Package leaflet: Information for the patient

Dexamethason Prolepha 4 mg/ml, oplossing voor injectie/infusie
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.

What is in this leaflet

1. What Dexamethason Prolepha is and what it is used for

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

Dexamethason Prolepha is used in
Diseases requiring treatment with glucocorticoids. Depending on the type and severity, these include:

Systemic use:
- Swelling of the brain caused by brain tumours, brain surgery, brain abscess, bacterial inflammation of the lining of the brain.
- States of shock after severe injuries, for prophylactic treatment of shock lung.
- Severe acute asthma attack.
- Initial treatment of extensive acute severe skin diseases such as erythroderma, pemphigus vulgaris, acute eczema.
- Treatment of systemic rheumatic diseases (rheumatic diseases that can affect internal organs) such as systemic lupus erythematosus.
- Active rheumatic inflammation of joints (rheumatoid arthritis) with a severe progressive course, e.g. forms rapidly leading to joint destruction, and/or where tissue outside the joints is affected.
- Severe infectious diseases with poisoning-like conditions (e.g. in tuberculosis, typhoid, brucellosis); only in addition to appropriate anti-infectious therapy.
- Supportive treatment in malignant tumours.
- Prevention and treatment of vomiting after surgery or in cytostatic treatment.
- Dexamethason Prolepha 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.

Local use:
- Injection into joints: persistent inflammation of one or a few joints after systemic treatment of chronic inflammatory joint diseases, activated osteoarthritis, acute forms of painful shoulder syndrome.

- Infiltration therapy (only if strictly indicated): non-bacterial inflammation of the tendons or bursa (a fluid-filled sac which forms under the skin, usually over the joints), inflammation around a joint, tendon disorder.
- Eye therapy: injection under the conjunctival sac in non-infectious inflammation of various parts of the eye (cornea and conjunctiva, inflammation of the corium, inflammation of the iris and the cilliary body), inflammation of the middle part of the eye (uveitis).

2. What you need to know before you are given Dexamethason Prolepha

Dexamethason Prolepha must not be given
- If you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6).

Severe allergic reactions (anaphylactic reactions) with circulatory collapse, cardiac arrest (heart stops beating), arrhythmia (abnormal heart rhythm), shortness of breath (bronchospasm) and/or drop or increase in blood pressure were observed in isolated cases during use of Dexamethason Prolepha.

Injection into the joints is contraindicated in
- infections of or in immediate proximity of the joint to be treated
- bacterial arthritis
- instability of the joint to be treated
- bleeding tendency (spontaneous or due to anti-coagulants)
- calcifications in the proximity of joints
- avascular osteonecrosis (disease in which bone tissue dies when there is no blood supply to the bone)
- rupture of a tendon
- Charcot's joint (loss of sensation in the joint)

Infiltration without additional causal therapy must not be performed in the case of infections at the site of administration; the same applies to subconjunctival administration in eye diseases caused by viruses, bacteria and fungi and in corneal injuries and ulcers.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Dexamethason Prolepha.

You should not stop taking any other steroid medications unless your doctor has instructed you to do so.
General precautions regarding steroid use in specific diseases, masking infection, medicines used at the same time etc. in line with current recommendations.

If particular situations of physical stress (accident, surgery, parturition, etc.) occur during Dexamethason Prolepha therapy, it may be necessary to increase the dose temporarily.

Dexamethason Prolepha may mask signs of infection and thus impede the diagnosis of existing or developing infections. Latent infections may be reactivated.

In the following illnesses, treatment with Dexamethason Prolepha should only be started if your doctor considers it essential. If necessary, medications that act against the pathogens should also be taken:
- Acute viral infections (hepatitis B, chickenpox, shingles, herpes simplex infections, inflammation of the cornea caused by herpes viruses).
- HBsAg-positive chronic active hepatitis (infectious liver inflammation).
- About 8 weeks prior to 2 weeks after vaccinations with attenuated pathogens (live vaccine).
- Acute and chronic bacterial infections.
- Fungal infections with involvement of internal organs.

