Kalcex

Package leaflet: information for the user

Dexamethasone 3.3 mg/ml solution for injection/infusion

dexamethasone

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, 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

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

Dexamethasone 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, neurosurgery, brain abscess, bacterial inflammation of the lining of the brain (e.g. in tuberculosis, typhoid, brucellosis)
- States of shock after severe injuries, prevention of post-traumatic 'shock lung' (acute respiratory insufficiency)
- 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
- Supportive treatment in malignant tumours
- Prevention and treatment of vomiting after surgery or in cytostatic treatment
- 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

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 Dexamethasone

You must not be given Dexamethasone
- If you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6)
- If you have an infection, including one which could have been caused by a fungus, which is not being treated
- Injection into the joints is contraindicated in:
  - infections of or in immediate proximity of the joint to be treated
  - joint inflammation caused by bacteria (bacterial arthritis)
  - instability of the joint to be treated
  - bleeding tendency (spontaneous or due to anticoagulants)
  - calcifications in the proximity of joints
  - localised death of bone tissue (avascular osteonecrosis)
  - tendon rupture
  - Charcot's 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 In the following diseases, treatment with dexamethasone should only be started if your doctor considers it essential. If necessary, medicines that act against the pathogens should also be taken:
- acute viral infections (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), Dexamethasone can lead to activation and mass proliferation of these parasites
- poliomyelitis
- 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 concomitant treatment with dexamethasone 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 pressure inside the eye (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

Talk to your doctor before receiving dexamethasone if you have or are suspected of having pheochromocytoma (a tumour of the adrenal glands).

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

Severe allergic reactions
Severe hypersensitivity reactions (anaphylactic reactions) with circulatory collapse, cardiac arrest, arrhythmia, shortness of breath (bronchospasm) and/or drop or increase in blood pressure were observed in isolated cases during use of dexamethasone.

Gastrointestinal disorders
Because of the risk of an intestinal perforation, dexamethasone may only be used 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, immediately after surgery

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

Other
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 particular situations of physical stress (e.g. accident, surgery, parturition) occur during dexamethasone therapy, it may be necessary to increase the dose temporarily.

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

If you are treated for COVID-19, you should not stop taking any other steroid medicines unless your doctor has instructed you to do.

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.

The risk of tendon disorders, tendon inflammation and tendon rupture are increased when fluoroquinolones (certain antibiotics) and dexamethasone 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 dexamethasone, sufficient potassium intake (e.g. vegetables, bananas) and limited salt intake should be ensured. The doctor will monitor your blood potassium levels.

Viral diseases (e.g. measles, chickenpox) may be very severe in patients treated with dexamethasone. 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 dexamethasone, they should immediately contact their doctor, who will introduce a preventative treatment if necessary.

Dexamethasone 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.

The use of dexamethasone can lead to positive results in doping controls.

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

Warnings related to specific methods of administration
- Intravenous 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.
- Administration of dexamethasone 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. Your doctor will take special care to reduce the particular risk of bacterial infection. Please be advised not to over-use joints that are still diseased, even if you do not suffer pain.
- Possible systemic side effects and interactions should be considered after local administration.

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

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

Tell your doctor if you use any of the following medicines as they may interact with the effect of dexamethasone:
- Medicines that accelerate the breakdown in the liver, such as certain sleeping pills (barbiturates), medicines used to treat seizures (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 dexamethasone may be increased.
- Ephedrine (e.g. medicines for hypotension, 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 effect of dexamethasone may be reduced.
- Ritonavir or cobicistat (medicines used to treat HIV) as this may increase the amount of dexamethasone in the blood.

