

Dexamethasone 3.3 mg/ml Injection
Dexamethasone 6.6 mg/ml Injection
Dexamethasone 8.3 mg/ml Injection

Important information about this medicine

- Your doctor or nurse will give you the injection
- If this injection causes you any problems talk to your doctor, nurse or pharmacist
- Please tell your doctor or pharmacist, if you have any other medical conditions or have an allergy to any of the ingredients of this medicine
- Please tell your doctor or pharmacist, if you are taking any other medicines

- **Dexamethasone is a steroid medicine**, prescribed for many different conditions, including serious illnesses.
- **You need to receive it regularly** to get the maximum benefit.
- **Don't stop 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 receiving 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 receive 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 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 the leaflet. It includes other important information on the safe and effective use of this medicine that might especially be important for you. **This leaflet was last updated on 03/05/2011.**

Dexamethasone – benefit information

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

- **Read all of this leaflet carefully** before you start using this medicine. In some circumstances **this may not be possible** and this leaflet will be kept in a safe place should you wish to read it.
- **Keep this leaflet.** You may need to read it again.
- If you have any further questions, please **ask your doctor or your pharmacist**.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

The name of your medicine is Dexamethasone 3.3 mg/ml Injection, Dexamethasone 6.6 mg/ml Injection and Dexamethasone 8.3 mg/ml Injection, which will be referred to as Dexamethasone Injection throughout this leaflet

Where to find information in this leaflet

1. What Dexamethasone Injection is and what it is used for
2. Before you are given Dexamethasone Injection
3. How to use Dexamethasone Injection
4. Possible side effects
5. Storing Dexamethasone Injection
6. Further information

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

Dexamethasone belongs to a group of medicines called **steroids**.

Dexamethasone is given by injection to patients unable to take a tablet form of the medicine. When given into a vein or muscle, dexamethasone reduces inflammation and suppresses the immune system and is used normally for patients with:

- severe **allergic** reactions causing swelling of the face and throat, low blood pressure and collapse (angioneurotic oedema and anaphylaxis)
- **shock** caused by infection or severe tuberculosis (also with anti-infective treatments e.g. antibiotics)
- raised **pressure** in the skull caused by tumours or infantile spasms
- Sometimes, the injection is given into the **painful area itself** e.g. inflammation of the joints (rheumatoid arthritis and osteoarthritis)

2. Before you are given Dexamethasone Injection

You should NOT be given Dexamethasone Injection if you:

- are **sensitive** or **allergic** to Dexamethasone or any of the other ingredients in this injection.
- have a **fungal** infection that has spread to involve the **whole** body.
- have any other **widespread infection** which is not currently being treated.
- are to be **vaccinated** with live virus vaccines.

Please tell your doctor or nurse before being given the 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.
- **any of your close family** has had these illnesses. If either of these applies to you, **talk to a doctor before receiving dexamethasone**.

Mental health 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 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 **stopped**.

You should avoid any exposure to infectious diseases. **If you do not have a definite history of chickenpox, you must avoid any contact with chickenpox** (herpes simplex), **shingles** (herpes zoster) or **measles**. This precaution applies also if your child is the patient treated with this medicine. If you think you may have been exposed to these, please seek advice from a doctor **immediately** as the consequences can be serious (the steroids can stop your body defending itself against these diseases which can become severe and widespread). If you develop these infections you will need immediate treatment in hospital.

Corticosteroids may mask some signs of infection and new infections may appear during their use. Your doctors will try to use the smallest dose necessary to help you. However there may be times when an increase in dose will be needed. Any reduction in dose will need to be made more slowly than an increase. Your doctor will explain this to you and will probably give you a **"steroid treatment card"** to show to other doctors while you need to take steroids (injected by mouth). Steroid treatment cards are also available from your pharmacist.

Very occasionally your body might give you **"withdrawal effects"** after taking steroids or during dose reduction, including fever, tiredness and aches and pains in muscles and joints. You should tell your doctor if you develop such symptoms even though there may be other causes for these symptoms.

Corticosteroids can lead to **raised blood pressure**, ankle **swelling** (by retention of salt) and a loss of potassium in your water. Your doctor will monitor your condition and treat these if they arise. Steroids are also used cautiously, even if necessary, if a patient taking them has a heart attack.

