Package leaflet: Information for the patient

Dexamethasone phosphate 4 mg/ml solution for injection

Dexamethasone phosphate

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.

The name of your medicine is Dexamethasone phosphate 4 mg/ml solution for injection, which will be referred to as Dexamethasone Injection throughout this leaflet.

What is in this leaflet

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

Dexamethasone Injection is a synthetic glucocorticoid (adrenocortical hormone) with an effect on metabolism, electrolyte balance, and tissue functions.

Dexamethasone Injection is used to treat diseases that require treatment with glucocorticoids. Depending on their nature and severity these include:

Via systemic use

- Brain swelling, caused by brain tumour, neurosurgical operations, brain abscess, bacterial meningitis.
- Shock following severe injuries, to prevent acute respiratory distress syndrome (ARDS).
- 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 in breathing and need of oxygen therapy.
- Severe acute asthma attack.
- Initial treatment of extensive acute severe skin diseases, such as erythroderma, pemphigus vulgaris, acute eczema.
- Systemic rheumatic diseases (rheumatic diseases that can affect internal organs), such as systemic lupus erythematosus.
- Active rheumatic joint diseases (rheumatoid arthritis) which is severe and progressive, e.g. forms that rapidly lead to destruction of joints and/or if tissue outside the joints is affected.
- Severe infectious diseases with states similar to poisoning (e.g. tuberculosis, typhus; only in addition to corresponding therapy to treat infection).
- Prevention and treatment of vomiting after operations or in case of cytostatic treatment.
- Supportive treatment of malignant tumours as dexamethasone can sometimes be given by injection or infusion into your vein or under the skin (subcutaneously) to relieve certain symptoms including pain, tiredness, weight loss and feeling and being sick.

Via local use

- Injection into joints: persistent inflammation in one or a few joints after general treatment of chronic inflammatory joint diseases, activated arthrosis, acute forms of humeroscapular periarthritis.
- Infiltration therapy (when strictly indicated): non-bacterial tendovaginitis and bursitis, periarthropathia, insertional tendinopathy.

2. What you need to know before you are given Dexamethasone Injection

Dexamethasone Injection must not be given:

- If you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6).

In individual cases, when Dexamethasone Injection is used, severe hypersensitivity reactions (anaphylactic reactions) have been observed, with circulatory failure, heart attack, cardiac arrhythmias, breathlessness (bronchospasms), and/or a fall or rise in blood pressure.

Injections into a joint may not be given if you have any of the following conditions:

- Infections within, or in an area close, to the joint being treated
- Bacterial joint infections
- Unstable joint
- Bleeding disorders (spontaneous or caused by anticoagulants)
- Calcifications near joints
- Avascular bone necrosis
- Tendon rupture
- Charcot joint

Local infiltration therapy should not be undertaken without prior additional anti-infective treatment when there is an infection in the area where dexamethasone would be administered.

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

Warnings and precautions
Talk to your doctor, pharmacist or nurse before being given the medicine.

If, during treatment with Dexamethasone Injection, particular physical stress situations occur (accident, operation, birth, etc.), a temporary increase in dose can be required.

Dexamethasone Injection can mask the signs of an infection and thus hamper the attempt to identify an existing or developing infection. Latent infections can be reactivated.

General precautions regarding steroid use in specific diseases, masking infection, concomitant medicines etc. in line with current recommendations.

Treatment with Dexamethasone Injection should be considered only if this is absolutely necessary with other medicines taken at the same time, targeting the pathogens causing the following disease:

- Acute viral infections (hepatitis B, chickenpox, shingles, *Herpes simplex* infections, inflammations of the cornea caused by *Herpes* viruses)
- HBsAg-positive chronic active hepatitis (infectious liver disease)
- Approximately 8 weeks before and up to 2 weeks after immunisations with a live vaccine
- Acute and chronic bacterial infections
- Systemic fungal infections
- Certain diseases caused by parasites (amoebas, worm infections). In patients with suspected or confirmed threadworm infection (*Strongyloides*), Dexamethasone Injection can lead to activation and large-scale multiplying of the parasites
- Poliomyelitis
- Lymph node disease after tuberculosis immunisation
- Tuberculosis in the medical history

Treatment with Dexamethasone Injection should be specifically monitored in patients with pre-existing medical conditions requiring treatment such as:

- Gastrointestinal ulcers
- Bone thinning (osteoporosis)
- Poorly controlled high blood pressure
- Poorly controlled diabetes mellitus
- Mental illnesses (including in the medical history), including suicide risk. Neurological or psychiatric monitoring is recommended.
- Increased intraocular pressure (narrow-angle and wide-angle glaucoma). Ophthalmological monitoring and accompanying therapy are recommended.
- Injuries and ulcers of the cornea. Ophthalmological monitoring and concomitant therapy are recommended.