- Certain diseases caused by parasites (amoebic, worm infections). In patients with suspected or confirmed infection with threadworms (nematodes), Dexamethason Prolepha can lead to activation and mass proliferation of these parasites.
- Poliomyelitis (infection cause by a virus).
- Lymph node disease after tuberculosis vaccination.
- In case of history of tuberculosis, use only together with medicines for tuberculosis.

The following diseases should be specifically monitored during treatment with Dexamethason Prolepha at the same time and treated according to the requirements:
- Gastrointestinal ulcers.
- Bone loss (osteoporosis).
- High blood pressure that is difficult to control.
- Diabetes that is difficult to control.
- Mental (psychological) disorders (also in the past), including suicidal tendencies. In this case, neurological or psychiatric monitoring is recommended.
- Increased intraocular pressure (narrow- and wide-angle glaucoma); ophthalmologic monitoring and adjunctive therapy are recommended.
- Injuries and ulcers of the cornea of the eye; ophthalmologic monitoring and adjunctive therapy are recommended.

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

Because of the risk of an intestinal perforation, Dexamethason Prolepha may only be taken if there are compelling medical reasons and under appropriate monitoring:
- in severe inflammation of the colon (ulcerative colitis) with threatened perforation, with abscesses or purulent inflammation, possibly without peritoneal irritation
- in inflamed pouches in the bowel wall (diverticulitis)
- after certain intestinal surgeries (enteroanastomosis), immediately after surgery

Signs of peritoneal irritation after gastrointestinal perforation may be absent in patients receiving high doses of glucocorticoids.

In patients with diabetes, metabolism should be checked regularly; the possibility of a higher need for medicines for the treatment of diabetes (insulin, oral antidiabetics) should be taken into consideration.

Patients with severely high blood pressure and/or severe heart failure should be carefully monitored due to the risk of deterioration. High doses can lead to slowing of the heartbeat.

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

The risk of tendon disorders, tendon inflammation and tendon rupture is increased when fluoroquinolones (certain antibiotics) and Dexamethason Prolepha are administered together.

During the treatment of a particular form of muscle paralysis (myasthenia gravis), the symptoms may worsen at the beginning.

Vaccinations with vaccines from killed pathogens (inactivated vaccines) are generally possible. However, it should be noted that the immune response and thus the vaccine may be compromised at higher doses of corticosteroids.

Especially with prolonged treatment with high doses of Dexamethason Prolepha, sufficient potassium intake (such as vegetables, bananas) and limited salt intake should be ensured. The doctor will monitor your blood potassium levels.

Viral diseases (such as measles, chickenpox) may be very severe in patients treated with Dexamethason Prolepha. Patients with a compromised immune system who have not had measles or chickenpox yet are particularly at risk. If these patients have contact with people infected with measles

or chickenpox during treatment with Dexamethason Prolepha, they should immediately contact their doctor, who will introduce a preventative treatment if necessary.

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 (blood cancers).

If you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands), talk to your doctor before taking Dexamethason Prolepha.
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 .high blood pressure. Contact your doctor immediately if you experience these signs.

Intravenous (into a vein) administration should be by slow (over 2-3 minutes) injection, since side effects such as unpleasant prickling or paraesthesia can occur if injected too rapidly.

Dexamethason Prolepha is intended for short-term use. If used improperly over a longer period, additional warnings and precautions, as described for long-term administration of glucocorticoid-containing medicines, should be considered.

Possible systemic side effects and interactions should be taken into account after local administration.

Administration of Dexamethason Prolepha into the joint increases the risk of joint infections. Long-term administration and repeated injections of glucocorticoids into weight-bearing joints can aggravate wear-related changes of the joints. This is probably due to overburdening of the affected joints after pain or other symptoms have been relieved.