Corticosteroids effects can be greater in patients with hypothyroidism (when the **thyroid** gland doesn't make enough thyroid hormone) or

cirrhosis (a serious scarring of the **liver**) and your doctor may need to adjust the dose.

You should also tell the doctor if you:

- suffer from **heart failure** or have had a recent **heart attack**
- suffer from **high blood pressure**
- suffer from **kidney** or **liver** problems
- suffer from **diabetes** or a relative has diabetes
- suffer from or have had a **stomach** or **duodenal ulcer**
- suffer from **osteoporosis** (thinning and weakness of the bone)
- have suffered from **muscle weakness** with this or other steroids in the past
- suffer from **myasthenia gravis** (a disease causing weak muscles)
- suffer from an **eye** infection with the **herpes** virus
- suffer from **glaucoma** (increased pressure within the eye) or a relative has glaucoma
- suffer from **epilepsy**
- suffer from **schizophrenia**
- have previously had **tuberculosis**
- have previously had amoebiasis (an infection which is specific to tropical countries and causes diarrhoea)

If **high doses** of this medicine are administered, you may be advised to reduce salt intake and to take extra potassium in the form of tablets.

Dexamethasone Injection contains 1.8 mmol (or 42 mg) **sodium** per maximum single dose of the medicinal product (420 mg for a person with 70 kg bodyweight).

To be taken into consideration by patients on a controlled sodium diet.

In the case of **local injection** of Dexamethasone Injection (e.g. injection into a joint), your doctor will take special care to reduce the particular risk of bacterial infection. This medicine should **not** be injected directly into an infected site. Please tell your doctor if you suffer from complications like a marked increase in pain accompanied by local swelling, further restriction of joint motion, fever or malaise after a local injection of this medicine. Your doctor will have to check if you suffer from blood poisoning and take the appropriate action.

Injection into unstable joints should be avoided.

Please be advised **not to over-use joints** that are still diseased, **even if you do not suffer pain!**

All patients taking steroid drugs for more than a few days should carry **"steroid treatment" cards**, which are available from your doctor or pharmacist. These cards carry details of your medicine and your doctor. If you have an accident, fall ill, require any surgery (including at the dentist's) or are to have any vaccinations (especially with so-called "live virus vaccines") during or after treatment with Dexamethasone Injection you must tell the doctor treating you that **you are taking or have taken steroids**.

Children

If the patient is a child, the doctor will monitor growth and development at intervals during treatment because this medicine can cause growth retardation. Treatment will be limited, where possible, to a single dose on alternate days.

Using other medicines:

Please tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. This is especially important with the following medicines as they may interact with your Dexamethasone Injection:

- aspirin or similar medicines
- phenytoin (used to treat epilepsy)
- barbiturates (sedative drugs used to treat sleeplessness and epilepsy)
- ephedrine (for nose decongestion)
- antibiotics called rifampicin and rifabutin (used to treat tuberculosis)
- carbamazepine (used to treat epilepsy, pain and manic depression)
- aminoglutethimide (an anticancer medicine)
- anticoagulant medicines which thin the blood e.g. warfarin
- medicines for diabetes
- certain diuretics (water tablets)

Because of the interactions with these drugs, your doctor might have to adjust the dosage of the medication given to you.

If you are receiving certain anticoagulants at the same time, your doctor will frequently check your blood clotting, in order to reduce the chance of bleeding.

Pregnancy or breast feeding:

Please tell your **doctor or nurse** before being given this injection if you are **pregnant** or **breast feeding**. The doctor will then decide if the injection is suitable for you.

When dexamethasone is administered for prolonged periods or repeatedly during pregnancy, there may be an increased risk for growth retardation in the unborn child.

If you are taking high doses of this medicine for prolonged periods and you are breast-feeding, your infant may take up dexamethasone through the breast milk. Your doctor will monitor this.

Driving and using machines:

You should **not drive or use machinery** if you are **affected** by the administration of Dexamethasone Injection.

3. How to use Dexamethasone Injection

Your nurse or doctor will give you the injection.

Your doctor will decide the **correct dosage** for you and **how and when** the injection will be given.

Since the injection will be given to you by a doctor or nurse, it is **unlikely** that you will be given too much or that you will miss a dose. If you think you have been **given too much** or that you have **missed a dose**, please contact your doctor immediately.