If blurred vision or other visual disturbances occur, contact your doctor.

Due to the risk of perforation of the intestinal wall, Dexamethasone Injection may be used only if there are compelling medical reasons and with corresponding monitoring:

- Severe inflammation of the colon (ulcerative colitis) with a risk of perforation, with abscesses, or with purulent inflammations, possibly also without peritonitis
- Inflamed intestinal pouches (diverticulitis)
- After certain intestinal operations (enteroanastomoses) immediately after the operation.

The signs of peritonitis after perforation of a gastrointestinal ulcer can be absent in patients receiving high doses of glucocorticoids.

In patients with diabetes mellitus, the glucose level in blood must be checked regularly as an increased need for medicines used to treat diabetes mellitus (insulin, oral antidiabetics) must be taken into account.

Patients with severe high blood pressure and/or severe heart failure must be monitored carefully, as there is a risk of deterioration.

A fall in heart rate can occur when high doses are administered.

Severe anaphylactic reactions (overreaction of the immune system) can occur.

The risk of tendon-related symptoms, tendonitis, and tendon ruptures is increased when fluoroquinolones (certain antibiotics) and Dexamethasone Injection are administered together.

In the treatment of a certain form of muscular paralysis (*myasthenia gravis*), a deterioration in symptoms can occur at the start.

Immunisations with vaccines from dead pathogens (inactivated vaccines) can be undertaken in principle. However, it must be taken into account that the immune response and thus the success of the immunisation can be impaired if higher doses of corticosteroids are used.

In particular, during a long-term treatment with high doses of Dexamethasone Injection, patients should be monitored to ensure sufficient intake of potassium (e.g. vegetables, bananas). Limited intake of salt may be required, and blood potassium levels should be monitored.

Viral diseases (e.g. measles, chickenpox) can have a particularly severe course in patients being treated with Dexamethasone Injection. At particular risk are patients with a compromised immune system who have never previously suffered from measles or chickenpox. If these patients have contact with individuals suffering from measles or chickenpox during treatment with Dexamethasone Injection, they should contact their doctor immediately, who may start preventative treatment.

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.

For an intravenous administration, the injection should be given slowly over 2-3 minutes. Following a too rapid administration, short and essentially harmless undesirable effects in the form of unpleasant tingling or paraesthesias, lasting up to 3 minutes can occur.

Dexamethasone Injection is a drug intended for short-term use. However, if it is used over a fairly long period, further warnings and precautions must be taken into account, as considered for drugs containing glucocorticoids that are intended for long-term use.

With local use, possible systemic side effects and interactions must be taken into account.

The intraarticular administration of glucocorticoids increases the risk of joint infections. Longer-term and repeated use of glucocorticoids in weight-bearing joints can lead to a deterioration of wear-related lesions due to possible overload of the joint following a reduction in pain or other symptoms.

Children and adolescents
Dexamethasone should not be routinely used in preterm neonates with respiratory problems.

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

In children, Dexamethasone Injection should be used only if there are compelling medical reasons, due to the risk of growth inhibition/ retardation. Growth must be regularly checked especially if used for a long-term treatment.

Dexamethasone Injection contains propylene glycol. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

Patients with hepatic or renal impairment
Dexamethasone Injection contains propylene glycol.
If you suffer from a liver or kidney disease you should not be given this medicine unless recommended by your doctor who may carry out extra checks while you are given this medicine.

Elderly
In elderly patients, a special benefit-risk assessment must be carried out due to the increased osteoporosis risk.

Note on doping
The use of Dexamethasone Injection can lead to positive results in doping tests.

Other medicines and Dexamethasone Injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important with the following medicines as they may interact with Dexamethasone Injection.

Other medicines that can influence the effect of Dexamethasone Injection:

- Medicines that accelerate breakdown in the liver, such as certain sleeping pills (barbiturates), medicines used to treat seizures (phenytoin, carbamazepine, primidone), and certain medicines used to treat tuberculosis (rifampicin) can reduce the corticoid effect.

- Medicines that slow breakdown in the liver, such as certain medicines used to treat fungal diseases (ketoconazole, itraconazole) can increase the effect of corticoids.