Local use in eye disease
Talk to your doctor if you experience swelling and weight gain around the trunk and in the face as these are usually the first manifestations of a syndrome called Cushing's syndrome. Suppression of the adrenal gland function may develop after stopping a long-term or intensive treatment with Dexamethason Prolepha. Talk to your doctor before stopping the treatment by yourself. These risks are especially important in children and patients treated with a medicine called ritonavir or cobicistat (medicines used to treat HIV).

Children and adolescents
Routine use of dexamethasone in premature infants with lung problems is not recommended.
This medicine must be given to children only if necessary, as it may slow down the growth in children. During long-term treatment with this medicine growth in height should be controlled regularly.

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

Elderly
A special benefit-risk assessment should be carried out because of the increased risk of osteoporosis.

Effects in case of misuse for doping purposes
The use of Dexamethason Prolepha can lead to positive results in doping controls.

Other medicines and Dexamethason Prolepha
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Tell your doctor if you are taking any of the following medicines as they might interact with the effect of Dexamethason Prolepha:

- Medicines that accelerate the breakdown in the liver, such as certain sleeping pills (barbiturates), medicines used to treat fits (phenytoin, carbamazepine, primidone) and certain medicines for tuberculosis (rifampicin), may reduce the effect of corticosteroids.
- Medicines that slow down the breakdown in the liver, such as certain medicines to treat fungal infections (ketoconazole, itraconazole), may increase the effect of corticosteroids.
- Certain female sex hormones, e.g. for the prevention of pregnancy (the pill): The effect of Dexamethason Prolepha may be increased.
- Ephedrine (such as medicines for low blood pressure, chronic bronchitis, asthma attacks, medicines used to reduce swelling of the mucous membranes in rhinitis and appetite suppressants can contain ephedrine): Through accelerated breakdown in the body, the effectiveness of Dexamethason Prolepha may be reduced.

Tell your doctor if you are using ritonavir or cobicistat (medicines used to treat HIV) as this may increase the amount of dexamethasone in the blood.

Tell your doctor if you are taking any of the following medicines as Dexamethason Prolepha may influence the effect of these medicines:
- During concomitant use with certain medicines for lowering blood pressure (ACE inhibitors), Dexamethason Prolepha may increase the risk of blood count changes.
- Dexamethason Prolepha may increase the effect of medicines that strengthen the heart (cardiac glycosides) by potassium deficiency.
- This medicine may increase the potassium excretion by diuretics (saluretics) or laxatives.
- Dexamethason Prolepha may decrease the blood glucose lowering effect of oral antidiabetics and insulin.
- Dexamethason Prolepha may weaken or increase the effects of medicines that reduce blood clotting (oral anticoagulants, coumarin). Your doctor will decide whether a dose adjustment of the anticoagulant is necessary.
- During concomitant use of anti-inflammatory and antirheumatic medicines (salicylates, indomethacin, and other NSAIDs), Dexamethason Prolepha may increase the risk of stomach ulcers and gastrointestinal bleeding.
- Dexamethason Prolepha may prolong the muscle-relaxing effect of certain medicines (non-depolarising muscle relaxants).
- This medicine may enhance the intraocular (inside the eye) pressure-increasing effect of certain medicines (atropine and other anticholinergics).
- Dexamethason Prolepha may decrease the effect of medicines for worm diseases (praziquantel).
- During concomitant use of medicines for malaria and rheumatic diseases (chloroquine, hydroxychloroquine, mefloquine), Dexamethason Prolepha may increase the risk of muscle diseases or heart muscle diseases (myopathies, cardiomyopathies).
- Dexamethason Prolepha may reduce the increase in thyroid-stimulating hormone (TSH) after administration of protirelin (TRH, a hormone of the midbrain).
- If used together with medicines that suppress the body's immune system (immunosuppressants), Dexamethason Prolepha may increase the susceptibility to infections and worsen the existing infections which perhaps have not erupted yet.
- Additionally, for cyclosporine (a medicine used to suppress the body's immune system): Dexamethason Prolepha may increase the concentration of cyclosporine in the blood and thereby the risk of seizures (fits).
- Fluoroquinolones, a certain group of antibiotics, may increase the risk of tendon ruptures.