Effects when treatment with Dexamethasone Injection is stopped:

It can be **dangerous** to have your treatment with Dexamethasone Injection **stopped abruptly**. After prolonged therapy your body may have gotten used to the administration of this medicine and may have reduced the normal production of hormones like the one contained in this medicine. How your treatment is stopped will depend on the disease you are being treated for and how much Dexamethasone Injection you have been given.

It **may** be necessary to **reduce** the amount of Dexamethasone Injection you are given **gradually** until you stop having it altogether.

Your doctor has to make sure that the disease you have been treated for is unlikely to relapse. Dosage reduction must be **adjusted** if you are subjected to unusual **stress** (e.g. another illness, trauma or surgical procedures).

When the treatment is stopped too quickly, withdrawal symptoms like fever, muscle pain, joint pain and tiredness may occur. Too rapid a reduction following prolonged treatment can lead to insufficiency of hormone production in the adrenal gland and low blood pressure (symptoms of which can be tiredness, dizziness, headache, palpitation). In extreme cases this may be fatal.

In a few cases, **mental health problems** have occurred when doses are being lowered or stopped – see section 4 below.

Therefore, if you suffer from any withdrawal symptoms, please tell your doctor as soon as possible!

4. Possible side effects

Like all medicines, Dexamethasone Injection can cause side effects, although not everybody gets them. Some side effects can happen straight away while others may take weeks or months.

If you feel unwell in any way, keep receiving your medicine, but **see your doctor straight away**

If you experience any of the following please contact your doctor **immediately** as you may need **urgent medical attention!**

- An **allergic reaction** which may include a sudden itchy **rash**, swelling of the extremities (such as your hands and feet) and a swelling of your mouth and throat (which may cause difficulty in breathing)
- If you experience sudden and (in cases of long-term therapy) unusual effects like a feeling you are going to faint, bleeding, extreme weakness, or a sudden pain in any of your organs,

The following unwanted side effects have been reported for Dexamethasone Injection and are listed below according to the organs that are affected.

Psychiatric disorders (mental health problems)

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 receiving Dexamethasone Injection should talk to a doctor **immediately** if the patient shows any signs of **mental health problems**. This is particularly important if the patient appears to be depressed, or mentions thoughts of suicide.

If you suffer from **schizophrenia** or **epilepsy** your symptoms may worsen.

Infections and infestations

You may experience more frequent and severe infections without noticing the symptoms as well as **opportunistic** infections (caused by a usually harmless microorganism in case of an impaired immune system) or the **recurrence** of dormant tuberculosis.

Abnormal growth of tissue

You may develop sterile abscesses (enclosed collections of pus, likely to turn into hard solid **lumps** as they scar).

Blood systems

There may be an abnormal **increase** in the number of white blood cells.

Hormonal (endocrine disorders)

Menstrual irregularities, lack of menstruation, abnormal **hair** growth, development of **Cushingoid** state (symptoms of which include central obesity with thin arms, thinning of the skin with easy bruising, muscle wasting and weakness, high blood pressure, uncontrolled blood sugar, osteoporosis).

Children and adolescents may have **suppressed growth**. Your **response** to **stress** caused by trauma, surgery or illness may be reduced. You may also experience decreased carbohydrate tolerance, onset of latent **diabetes** mellitus, increased need for insulin or other medicines if you are diabetic.

Metabolism and nutrition disorders

You may notice that you gain **weight** or have an increased **appetite**. Your body may also have difficulty in handling nitrogen, calcium, sodium or potassium appropriately.

Nervous system disorders

You may feel increased **pressure** in your **head** with impaired vision, **vertigo**, headache or in preterm infants cerebral palsy (malformation of the brain) may occur.

Eye disorders

You may develop **cataracts** or feel increased **pressure** in the eye or notice abnormal bulging out of the eyeballs or thinning of the cornea or the white, outer coat of the eyeball. Your vision may become **blurred** due to congestion of the optic disc or glaucoma with possible damage to the optic nerves. Secondary eye **infections** due to fungi or viruses can occur as can rare instances of **blindness** associated with **local therapy** around the face and head. Premature babies may suffer **retinopathy**.