- Certain female sex hormones, e.g. to prevent pregnancy (the pill): the effect of Dexamethasone Injection can be increased.

- Ephedrine (in medicines used to treat hypotension, chronic bronchitis, asthma attacks, and to reduce the swelling of mucous membranes in colds and as a component in appetite suppressants): through accelerated breakdown in the body, the efficacy of Dexamethasone Injection can be reduced.

- Some medicines for HIV: ritonavir, cobicistat as they may increase the effects of Dexamethasone Injection and your doctor may wish to monitor you carefully if you are taking these medicines.

Dexamethasone Injection can influence the effect of other medicines such as:

- Medicines used to reduce blood pressure (ACE inhibitors). When Dexamethasone Injection is used at the same time it can increase the risk of blood count changes.

- Medicines used to strengthen the heart (cardiac glycosides) as due to potassium deficiency Dexamethasone Injection can increase their effect.

- Medicines that promote loss of salt upon urination (saluretics) or laxatives as Dexamethasone Injection can increase potassium excretion caused by these medicines.

- Oral antidiabetics and insulin as Dexamethasone Injection can reduce their antidiabetic effects (not effective in decreasing glucose levels in the blood).

- Medicines used to inhibit blood coagulation (oral anticoagulants, coumarin). Their effect can be weakened or strengthened by Dexamethasone Injection. Your doctor will decide whether a dose adjustment of the anticoagulant is necessary.

- Medicines used to treat inflammations and rheumatism (salicylates, indomethacin, and other non-steroidal anti-inflammatory drugs) as Dexamethasone Injection when used at the same time as those medicines can increase the risk of gastric ulcers and gastrointestinal bleeding.

- Non-depolarising muscle relaxants as their muscle-relaxing effect can be prolonged by Dexamethasone Injection.

- Certain medicines used to increase intraocular pressure (atropine and other anticholinergics) as their effect may be increased by Dexamethasone Injection.

- Medicines used to treat diseases caused by worms (praziquantel) as Dexamethasone Injection can reduce their effect.

- Medicines used to treat malaria or rheumatic diseases (chloroquine, hydrochloroquine, mefloquine). There is an increased risk of body muscle or heart muscle diseases (myopathies, cardiomyopathies) when used at the same time as Dexamethasone Injection.

- Protirelin (TRH, a hormone produced in the diencephalon) as following its administration, Dexamethasone Injection can reduce the increase in thyroid-stimulating hormone (TSH).

- Medicines used to suppress the body's own immune system (immunosuppressants). When they are used with Dexamethasone Injection there is an increased susceptibility to infections and worsening of existing infections that may not yet have become symptomatic.

- Ciclosporin (a medicine used to suppress the body's own immune system), as Dexamethasone Injection can increase the ciclosporin level and thus the risk of seizures.

- Fluoroquinolones, a certain group of antibiotics, can increase the risk of tendon ruptures.

Impact on investigation methods:
Glucocorticoids can suppress skin reactions to allergy tests.

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

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before being given this medicine.
The doctor will then decide if the medicine is suitable for you and may carry out extra checks while you are given this medicine.
Dexamethasone crosses the placenta. During pregnancy, particularly in the first three months, treatment should take place only after a careful benefit-risk assessment.
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 glucocorticoids are used at the end of pregnancy, underactivity of the adrenal cortex can occur, which can necessitate tapering/ replacement treatment in the newborn.
Newborn babies of mothers who received Dexamethasone Injection near the end of pregnancy may have low blood sugar levels after birth.

Glucocorticoids, including dexamethasone, are excreted in breast milk. There have been no reports of the infant being harmed, however, if higher doses are necessary, breast-feeding should be discontinued.

Driving and using machines
There is no evidence to date that Dexamethasone Injection reduces the ability to drive or use machines. The same applies to working in a hazardous setting.

Dexamethasone Injection contains propylene glycol
This medicine contains 20 mg of propylene glycol in 1 ml solution.

Dexamethasone Injection contains sodium
This medicine contains up to 43 mg (1.9 mmol) sodium (main component of cooking/table salt) in each maximum single dose (350 mg for a person with 70 kg body weight). This is equivalent to 2.15% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Dexamethasone Injection

Your nurse or doctor will give you this medicine. Your doctor will decide the correct dosage for you and how and when the medicine will be given.

This medicine is a solution for injection into a vein (IV), a muscle (IM) or under the skin (SC) or tissue.

