

Package leaflet: Information for the user

Dexamethasone Phosphate 4 mg/ml Solution for Injection

dexamethasone phosphate

- **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 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**.

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

- 1. What Dexamethasone Phosphate Solution for Injection is and what it is used for**

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

Dexamethasone phosphate is a steroid which is used to:

- treat acute adrenocortical insufficiency and other conditions that respond to steroid therapy
- treat shock caused by excessive bleeding, serious injury, before and after surgery
- treat allergic conditions which occur suddenly, such as swelling of the face, neck and throat and acute deterioration of long term conditions such as bronchial asthma or serum sickness
- treat inflammation of the joints e.g. rheumatoid arthritis

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

Do not use this product

if you have any of the following conditions:

- if you are allergic to dexamethasone phosphate or any of the other ingredients of this medicine (listed in section 6)
- infection affecting the whole body (unless you are taking appropriate antibiotics)
- infection at the injection site, particularly in the joint where dexamethasone phosphate will be injected (unless you are taking the appropriate antibiotic)
- unstable joints (this is a condition where joints, such as knee, can suddenly give way), where Dexamethasone Solution for Injection will be injected
- stomach ulcer
- active tuberculosis
- acute psychosis (a form of mental condition)
- you have a severe allergy to sulfites

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

Check with your doctor first

- **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 either of these applies to you, **talk to a doctor before taking dexamethasone.**

Warnings and precautions

Talk to your doctor before taking Dexamethasone Phosphate Solution for Injection

- 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 suffer from or have suffered from head injury or stroke
- if you suffer from or have suffered from heart problems, kidney problems, liver problems, high blood pressure, epilepsy or migraine
- if you have a stomach ulcer
- if you suffer from osteoporosis (post-menopausal women are at particular risk)
- if you have low output from the thyroid (hypothyroid)
- if you have had tuberculosis in the past
- if you suffer from a specific infection called amoebiasis
- if you have a herpes infection of the eye
- 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
- if you have diabetes or a family history of diabetes
- if you suffer from glaucoma or have a family history of glaucoma (increased pressure in the eye)
- if you suffer from muscle weakness caused by steroids
- if you have measles
- in premature babies
- in children
- if you are elderly
- if you take a repeat course, or have taken a recent or current course of corticosteroids, or take repeat evening doses
- if you have adrenocortical insufficiency
- if you are taking high doses of corticosteroids (more than 6 mg per day)
- if you have had exposure to chicken pox, varicella virus or measles
- if you have an illness, suffered trauma or have had surgery whilst taking this product as you might have false negative lab test results for bacterial infection when taking this product as severe infections may be masked
- if you suffer from Cushing's syndrome
- if you have stunted growth
- if you have an inflammation of a tendon or of the fluid-filled sheath that surrounds the tendon
- if you have been diagnosed with Acute Respiratory Distress Syndrome (ARDS, a serious lung disease) for over 2 weeks
- if you have or are suspected of having pheochromocytoma (a tumour of the adrenal glands).

Treatment with this medicine may cause pheochromocytoma crisis, which can be fatal. Pheochromocytoma is a rare tumor of the adrenal glands. Crisis can occur with following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience these signs.

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.

Children

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

Dexamethasone should not be used routinely in preterm 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.

The lowest effective dose of corticosteroid should be used to control the condition under treatment for the minimum period.