Disorders of the blood vessels or heart

High blood pressure, blood **clots** in the veins. Susceptible patients may develop heart **failure**, or the heart tissue may **rupture** following a recent heart attack. In infants with a low birth weight a heart muscle disease (hypertrophic **cardiomyopathy**) may occur.

Disorders of the stomach or the digestive system

You may suffer **nausea**, **hiccups**, **heartburn** or **reflux** or infection or inflammation of the tube that leads to your stomach. Peptic **ulcer** may occur with possible **bleeding** or **perforation** of the small and large bowel (particularly if you have inflammatory bowel disease). Your pancreas may become inflamed (**pancreatitis**) or your stomach may swell.

Skin disorders

Your skin may become **thin** or fragile with red or blood **spots** or bruising or it may become **lighter** or **darker** (hypo- or hyperpigmentation). Your face may become unusually red or you may have **acne**, swelling around the eyes, mouth and hands, hives, allergic **dermatitis** or **stretch** marks. Wounds may take **longer to heal**, skin tests may be affected and you may **sweat** more. After injection into a vein you may feel a burning or tingling sensation especially in the perineal area (skin between anus and genital organs).

Muscle and bone disorders

You may suffer muscle **weakness**, loss of muscle mass, **osteoporosis** (loss of bone density) especially if you are postmenopausal, vertebral compression **fractures** (collapsing of a bone in the spine), aseptic necrosis of femoral and humeral heads (severe knee and hip **joint** problem, possibly requiring replacement joints), fracture of long bones, tendon rupture, post-injection flare (following local injection e.g. into a joint).

Reproductive system

The number and activity of **spermatozoa** may be affected in men.

General disorders

You may have a general ill feeling.

Many of these side effects are serious therefore please tell your doctor about your symptoms as soon as possible.

Please note that it is very important that you do **not** suddenly stop taking this medicine (even if you are suffering from a side effect) unless your doctor tells you to (see **“Effects when treatment with Dexamethasone Injection is stopped”** in the previous section of this leaflet).

If you think this injection is causing you **any problems**, or you are at all worried, **talk to your doctor, nurse or pharmacist**.

5. Storing Dexamethasone Injection

Store below 25°C. Do not freeze.

Keep the container in the outer carton, in order to protect from light.

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

On the label you will find the letters “exp. date” followed by some numbers. These numbers are the date when the medicine is no longer fit for use. Do not use this medicine after this date.

6. Further information

What Dexamethasone Injection contains:

This injection contains the **active ingredient** dexamethasone sodium phosphate.

Dexamethasone 3.3 mg/ml Injection

Each ml of solution for injection contains 4 mg of dexamethasone phosphate (as dexamethasone sodium phosphate) equivalent to 3.3 mg of dexamethasone.

Dexamethasone 6.6 mg/ml Injection

Each ml of solution for injection contains 8 mg of dexamethasone phosphate (as dexamethasone sodium phosphate) equivalent to 6.6 mg of dexamethasone.

Dexamethasone 8.3 mg/ml Injection

Each ml of solution for injection contains 10 mg of dexamethasone phosphate (as dexamethasone sodium phosphate) equivalent to 8.3 mg of dexamethasone.

This injection contains the following **inactive ingredients**: propylene glycol, disodium edetate, sodium hydroxide and water for injections.

What Dexamethasone Injection looks like and contents of the pack:

Dexamethasone Injection is a clear, colourless and sterile solution contained in clear glass ampoules.

Dexamethasone 3.3 mg/ml Injection is available in packs of 1, 5 and 10 ampoules, each ampoule containing **1 ml** or **2 ml** solution.

Dexamethasone 6.6 mg/ml Injection is available in packs of 1, 5 and 10 ampoules, each ampoule containing **5 ml** solution.

Dexamethasone 8.3 mg/ml Injection is available in packs of 1 and 5 ampoules, each ampoule containing **10 ml** solution.

Not all pack sizes may be marketed.

The marketing authorisation numbers of these medicine are

Dexamethasone 3.3 mg/ml Injection:
PL 01502/0079

Dexamethasone 6.6 mg/ml Injection:
PL 01502/0080

Dexamethasone 8.3 mg/ml Injection:
PL 01502/0081

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For any information about this medicine, please contact the marketing authorisation holder

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