Dexamethasone Injection should be given slowly into a vein (over 2-3 minutes). If administration into a vein is not possible, and if circulatory function is unimpaired, Dexamethasone Injection can also be administered into a muscle. Dexamethasone Injection can sometimes also be given by injection or continuous infusion under the skin (subcutaneously).
Dexamethasone Injection can also be administered by way of infiltration or injection into a joint.

Intraarticular injection should be administered under strict aseptic conditions. A single intraarticular injection is generally sufficient to successfully relieve symptoms. If a further injection is considered necessary, this should be given 3-4 weeks later at the earliest. The number of injections per joint should be limited to 3-4. In particular, after each consecutive injection, medical examination of the joint is indicated.
Dexamethasone Injection can also be administered into the area of the greatest pain or the tendon attachments but not directly into the tendon itself. Injections at short intervals should be avoided and rigorous aseptic precautions should be ensured.

In case high doses are required for a single treatment, use of dexamethasone medicinal products with higher strengths/volume should be considered.

Systemic use

- Cerebral swelling: in acute forms, depending on cause and severity, initially 8-10 mg (up to 80 mg) into a vein IV, then 16-24 mg (up to 48 mg)/day distributed across 3-4 (up to 6) individual doses into a vein over 4-8 days.

- Cerebral oedema due to bacterial meningitis: 0.15 mg/kg of body weight every 6 hours over 4 days, children: 0.4 mg/kg of body weight every 12 hours over 2 days, starting before the first administration of antibiotics.

- Shock after severe injuries: initially, 40-100 mg (children 40 mg) IV, repetition of the dose after 12 hours or every 6 hours 16-40 mg over 2-3 days.

- Treatment of COVID-19: adult patients are recommended to be given 6 mg IV once a day for up to 10 days. Paediatric patients (adolescents of 12 years of age or older) are recommended to be given 6 mg IV once a day for up to 10 days.

- Severe acute asthma attack: as early as possible, 8-20 mg IV, where necessary repeated injections with 8 mg every 4 hours. Children: 0.15-0.3 mg /kg of body weight or 1.2 mg/kg of body weight IV as a bolus, then 0.3 mg/kg every 4-6 hours.

- Acute skin diseases: depending on the nature and the extent of the disease, daily doses of 8-40 mg IV, in individual cases up to 100 mg. Then further oral treatment at decreasing doses.

- Systemic lupus erythematosus: 6-16 mg.

- Active rheumatoid arthritis with a severe progressive course, e.g. forms that rapidly lead to joint destruction: 12-16 mg, when tissue outside the joint is affected: 6-12 mg.

- Severe infectious diseases with states similar to poisoning: 4-20 mg/day IV over several days, only in addition to corresponding therapy to treat infection; in individual cases (e.g. typhus) with initial doses up to 200 mg IV, and then taper off.

- Prophylaxis and treatment of vomiting after operations: individual dose of 8-20 mg before the start of the operation, children from the age of 2: 0.15-0.5 mg/kg of body weight (maximum of 16 mg).

- Supportive therapy in the case of malignant tumours: initially 8-16 mg/day, in the case of longer-term treatment, 4-12 mg/day.

- Prevention and treatment of vomiting during cytostatic treatment in the context of certain regimens: 10-20 mg IV before the start of chemotherapy, then, where necessary, 2-3 times daily 4-8 mg over 1-3 days (moderately emetogenic chemotherapy) or up to 6 days (highly emetogenic chemotherapy).
- In palliative care and as a prevention and treatment of chemotherapy-induced nausea and vomiting (CINV) doses usually range between 4.82 mg to 19.3 mg SC over 24 hours, taking into consideration local clinical guidelines, and should be titrated according to the response.

Local use

Doses for local infiltration and injection therapies are typically carried out at 4-8 mg. For an injection into a small joint, 2 mg is sufficient.

If possible, the daily dose should be given in the morning as a single dose. However, for treatment of diseases that require higher doses, more than one single dose in the morning is often necessary to achieve a maximum effect.

The duration of the treatment is determined based on the underlying disease and its course. Your doctor establishes a treatment schedule, which you must adhere to strictly. As soon as a satisfactory treatment result has been achieved, the dose will be reduced to a maintenance dose or ended.

Abrupt discontinuation of medicine administered for more than approximately 10 days can lead to the occurrence of acute adrenal cortex failure, so the dose needs to be gradually reduced before discontinuation.