Other medicines and Dexamethasone Phosphate Solution for Injection

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

In particular the following may affect the use of dexamethasone phosphate:

- barbiturates (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 used in the treatment of TB)
- carbamazepine, phenytoin or primidone (drugs used in the treatment of epilepsy)
- aminoglutethimide (anti-cancer medicine)
- drugs used to thin the blood (anti-coagulants) – your prothrombin time may need to be monitored more frequently
- drugs used to treat diabetes (hypoglycaemic agents and insulin)
- salicylates, including aspirin
- phenylbutazone, non-steroidal anti-inflammatory drugs (pain-killers)
- some water tablets (diuretics)
- carbenoxolone (medicine for treating stomach ulcers)
- specific heart drugs such as cardiac glycosides (e.g. digoxin)
- medicines used to treat high blood pressure (antihypertensives)
- vaccinations – some vaccines (live vaccines) should not be used and the response to other vaccines may be altered

- acetazolamide (medicine used to treat glaucoma)
- anticholinesterases (medicines used in the treatment of 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 may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should only be given dexamethasone phosphate if your doctor thinks it is essential, as it may cause birth or growth defects and hormonal problems in the baby, especially if given in high doses for a long time. Newborn babies of mothers who received Dexamethasone near the end of pregnancy may have low blood sugar levels after birth.

Driving and using machines

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

Dexamethasone Phosphate Solution for Injection contains sodium and sulfites

This medicinal product contains less than 1 mmol sodium (23 mg) per 2 ml, that is to say essentially 'sodium-free'.

Sodium sulfite may rarely cause severe hypersensitivity reactions and bronchospasm.

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

3. How to use Dexamethasone Phosphate Solution for Injection

Dexamethasone phosphate may be given into a vein (iv), a muscle (im), or into an affected joint or soft tissue (tendon sheath or ganglion).

The usual iv or im dose is between 0.5 and 24 mg daily but the dose used will usually depend on how serious your condition is, your body weight and your response to the treatment.

If the injection is being given into a joint or soft tissue, the dose will vary between 0.4 and 6 mg and may be repeated every 3 to 5 days for soft tissues or every 2 to 3 weeks for joints.

As this medicine will be given to you by a healthcare professional, it is unlikely that you will be given too little or too much; however, tell your doctor or pharmacist if you have any concerns.

Your doctor will monitor the dose frequently to make sure you are getting the correct dose for your condition. The treatment should not be stopped suddenly without your doctor telling you to do so.

If you receive dexamethasone phosphate injection into a joint or soft tissue, your doctor will advise you to not overuse the joint. The inflammation in the joint may still be present even though the pain in the joint may be reduced.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The severity and significance of the side effects vary with the dose and the length of time the drug was used.

If any of the following happen, tell the doctor immediately:

- severe allergic reaction (hypersensitivity) - 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
- glaucoma. If you have any severe eye pain, especially if it occurs with vomiting, or seeing haloes around lights, obtain medical attention at once.

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**.

High doses of dexamethasone phosphate are intended for short term therapy and therefore adverse reactions are uncommon.

Visual disturbance, blurred vision and loss of vision may occur, but the frequency is not known.

However, stomach ulceration (abdominal pain) and severe breathlessness may occur even with use over a short time.

Joint problems such as pain, inflammation and infection may occur where the dexamethasone phosphate injection has been made into a joint.

Be careful not to overuse your joints if you have been given dexamethasone phosphate to relieve symptoms in them, as the inflammatory process that causes the pain may still be there.

Prolonged use of this product may cause:

- Influence on hormones (hypothalamic-pituitary-adrenal axis) may cause:
 - lowered response to stress (such as surgery or trauma) showing as weakness, fatigue, muscle pain, light-headedness
 - sodium and water retention
 - increased blood pressure
 - increased loss of potassium, calcium and protein
 - muscle cramps which may be due to low potassium and changed blood acidity
 - increased sweating
 - increased appetite and weight gain
 - high blood sugar with increased need for anti-diabetic drugs
 - changes in facial appearance (moon face due to Cushing-like condition)
 - excessive body hair growth
 - irregularity in the menstrual cycle (periods) or complete absence of periods
- Eye problems including cataracts, eye infections and glaucoma
- Blindness associated with injecting the product directly into lesions around the face and neck
- Muscular weakness, wasting and pain, brittleness of bones (osteoporosis and osteonecrosis) which may increase likelihood of breaks or fractures
- Tendon rupture
- Increased chance of picking up infections and mild infections may be more severe with the symptoms being less obvious
- Recurrence of previous tuberculosis (TB)
- The long bones in children may not grow fully if the drug is used for a long time so that growth in infants, children and adolescents may be reduced
- Stomach ulcers which may perforate or bleed - tell your doctor if you begin to notice heartburn or stomach pains
- Ulcers of the food-pipe (oesophageal ulcerations)
- Sudden or gradual pain in the upper middle or upper left part of the abdomen (pancreatitis)
- Pain in the upper abdomen, bloating and feeling full (dyspepsia)
- White spots (yeast infections) in the mouth or throat
- Thinning of the skin and increased bruising
- The skin may appear lighter or darker
- Wounds may heal more slowly and red marks may appear on the skin
- Burning, tingling, itching, acne and yeast infections (candidiasis or thrush) of the skin may occur
- Burning or tingling sensation around the genitals and anus
- Allergic dermatitis
- Reduced reaction to skin tests and vaccinations
- Increased pressure in the brain with specific eye signs (papilloedema) in children

- Abscesses that are not due to infection
- Charcot-like arthropathy (breakdown of weight-bearing joints)
- Blood clots that may be local or spread
- Swelling caused by fluid under the skin (oedema)
- Mental disturbances, schizophrenia may get worse, psychological dependence, euphoria, depression, insomnia, headache, convulsions (epilepsy may get worse) and vertigo may happen after stopping treatment

Tests may also show increased white blood cell counts.

If you or your carer notices any worrying psychological symptoms develop such as feeling depressed or suicidal, please tell your doctor immediately.

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).

Withdrawal

Suddenly stopping treatment (withdrawal) after prolonged treatment (greater than three weeks) or large doses can have very serious consequences. The symptoms that you may get with 'withdrawal syndrome' are fever, muscle aches, joint pains, runny nose, red eyes, painful itchy skin lumps, and weight loss. Stopping too quickly may lead to insufficient adrenal hormones, low blood pressure and death.

Psychiatric reactions may occur on withdrawal of corticosteroids, including affective disorders (such as being irritable, euphoric, depressed, having severe mood swings or suicidal thoughts), psychotic reactions (including being manic, having delusions or hallucinations and aggravation of schizophrenia), changes in behaviour, feeling irritable or anxious, having disturbed sleep, feeling confused or having amnesia.

If you or your carer notices any psychiatric reactions that may occur either during or immediately after reducing the amount, or stopping treatment of steroids, please tell your doctor.

Reporting of side effects

If you get any of the 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 HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexamethasone Phosphate Solution for Injection

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

Do not store above 25°C.

Do not freeze.

Keep vial in outer carton in order to protect from light.

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.

Do not use this product if you notice visible signs of deterioration. Only use the injection if it is clear and free from visible particles.

Do not store opened vials. Discard unused product immediately. When diluted, use the bags immediately or store in the fridge at 2-8°C for no longer than 24 hours from the time of preparation.

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

6. Contents of the pack and other information

What Dexamethasone Phosphate Solution for Injection contains

- The active substance is dexamethasone phosphate. Each ml of solution contains 3.32 mg of dexamethasone (as sodium phosphate) which is equivalent to 4.00 mg dexamethasone phosphate or 4.37 mg dexamethasone sodium phosphate. Each 2 ml of solution contains 6.64 mg of dexamethasone (as sodium phosphate) which is equivalent to 8.00 mg dexamethasone phosphate or 8.74 mg dexamethasone sodium phosphate.
- The other ingredients are sodium citrate, disodium edetate, sodium sulfite anhydrous (E221), sodium hydroxide, hydrochloric acid and water for injections (see section 2 ‘Dexamethasone contains sodium and sulfites’).

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

Dexamethasone Phosphate Solution for Injection is a clear, colourless solution presented in amber glass vials with a chlorobutyl-based stopper containing 2 ml of solution (5 vials per pack).

Marketing Authorisation Holder

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