disturbance, blurred vision and loss of vision may occur, but the frequency is not known

Tests may also show

- increased loss of potassium, calcium and nitrogen
- high blood sugar
- increased white blood cell counts

Dexamethasone can also cause side effects when you stop using it. See section 3, “When you stop using Dexamethasone Solution for Injection”.

Many of the above side effects only occur after high dose treatment or if treatment continues for a long period of time.

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

Frequency 'Not known': Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies, that generally returns to normal after stopping treatment (see section 2).

#### **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 Dexamethasone Solution For Injection**

Keep out of the sight and reach of children.

### **Expiry**

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

### **Storage**

Do not store above 25°C. Keep the vials in the outer carton, in order to protect from light. Do not freeze.

Unused portions of opened vials must not be stored for later use.

Prepared infusions should be used immediately, however, if this is not possible they can be stored for up to 24 hours in a refrigerator.

### **Visible signs of deterioration**

Do not use this medicine if you notice any particulates in the solution. Only clear, particle free solutions should be used.

### **Disposal**

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Dexamethasone Solution for Injection contains**

The active substance is dexamethasone. Each millilitre (ml) of solution contains 3.3 milligrams (mg) of dexamethasone (as sodium phosphate) which is equivalent to 4 mg dexamethasone phosphate or 4.3 mg dexamethasone sodium phosphate.

The other ingredients are sodium citrate, disodium edetate, sodium sulfite (E221), sodium hydroxide, hydrochloric acid and water for injections (see section 2 'Information on sodium content and sulfites').

### **What Dexamethasone Solution for Injection looks like and contents of the pack**

This medicine is presented in glass containers called vials. Each 2 ml of solution contains 6.6 mg of dexamethasone (as sodium phosphate) which is equivalent to 8 mg dexamethasone phosphate or 8.6 mg dexamethasone sodium phosphate. It is available in packs containing 5 vials.

### **Marketing Authorisation Holder and Manufacturer**

Hospira UK Limited, Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom.

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## **Dexamethasone 3.3 mg/ml Solution for Injection**

### **The following information is intended for medical or healthcare professionals only**

Dexamethasone Solution for Injection is for intravenous, intramuscular, intraarticular and intralesional use.

Dexamethasone Solution for Injection is not for intrathecal use as it contains sulfites.

The intravenous and intramuscular route of administration of dexamethasone should only be used where acute illness or life-threatening situations exist. Oral therapy should be substituted as soon as possible.

Each 2 ml of the solution for injection contains 6.6 mg dexamethasone (as sodium phosphate) which is equivalent to 8 mg dexamethasone phosphate or 8.6 mg dexamethasone sodium phosphate.

### **Incompatibilities**

Dexamethasone (as sodium phosphate) is physically incompatible with daunorubicin, doxorubicin and vancomycin and should not be admixed with solutions containing these drugs. It is also incompatible with doxapram hydrochloride and glycopyrrolate in a syringe.

### **Instructions for use and handling**

When dexamethasone (as sodium phosphate) is given by intravenous infusion only Sodium Chloride Injection BP or Glucose Injection BP should be used as diluents. The exact concentration of dexamethasone (as sodium phosphate) per infusion container should be determined by the desired dose, patient fluid intake and drip rate required.

The product should only be used when the solution is clear and particle free.

For single use only. Discard any unused contents.

### **In-use storage precautions**

From a microbiological point of view, the product should be used immediately after dilution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would not normally be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.

The vial stopper contains dry natural rubber (a derivative of latex), which may cause severe allergic reactions.