Effect on investigation methods
Glucocorticoids can suppress skin reactions in allergy tests.

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 taking this medicine.

Pregnancy

Dexamethasone crosses the placenta. During pregnancy, especially in the first three months, the medicine should only be used after careful benefit-risk assessment. Therefore, women should inform the doctor if they are already pregnant or if they become pregnant.
During long-term treatment with glucocorticoids during pregnancy, growth disorders in the unborn child cannot be excluded. If glucocorticoids are administered towards the end of pregnancy, there is a risk of underactive adrenal cortex in the newborn, which may necessitate replacement therapy that has to be slowly reduced.
Newborn babies of mothers who received dexamethasone near the end of pregnancy may have low blood sugar levels after birth.

Breast-feeding
Glucocorticoids, including dexamethasone, are excreted in breast milk. Harm to the infant is not yet known. Nevertheless, the need for treatment during lactation should be closely examined. If the disease requires higher doses, breast-feeding should be discontinued. Please contact your doctor immediately.
Ask your doctor or pharmacist for advice before you take/use any medicine.

Driving and using machines
To date there is no evidence that Dexamethason Prolepha affects the ability to drive or operate machinery, or work without safe foothold.

Dexamethason Prolepha contains sodium.
This medicine contains 3.12 mg sodium (main component of cooking/table salt) in 1 ml ampoule. This is equivalent to 0.15% of the recommended maximum daily dietary intake of sodium for an adult.
This medicine contains 6.24 mg sodium (main component of cooking/table salt) in 2 ml ampoule. This is equivalent to 0.30% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Dexamethason Prolepha is given

Your doctor will decide how long you should take dexamethasone for. The doctor will determine your dose individually. Please follow the instructions in order for Dexamethason Prolepha to have the proper effect.
Check with your doctor or pharmacist if you are not sure.

Method of administration
This medicine will be given to you by a trained healthcare professional. It will be given as an injection into a vein. It can also be given into a muscle, directly into a joint or soft tissue.
Dexamethason Prolepha should be administered by slow (over 2-3 minutes) intravenous injection (into the vein), but may also be administered intramuscularly (into the muscle) if problems occur with access to the vein and blood circulation is adequate.
Dexamethason Prolepha can also be used intraarticular (into a joint), intralesional (into a lesion or the skin) or subconjunctival (into the eyelid) use.
The direct intravenous administration or injection into an i.v. line should be given before an infusion of preference.

The daily dose should be administered as a single dose in the morning, if possible. However, in conditions requiring high-dose therapy several doses during the day are often required for maximal effect.
The **duration of treatment** depends on the underlying disease and the course of the disease. Your doctor will specify a treatment regimen, which you should strictly follow. Once a satisfactory treatment result is achieved, the dose will be reduced to a maintenance dose or treatment terminated.

Abrupt discontinuation of treatment after about 10 days can result in acute adrenocortical insufficiency; therefore, the dose should be slowly reduced if treatment is to be discontinued.

In underactive thyroid or liver cirrhosis, your doctor may prescribe you low doses of this medicine or your dose may be reduced.

When high doses are necessary in a single treatment, consideration should be given to taking medicines containing dexamethasone at a higher strength/amount.