How does dexamethasone influence the effect of other medicines?
- During concomitant use with certain medicines for lowering blood pressure (ACE inhibitors), dexamethasone may increase the risk of blood count changes.
- Dexamethasone may increase the effect of medicines that strengthen the heart (cardiac glycosides) by potassium deficiency.
- Dexamethasone may increase the potassium excretion by diuretics or laxatives.
- Dexamethasone may decrease the blood glucose lowering effect of oral antidiabetics and insulin.
- Dexamethasone 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 drugs (salicylates, indomethacin, and other NSAIDs), dexamethasone may increase the risk of stomach ulcers and gastrointestinal bleeding.
- Dexamethasone may prolong the muscle-relaxing effect of certain medicines (non-depolarising muscle relaxants).
- Dexamethasone may enhance the intraocular pressure-increasing effect of certain medicines (atropine and other anticholinergics).

The following information is intended for healthcare professionals only:

Posology and method of administration

Posology

Dosage depends on the nature and severity of the disease and the individual response of the patient to treatment. In general, relatively high initial doses are administered, and they should be significantly higher in acute severe forms than in chronic diseases.

All doses are expressed as mg dexamethasone base.

Unless otherwise prescribed, the following dosage recommendations apply:

Systemic administration

Cerebral oedema: Adults: depending on the cause and severity, initial dose of 6.6-8.25 mg (up to 66 mg) IV, followed by 13.2-19.8 mg (up to 39.6 mg)/day IV, divided into 3-4 (6) individual doses for 4-8 days.
A longer-term, lower-dose administration of dexamethasone may be required during irradiation and in the conservative treatment of inoperable brain tumours.

Cerebral oedema due to bacterial meningitis:
0.12 mg/kg body weight every 6 hours for 4 days, children 0.33 mg/kg body weight every 12 hours for 2 days; starting before the first administration of the antibiotic. Severe cases, toxic states (e.g. tuberculosis, typhoid; only with concomitant anti-infective therapy): 3.3-16.5 mg/day IV, in single cases (e.g. typhoid) initially up to 165 mg.

Consideration should be given to official guidance for the resort to corticotherapy for the adequate management of infectious diseases.

Post-traumatic shock/prophylaxis of post-traumatic shock-lung syndrome: initially 33-82.5 mg (children 33 mg) IV, a repeated dose after 12 hours, or 13.2–33 mg every 6 hours for 2-3 days.

Severe acute asthma attack: Adults: 6.6-16.5 mg IV as early as possible. Children: 0.12-0.25 mg/kg body weight IV. Doses should be repeated, if necessary, based on the individual response and clinical need.

Acute skin diseases: Depending on the nature and extent of the disease, daily doses of 6.6-33 mg IV, in severe cases up to 82.5 mg. Followed by treatment with decreasing doses.

Active phases of rheumatic systemic diseases: systemic lupus erythematosus 4.95-13.2 mg/day.

Active rheumatoid arthritis with a severe, progressive course: in rapidly destructive forms 9.9-13.2 mg/day, in extra-articular manifestations 4.95-9.9 mg/day.

Palliative treatment of malignant tumours: initially 6.6-13.2 mg/day, in prolonged treatment 3.3-9.9 mg/day.

Prophylaxis and treatment of cytostatic-induced vomiting in anti-emetic regimens: 6.6-16.5 mg IV before starting chemotherapy, then 3.3-6.6 mg one to two times daily for 2-3 days as necessary (moderately emetogenic chemotherapy), or up to 3-4 days (highly emetogenic chemotherapy).

Prophylaxis and treatment of post-operative vomiting: a single dose of 3.3-6.6 mg IV before the start of surgery; in children over 2 years of age: 0.12 mg/kg body weight (max. up to 4.13 mg).

Treatment of COVID-19:
Adult patients: 6 mg IV, once a day for up to 10 days.

Paediatric population: paediatric patients (adolescents aged 12 years and older) are recommended to use 6 mg/dose IV, once a day for up to 10 days.

Duration of treatment should be guided by clinical response and individual patient requirements.

Elderly, renal impairment, hepatic impairment: No dose adjustment is needed.

Local administration

Local infiltration and injection therapy is usually carried out with 3.3-6.6 mg; 1.65 mg of dexamethasone is sufficient if injected into small joints or administered by subconjunctival injection.