In case of underactive adrenal gland or liver cirrhosis, relatively low doses can be sufficient, or dose reduction can be necessary.

If you think you have been given more Dexamethasone Injection than you should or that you have missed a dose
Since the medicine 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 are concerned, talk to your doctor or nurse.

In general, Dexamethasone Injection is tolerated in large quantities without complications even during short-term use. There are no special measures necessary. If you observe more severe or unusual side effects in yourself, you should consult your doctor.

If a dose is missed, it can be given later on the same day, and the dose prescribed by your doctor can continue to be given as usual from the next day onwards. If more than one dose is missed, this can lead to a flare-up or deterioration of the disease being treated. You should consult your doctor, who will review the treatment and adjust the dose if necessary.
Do not take a double dose to make up for a forgotten dose.

If you stop using Dexamethasone Injection

Always follow the dosing schedule prescribed by your doctor. Dexamethasone Injection may never be discontinued independently, as, in particular, a relatively long treatment can result in suppression of the body's own production of glucocorticoids (underactivity of the adrenal gland). A pronounced physical stress situation without sufficient glucocorticoid production can be life-threatening.

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

4. Possible side effects

The risk of side effects is low during short-term dexamethasone therapy. However, in case of short-term and high-dose parenteral therapy, the risk of electrolyte changes, oedema, possible increase in blood pressure, heart failure, cardiac arrhythmias, or seizures must be considered, and the clinical manifestations of infection should also be anticipated. Clinicians should be alert to the possibility of gastrointestinal ulcers which are often stress-related, and which can be relatively asymptomatic during corticosteroid treatment, and a reduction in glucose tolerance.
Dexamethasone Injection can cause allergic reactions, including anaphylactic shock in very rare cases.

In particular, if high doses are used for a longer-term, side effects are expected to occur regularly with varying severity.

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

Frequency not known (cannot be estimated from available data)

Infections and infestations:
Masking of infections, occurrence, recurrence, and deterioration of viral, fungal, and bacterial infections and parasitic or opportunistic infections, activation of threadworm infection.

Blood and lymphatic system disorders:
Changes in the blood count (proliferation of white blood cells or all blood cells, reduction in certain white blood cells).

Immune system disorders:
Hypersensitivity reactions (e.g. drug-induced skin rash), severe anaphylactic reactions, such as arrhythmias, bronchospasms (spasms of the smooth bronchial musculature), excessively high or excessively low blood pressure, circulatory collapse, cardiac arrest, weakening of the immune system.

Endocrine disorders:

The development of Cushing's syndrome (typical symptoms include moon face, abdominal obesity, and facial redness), suppression or loss of adrenal cortex function.

Metabolism and nutrition disorders:
Weight gain, increased blood sugar values, diabetes mellitus, increase in blood lipid values (cholesterol and triglycerides), increased sodium level with tissue swelling (oedema), potassium deficiency due to increased potassium excretion (which can lead to cardiac arrhythmias), increase in appetite.

Psychiatric disorders:
Depression, irritation, euphoria, increased drive, psychoses, mania, hallucinations, affect lability, feelings of anxiety, sleep disturbances, risk of suicide.

Nervous system disorders:
Increased pressure inside the skull, occurrence of previously unknown seizures (epilepsy), increased occurrence of seizures in previously diagnosed epilepsy.

Eye disorders:
Increase in intraocular pressure (glaucoma), opacification of the lens (cataract), deterioration in corneal ulcers, increased risk of, or deterioration, of eye inflammations caused by viruses, bacteria, or fungi; deterioration of bacterial inflammations of the cornea, drooping eyelid, dilated pupils, swelling of the conjunctiva, perforation of the sclera, visual disturbances, loss of vision.

In rare cases, reversible bulging of the eyeball.

Cardiac disorders:
Thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies, that generally returns to normal after stopping treatment.

Vascular disorders:
High blood pressure, increase in the risk of arteriosclerosis and thrombosis, inflammation of blood vessels (also as withdrawal syndrome after long-term therapy), increased fragility of blood vessels.

Gastrointestinal disorders:
Stomach and intestinal ulcers, stomach and intestinal bleeds, pancreatitis, stomach symptoms.

Skin and subcutaneous tissue disorders:
Skin stretch marks, thinning of the skin (parchment skin), dilation of blood vessels, a tendency to develop bruising, points or areas of skin bleeding, increased body hair, acne, inflammatory skin lesions in the face, especially around the mouth, nose, and eyes, changes in skin pigmentation.