Unless otherwise prescribed by your doctor, the recommended dose is:

Systemic use
- Swelling of the brain: initially, in acute states, depending on the cause and severity 8-10 mg (up to 80 mg) into a vein (i.v.), then 16-24 mg (up to 48 mg) daily, divided into 3-4 (up to 6) individual doses for 4-8 days.
- Swelling of the brain due to bacterial meningitis:
  - Use in adult: 0.15 mg/kg body weight every 6 hours for 4 days;
  - Use in children: 0.4 mg/kg body weight every 12 hours for 2 days, starting before the first antibiotics.
- Shock states after severe injury:
  - Use in adults: initially 40-100 mg i.v., a repeated dose after 12 hours or 16-40 mg every 6 hours for 2-3 days.
  - Use in children: initially 40 mg i.v., a repeated dose after 12 hours or 16-40 mg every 6 hours for 2-3 days.
- Severe acute asthma attack:
  - Use in adults: 8-20 mg i.v. as soon as possible, if necessary, another dose of 8 mg every 4 hours should be repeated.
  - Use in children: 0.15-0.3 mg/kg body weight, or 1.2 mg/kg body weight i.v. as a bolus, then 0.3 mg/kg every 4-6 hours.
- Acute skin diseases: Depending on the nature and extent of the disease, daily doses of 8-40 mg i.v., in single cases up to 100 mg. Followed by treatment with tablets at decreasing doses.
- Systemic lupus erythematosus: 6-16 mg/day.
- Severely progressive form of rheumatoid arthritis, e.g. forms that quickly lead to joint destruction: 12-16 mg/day, when tissue outside the joints is affected: 6-12 mg/day.
- Severe cases with intoxication-like conditions: 4-20 mg i.v. daily, for a few days, only in conjunction with adequate anti-infectious therapy; in single cases (e.g. typhoid) initial doses up to 200 mg i.v., then gradually reduced.
- Supportive treatment in malignant tumours: initially 8-16 mg/day, during longer lasting treatment 4-12 mg/day.
- Prevention and treatment of cytostatic-induced vomiting in anti-emetic regimens: 10-20 mg i.v. before starting chemotherapy, then 4-8 mg two to three times daily for 1-3 days as necessary (moderately emetogenic chemotherapy), or up to 6 days (highly emetogenic chemotherapy).
- Prevention and treatment of post-operative vomiting:
  - Use in adults: a single dose of 8-20 mg i.v. before the start of surgery;
  - Use in children over 2 years of age: 0.15-0.5 mg/kg body weight (max. up to 16 mg).
- Treatment of Covid-19:
  - Adult patients are recommended to be given 7.2 mg i.v. of dexamethasone phosphate (equivalent to 6 mg dexamethasone i.v.) once a day for up to 10 days.
  - Adolescents of 12 years of age or older: are recommended to be given 7.2 mg of dexamethasone phosphate/dose i.v. (equivalent to 6 mg dexamethasone) once a day for up to 10 days.

Local use
Local infiltration and injection therapy is usually carried out with 4-8 mg; 2 mg of dexamethasone sodium phosphate is sufficient if injected into small joints or administered by subconjunctival injection.

If you are given more Dexamethason Prolepha than you should

In general, dexamethasone is tolerated without complications even with short-term use of large amounts. This medicine will be given to you by a doctor or nurse. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

If you miss a dose of Dexamethason Prolepha
A missed dose may be given on the same day and the next day the dose prescribed by your doctor should be given as usual. If you are not given several doses, this can lead to a recurrence or worsening of the disease being treated. In such cases, you should talk to your doctor, who will review the treatment and adjust it, if needed.
Do not take a double dose to make up for a forgotten dose.

If you stop receiving Dexamethason Prolepha
Always follow the dosing schedule prescribed by the doctor. Do not stop receiving this medicine suddenly as this might be dangerous. Your doctor will tell you how the treatment will be gradually reduced. Dexamethason Prolepha must never be discontinued without permission, particularly since long-term treatment can lead to a decrease in the body's production of glucocorticoids. A highly physically stressful situation without adequate glucocorticoid production can be fatal.

