

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Dexamethasone Phosphate 4 mg/ml Solution for Injection or Infusion

Important information about this medicine

- **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: Possible side effects). 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).
- **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 this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you. **This leaflet was last updated in March 2022.**

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, pharmacist or nurse
- 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 Dexamethasone is and what it is used for
2. What you need to know before you are given Dexamethasone
3. How you are given Dexamethasone
4. Possible side effects
5. How to store Dexamethasone
6. Contents of the pack and other information

1. WHAT DEXAMETHASONE IS AND WHAT IT IS USED FOR

The name of your medicine is Dexamethasone Phosphate 4 mg/ml Solution for Injection or Infusion (called 'Dexamethasone' in this leaflet). It belongs to a group of medicines called corticosteroids. Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone). Corticosteroids are hormones that are found naturally in your body that help to keep you

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

Dexamethasone can be used to:

- Reduce inflammation
- Treat a number of different diseases of the immune system

Dexamethasone is used as a treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) with difficulty breathing and need of oxygen therapy.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN DEXAMETHASONE

You should NOT be given Dexamethasone if:

- You are allergic (hypersensitive) to dexamethasone or any other ingredients in this medicine (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- You have an infection that affects the whole body
- You have an infection of a joint
- You have unstable joints. This is a condition where joints, such as the knee, can suddenly give way.
- You have stomach ulcer
- You have active tuberculosis
- You have acute psychosis (a form of mental condition)

If any of the above apply to you, **talk to your doctor, pharmacist or nurse before being given Dexamethasone.**

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

- Any of your close family has had these illnesses

If either of these applies to you, **talk to your doctor, pharmacist or nurse before being given Dexamethasone.**

Mental problems while having Dexamethasone

Mental health problems can happen while having 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 may be 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.

Take special care with Dexamethasone

Before you are given Dexamethasone, tell your doctor 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
- You have kidney or liver problems
- You have high blood pressure or heart disease
- You have diabetes or there is a family history of diabetes
- You have thinning of the bones (osteoporosis), particularly if you are a female who has been through the menopause
- You have had muscle weakness with this or other steroids in the past
- You have raised eye pressure (glaucoma) or there is a family history of glaucoma
- You have a stomach (peptic) ulcer
- You have mental problems or you have had a mental illness which was made worse by this type of medicine such as 'steroid psychosis'
- You have epilepsy
- You have migraines
- You have an infection with parasites
- You have tuberculosis (TB)
- You have stunted growth
- You have 'Cushing's syndrome'
- You have had a head injury
- You have had a stroke
- 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 tumour of the adrenal glands. Crisis can occur with following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience these signs.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before having Dexamethasone.

More important information about having this kind of medicine

If you develop an infection while you are having this medicine, you should talk to your doctor. Please tell any doctor, dentist or person who may be giving you treatment that you are currently taking steroids or have taken them in the past.

Do not use Dexamethasone for the treatment of Acute Respiratory Distress Syndrome (ARDS; a serious lung disease) if you have been diagnosed with this condition for over 2 weeks.

Dexamethasone and viral infections

While you are having this kind of medicine, you should not come into contact with anyone who has chicken pox, shingles or measles if you have not had these illnesses. This is because you may need specialist treatment if you get these diseases. If you think you may have had exposure to any of these diseases, you should talk to your doctor **straight away**. You should also tell your doctor if you have ever had infectious diseases such as measles or chicken pox and if you have had any vaccinations for these conditions in the past.

Please tell a doctor or anyone giving you treatment, such as at a hospital, if:

- You have an accident
- You are ill
- You need any surgery. This includes any surgery you may have at your dentist's
- You need to have a vaccination

If any of the above apply to you, you should tell your doctor or the person treating you even if you have stopped having this medicine.

If a child is having this medicine, it is important that the doctor monitors their growth and development regularly. Dexamethasone should not be routinely given to premature babies with respiratory problems.