Musculoskeletal and connective tissues disorders:
Muscle diseases, muscle weakness and muscle loss, and bone thinning (osteoporosis) occur in a dose-dependent fashion and are possible during only short-term use; other forms of bone loss (bone necroses), tendon-related symptoms, tendonitis, tendon ruptures, fat deposits in the spine (epidural lipomatosis), growth inhibition in children.

If the dose is reduced too quickly after long-term treatment, withdrawal symptoms can occur, amongst other things, which can manifest in symptoms such as muscle and joint pain.

Reproductive system and breast disorders:
Disturbances in sex hormone secretion (causing irregular menstruation or a halt to menstruation altogether (amenorrhoea), male body hair patterns in women (hirsutism), impotence).

General disorders and administration site conditions: delayed wound healing.

Local use:
Local irritation and intolerance are possible (sensation of heat, relatively persistent pain). Skin or subcutaneous tissue thinning (atrophy) at the injection site can occur if corticosteroids are not injected carefully into a joint cavity.

If you experience any of the following, please **contact your doctor immediately:**
- gastrointestinal symptoms,
- pain affecting the back, shoulder, or hip,
- mood disorders,
- marked blood sugar fluctuations in diabetic patients.

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 section 2 and 3).

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 Injection

Store below 25°C. Do not freeze.
Keep the ampoule in the outer carton in order to protect from light.
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 ampoule label and carton after EXP. The expiry date refers to the last day of that month.

This product is for single use only. Any unused solution should be discarded.
Do not use this medicine if you notice some visible particles in the solution.

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 Injection contains
- The active substance is dexamethasone sodium phosphate.

Each 1 millilitre (ml) of solution for injection contains 3.32 mg of dexamethasone base (as dexamethasone sodium phosphate) which is equivalent to 4.00 mg of dexamethasone phosphate or 4.37 mg dexamethasone sodium phosphate.

Each 2 millilitres (ml) of solution for injection contains 6.64 mg of dexamethasone base (as dexamethasone sodium phosphate) which is equivalent to 8.00 mg of dexamethasone phosphate or 8.74 mg dexamethasone sodium phosphate.
- The other ingredients are propylene glycol, disodium edetate, sodium hydroxide (for pH adjustment) and water for injections.

What Dexamethasone Injection looks like and contents of the pack
Dexamethasone phosphate 4 mg/ml solution for injection (injection) is a clear and colourless solution, free of visible particles.
Dexamethasone Injection is available in packs of 5 or 10 ampoules, each ampoule containing 1 ml or 2 ml solution.

Not all pack sizes may be marketed.

Marketing authorisation holder
hameln pharma gmbh, Inselstraße 1, 31787 Hameln, Germany

Manufacturer
Siegfried Hameln GmbH, Langes Feld 13, 31789 Hameln, Germany

HBM Pharma s.r.o., Sklabinská 30, 036 80 Martin, Slovakia

hameln rds s.r.o., Horná 36, 900 01 Modra, Slovakia

This medicinal product is authorized in the Member States of the EEA under the following names:

Austria	Dexamethason-hameln 4 mg/ml Injektionslösung
Belgium	Dexamethason hameln 4 mg/ml solution injectable Dexamethason hameln 4 mg/ml oplossing voor injectie Dexamethason hameln 4 mg/ml Injektionslösung
Bulgaria	Dexamethasone phosphate hameln 4 mg/ml solution for injection Дексаметазон фосфат хамелн 4 mg/ml инжекционен разтвор
Croatia	Deksametazon hameln 4 mg/ml otopina za injekciju
Czechia	Dexamethasone hameln
Denmark	Dexamethasone phosphate hameln
Finland	Dexamethasone phosphate hameln, 4 mg/ml injektioneste, liuos
Germany	Dexamethason-hameln 4 mg/ml Injektionslösung
Hungary	Dexametazon hameln 4 mg/ml oldatos injekció
Ireland	Dexamethasone phosphate 4 mg/ml solution for injection
Italy	Desametasone hameln
Netherlands	Dexamethason hameln 4 mg/ml oplossing voor injectie
Norway	Dexamethasone phosphate hameln
Poland	Dexamethasone hameln
Portugal	Dexametasona hameln
Romania	Dexametazonă fosfat hameln 4 mg/ml soluţie injectabilă
Slovakia	Dexamethasone hameln 4 mg/ml injekčný roztok
Slovenia	Deksametazon hameln 4 mg/ml raztopina za injiciranje

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