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

4. Possible side effects

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

Please talk to your doctor or pharmacist if you notice any of the listed side effects or other side effects during treatment with Dexamethason Prolepha. Never stop treatment on your own.

The risk of undesirable effects is low during short-term treatment with dexamethasone, with the exception of parenteral high-dose therapy where changes in electrolytes, occurrence of swelling, possible increase in blood pressure, heart arrest, heart rhythm disturbances or seizures can occur, and clinical manifestations of infections can also be observed during short-term treatment. Attention should be paid to possible gastric and intestinal ulcerations (often stress-induced), because corticoid treatment can reduce their symptoms, and to decrease in glucose tolerance.

If any of the following happen, tell your doctor straight away:
- Severe allergic reactions up to anaphylactic shock (very rare cases). 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.
- Discomfort in your stomach or intestine, pain in the back, shoulder or hip area, psychological problems, abnormal blood sugar fluctuations (in diabetics).

During long-term treatment with this medicine, especially of high doses side effects of varying degrees can be expected regularly (frequency cannot be estimated from the available data).

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

Blood and lymphatic system disorders
Blood count changes (increased number of white blood cells or all blood cells, decreased number of certain white blood cells).

Immune system disorders

Hypersensitivity reactions (e.g. drug eruption), severe anaphylactic reactions, such as heart rhythm disorders, bronchospasm (spasm of the bronchial smooth muscle), high or low blood pressure, circulatory collapse, heart arrest, weakening of the immune system.

Endocrine disorders
Cushing's syndrome (typical signs include moon face, central obesity and flushing), reduced function or shrinking of the adrenal gland.

Metabolism and nutrition disorders
Weight gain, elevated blood sugar, diabetes, increased blood lipids (cholesterol and triglycerides), increased sodium levels with swelling (oedema), potassium deficiency due to increased potassium excretion (may lead to heart rhythm disorders), increased appetite.

Psychiatric disorders
Depression, irritability, euphoria, increased drive, psychoses, mania, hallucinations, mood swings, anxiety, sleep disorders, suicidal tendencies.

Nervous system disorders
Increased intracranial pressure, occurrence of previously unrecognized epilepsy, more frequent seizures in already known epilepsy.

Eye disorders
Increase in intraocular pressure (glaucoma), clouding of the lens (cataract), worsening of corneal ulcers, increased occurrence or worsening of eye inflammation caused by viruses, bacteria or fungi; worsening of bacterial inflammation of the cornea, drooping eyelid, pupil dilation, conjunctival swelling, perforation of the white of the eye, visual disturbances, loss of vision. Rare cases of reversible exophthalmos (bulging of the eye), and after subconjunctival administration also herpes simplex keratitis, corneal perforation in cases of existing keratitis, blurred vision.

Cardiac (heart) 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, increased risk of atherosclerosis and thrombosis (blood clot in the vein), inflammation of blood vessels (also as withdrawal syndrome after long-term treatment), increased fragility of blood vessels.

Gastrointestinal (stomach and intestine) disorders
Gastrointestinal ulcers, gastrointestinal bleeding, inflammation of the pancreas, stomach discomfort, hiccup.

Skin and subcutaneous tissue disorders
Stretch marks on the skin, thinning of the skin ("parchment skin"), enlargement of skin blood vessels, tendency to bruising, skin bleeding in dots or patches, increased body hair, acne, inflammatory skin changes on the face, especially around the mouth, nose and eyes, changes in skin pigmentation.

Musculoskeletal, connective tissue and bone disorders
Muscle diseases, muscle weakness and wasting, bone loss (osteoporosis) are dose-related and possible even with only short-term use, other forms of bone death (osteonecrosis), tendon disorders, tendinitis (inflammation of the tendon), tendon ruptures, fat deposits in the spine (epidural lipomatosis), growth inhibition in children.
Note: Too rapid dose reduction after long-term treatment may cause a withdrawal syndrome with symptoms such as muscle and joint pain.