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 have low output from the thyroid (hypothyroid)
- if you suffer from a specific infection called amoebiasis
- if you have a herpes infection of the eye
- 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 have an inflammation of a tendon or of the fluid-filled sheath that surrounds the tendon

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

- Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
- Some medicines may increase the effects of Dexamethasone and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Other medicines can affect the way Dexamethasone works or Dexamethasone can affect the way they work. In particular:

- Medicines to treat heart and blood problems, such as warfarin, high blood pressure medicine, water tablets (diuretics) and specific heart drugs such as cardiac glycosides (e.g. digoxin).
- Antibiotics such as rifampicin and rifabutin
- Medicines to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone and primidone
- Medicines that control pain or lower inflammation, such as aspirin or phenylbutazone
- Medicines used to treat diabetes
- Medicines used to lower potassium levels
- Medicines used to treat myasthenia
- Anti-cancer treatments, such as aminoglutethimide
- Ephedrine used to relieve symptoms of a blocked nose
- Acetazolamide used for glaucoma
- Carbenoxolone sometimes used for ulcers
- salicylates, including aspirin
- vaccinations – some vaccines (live vaccines) should not be used and the response to other vaccines may be altered

You should not stop taking any other steroid medications unless your doctor has instructed you to do.

Talk to your doctor, pharmacist or nurse before you are given Dexamethasone.

General precautions regarding steroid use in specific diseases, masking infection, and use with other medicines remain in line with current recommendations.

Pregnancy and breast-feeding

Talk to your doctor before having this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

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

Driving and using machines

Dexamethasone is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients

This medicine contains less than 1 mmol sodium per ampoule (less than 23 mg per ampoule), i.e. it is essentially sodium free.

3. HOW YOU ARE GIVEN DEXAMETHASONE

Dexamethasone is normally given by a doctor. It will be given as an injection into a muscle or under your skin. It can also be given as an injection into a vein. The dose depends on your illness and how bad it is. The dose in adults is normally from 0.5 to 24 mg daily, and in children 0.2 to 0.4 mg/kg daily. Your doctor will decide the dose.

For the treatment of COVID-19

Adult patients are recommended to be given 6 mg once a day for up to 10 days.

Use in adolescents

Paediatric patients (adolescents of 12 years of age or older) are recommended to be given 6 mg once a day for up to 10 days.

If you are given more Dexamethasone than you should

If you think you have been given too much Dexamethasone, tell your doctor straight away. The following effects may happen:

- Swelling of the throat
- Skin reaction
- Difficulty breathing

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dexamethasone can cause side effects, although not everybody gets them. Dexamethasone can also cause side effects when you stop using it.

- See Section 3, 'If you stop having Dexamethasone'

Serious side 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. These include:

- 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 that do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone
- Visual disturbances, blurred vision, loss of vision may occur, but the frequency is no known

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

If you have an allergic reaction to Dexamethasone see a doctor straight away

An allergic reaction may include:

- Any kind of skin rash or itching of the skin
- Difficulty in breathing or collapse.

If you get any of the following side effects see your doctor as soon as possible:

- **Stomach and gut problems:** stomach ulcers which may perforate or bleed, indigestion, having more of an appetite than usual, feeling or being sick. Ulcers of the food-pipe (oesophageal ulcerations). Pain in the upper abdomen, bloating and feeling full (dyspepsia).
- **Inflamed pancreas:** this may cause severe pain in the back or tummy. Sudden or gradual pain in the upper middle or upper left part of the abdomen (pancreatitis).
- **Problems with salts in your blood** such as too much sodium or low potassium or calcium. You may have water retention. Swelling caused by fluid under the skin (oedema).
- **Problems with sugar in your blood:** an excess of sugar (hyperglycaemia).
- **Heart and blood problems:** high blood pressure, blood clots.
- **Bone problems:** thinning of the bones (osteoporosis and osteonecrosis) with an increased risk of fractures, bone disease, damaged tendons or tendon rupture, damage to the joint where the injection was given. Charcot-like arthropathy (breakdown of weight-bearing joints). Muscular weakness wasting and pain.
- **Recurring infections** that get worse each time such as chicken pox. White spots (yeast infections) in the mouth or throat. Burning, tingling, itching, acne and yeast infections (candidiasis or thrush) of the skin may occur.
- **Skin problems:** wounds that heal more slowly, bruising, acne, sweating more than usual. Burning, redness and swelling where the injection was given. This does not last long. Burning or tingling sensation around the genitals and anus. Allergic dermatitis. Abscesses that are not due to infection.
- **Eye problems:** increased pressure in the eye including glaucoma, eye disorders such as cataracts, eye infections. Blindness associated with injecting the product directly into lesions around the face and neck
- **Hormone problems:** irregular or missing periods, stunted growth in children and teenagers, swelling of the face (called a 'Cushingoid' or 'moon' face), it may affect your diabetes and you may notice you start needing higher doses of the medicine you take for diabetes, your body may not be able to respond normally to severe stress such as accidents, surgery or illness, growth of extra body hair (particularly in women), increased appetite or weight gain
- **Nervous system problems:** fits or epilepsy may become worse, severe unusual headache with visual problems, being unable to sleep, feeling depressed, extreme mood swings, schizophrenia has become worse, headache or problems with your vision (including eye pain or swelling)

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). Increased pressure in the brain with specific eye signs (papilloedema) in children.

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 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

- Keep this medicine out of sight and reach of children
- Do not store above 25°C
- Do not refrigerate or freeze
- Store in the original package in order to protect from light
- Do not use this medicine after the expiry date which is stated on the carton and ampoule after “Exp.”. The expiry date refers to the last day of that month
- Do not use this medicine if you notice damages to the glass ampoule
- Do not throw away any medicine via wastewater or household waste. 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 contains

- The active ingredient is dexamethasone sodium phosphate. Each ml contains 4 mg dexamethasone phosphate (as sodium phosphate) which is equivalent to 3.3 mg dexamethasone and to 4.37 mg dexamethasone sodium phosphate. Each 2 ml contains 8 mg

dexamethasone phosphate (as sodium phosphate) which is equivalent to 6.6 mg dexamethasone and to 8.74 mg dexamethasone sodium phosphate.

- The other ingredients are creatinine, ascorbic acid (E300), water for injection, sodium hydroxide (E524), sodium citrate (E331).

What Dexamethasone looks like and contents of the pack

Dexamethasone is a clear, colourless to slightly yellowish liquid. It comes in 1 ml ampoules in packs of 5 or 10, and in 2 ml ampoules in packs of 5.

The Marketing authorisation holder is:

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

The Manufacturer is:

Biologici Italia Laboratories S.r.l., Via F. Serpero 2, I-20060 Masate (Milano), Italy.

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INFORMATION FOR HEALTHCARE PROFESSIONALS

The following information is intended for medical or healthcare professionals only

Dexamethasone Phosphate 4 mg/ml Solution for Injection or Infusion may be administered intravenously, subcutaneously, intramuscularly, by local injection or as a rectal drip.

Dexamethasone is a clear, colourless to slightly yellowish liquid. The change of appearance of the solution from clear to yellowish is not a sign of deterioration of the product.

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

Dexamethasone can be diluted with the following infusion fluids:

sodium chloride 0.9%

anhydrous glucose 5%

invert sugar 10%

sorbitol 5%

ringer's solution

ringer-lactate

dextran 40 10% w/v

Using these infusion fluids, Dexamethasone Injection can also be injected into the infusion line without causing precipitation of the ingredients. Direct injection into the infusion line is also possible with mannitol 10%.

For single use only.

Discard any unused contents. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

In-use storage precautions

Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature and in daylight conditions when diluted with the above infusion fluids.

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 normally not be longer than 24 hours at 2-8°C, unless dilution has taken place in controlled and validated aseptic conditions.