Reproductive system and breast disorders

Disorders of sexual hormone secretion (consequently: irregular or absent menstruation (amenorrhea), male-like body hair in women (hirsutism), impotence).

General disorders and administration site conditions
Delayed wound healing.

Local use
Local irritation and hypersensitivity reactions can occur (burning sensation, persistent pain), in particular when applied to the eye. Skin atrophy and atrophy of subcutaneous tissue at the injection site cannot be excluded if corticosteroids are not carefully injected into the articular cavity.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexamethason Prolepha

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 label and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C. Keep the ampoules in the outer carton, in order to protect from light.

Do not throw away any medicines 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 Dexamethason Prolepha contains
- The active substance is dexamethasone phosphate.
  Each ampoule of 1 ml contains 4 mg dexamethasone phosphate (as dexamethasone sodium phosphate).
  Each ampoule of 2 ml contains 8 mg dexamethasone phosphate (as dexamethasone sodium phosphate).
- The other ingredients are: sodium citrate (E331), disodium edetate (E386), creatinine, water for injections, sodium hydroxide (E524), concentrated hydrochloric acid (E507).

What Dexamethason Prolepha looks like and contents of the pack
Clear, colourless to slightly yellowish solution. pH 7.0 to 8.5. Osmolality: 160 to 230 mOsm/Kg.
Type I (Ph.Eur), 2 ml capacity, clear glass ampoule.
Boxes of 5, 10 or 100 ampoules are available.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
Prolepha Research B.V.
Molenzicht 7,
4881BW Zundert
Nederland

Manufacturer
Medochemie LTD (Ampoule Injectable Facility)
48 Iapetou Street, Agios Athanassios Industrial Area, 4101 Agios Athanassios, Limassol, Cyprus

Deze bijsluiter is voor het laatst goedgekeurd in oktober 2023

The following information is intended for healthcare professionals only:

Dexamethason Prolepha solution for injection/infusion is for intravenous, intramuscular, intraarticular, intralesional or subconjunctival use.

Method of administration
Dexamethason Prolepha should be administered by slow (over 2-3 minutes) intravenous injection, or by infusion, but may also be administered intramuscularly if problems occur with venous access and blood circulation is adequate. Dexamethason Prolepha may also be administered by infiltration and by intra-articular or subconjunctival injection. Treatment duration depends on the indication.

In hypothyroidism or liver cirrhosis, low doses may be sufficient or a dose reduction may be necessary.

Administration by intra-articular injection should be considered open joint procedure and carried out under strict aseptic conditions. A single intra-articular injection is usually sufficient for effective symptom relief. Should a repeated injection be necessary, it should not be administered sooner than after 3–4 weeks. Not more than 3–4 injections should be used on one joint. A medical check of the joint is required, especially after repeated injections.

Infiltration: The region of greatest pain or tendon attachments is infiltrated with Dexamethason Prolepha. Caution, do not inject into tendon! Frequent injections should be avoided and strict aseptic precautions should be observed.

Suitability for use
Only clear solutions should be used. The content of the ampoule is intended for single withdrawal. Any remaining solution for injection should be disposed.

Instructions for use and handling
Dexamethason Prolepha 4 mg/ml solution for injection/infusion is preferably administered by direct intravenous injection or injected into the infusion tube. Solution for injection/infusion is compatible with the following infusion solutions and intended to be used within 24 hours:
- Isotonic saline solution
- Ringer's solution
- Glucose solution 5%
- Glucose solution 10%
- Dextrose solution 5%

Incompatibilities
When used in combination with solutions for infusion, each supplier's information on their solutions for infusion, including information on compatibility, contraindications, undesirable effects and interactions should be considered.

In-use storage precautions
Chemical and physical in-use stability has been demonstrated for 24 hours at 25ºC and 2–8ºC.
From a microbiological point of view, the product should be used immediately. 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 2–8ºC, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.