Method of administration

Dexamethasone 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.
Dexamethasone may also be administered by infiltration and by intraarticular 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 intraarticular injection should be considered open joint procedure and carried out under strict aseptic conditions. A single intraarticular 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 dexamethasone. Caution: do not inject into tendon! Frequent injections should be avoided, and strict aseptic precautions should be observed.

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

Instructions for use and other handling
For single use only.
Once opened, the medicinal product should be used immediately. Discard any remaining contents.

Inspect the ampoule visually prior to use. Only clear solutions free from particles should be used.
pH of solution between 7.0 – 8.5

This medicinal product must not be mixed with other medicinal products except those mentioned in below.

- Dexamethasone may decrease the effect of medicines for worm diseases (praziquantel).
- During concomitant use of medicines for malaria and rheumatic diseases (chloroquine, hydroxychloroquine, mefloquine), dexamethasone may increase the risk of muscle diseases or heart muscle diseases.
- Dexamethasone 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), dexamethasone 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): dexamethasone may increase the concentration of cyclosporine in the blood and thereby the risk of seizures.
- 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, 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 or pharmacist for advice before being given this medicine.

Pregnancy
Dexamethasone crosses the placenta. During pregnancy, especially in the first three months, the medicine should only be used after a 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 breast-feeding should be closely examined. If the disease requires higher doses, breast-feeding should be discontinued. Please contact your doctor immediately.

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

Dexamethasone contains sodium
This medicine contains about 3 mg sodium (main component of cooking/table salt) in each ml of solution. This is equivalent to 0.15 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Dexamethasone will be given

Use dexamethasone only as prescribed by your doctor. 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 or into the eye.
The daily dose will 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.

Dosage
The doctor will determine your dose individually depending on your condition. Please follow the instructions in order for dexamethasone to have the proper effect. 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.
In underactive thyroid or liver cirrhosis, your doctor may prescribe you low doses of this medicine or your dose may be reduced.

Duration of treatment
Your doctor will decide how long you should use dexamethasone for. The duration of treatment depends on the underlying disease and the course of the disease.

If you are given more Dexamethasone than you should
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 are not given Dexamethasone
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 receive a double dose to make up for a forgotten dose.

If you stop receiving Dexamethasone
Always follow the dosing schedule prescribed by the doctor. Do not stop using this medicine suddenly as this might be dangerous. 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. Your doctor will tell you how the treatment will be gradually reduced. Dexamethasone 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 or pharmacist.

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 dexamethasone. 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 reaction (rare) – 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, fungal, 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 or loss of vision. Rare cases of reversible exophthalmos, and after subconjunctival administration also herpes simplex keratitis, corneal perforation in cases of existing keratitis, blurred vision.

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, increased risk of atherosclerosis and thrombosis, inflammation of blood vessels (also as withdrawal syndrome after long-term treatment), increased fragility of blood vessels.

Gastrointestinal disorders
Gastrointestinal ulcers, gastrointestinal bleeding, inflammation of the pancreas, stomach discomfort, hiccup.

Skin and subcutaneous tissue disorders
Stretch marks, 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 and connective tissue 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, 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 sex 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 the sight and reach of children.

Do not store above 30 °C.
Keep the ampoules in the outer carton in order to protect from light.

After opening the ampoule: Once opened, the medicinal product should be used immediately.

Shelf life after dilution
Chemical and physical in-use stability has been demonstrated for 48 hours at 25 °C (protected from light) and 2 to 8 °C.
From a microbiological point of view, the diluted 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 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use this medicine after the expiry date which is stated on the outer carton and ampoule after EXP. The expiry date refers to the last day of that month.

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 Dexamethasone contains
– The active substance is dexamethasone.
Each 1 ml ampoule contains 3.3 mg of dexamethasone (as dexamethasone sodium phosphate).
Each 2 ml ampoule contains 6.6 mg of dexamethasone (as dexamethasone sodium phosphate).

– The other ingredients are creatinine, sodium citrate, disodium edetate, sodium hydroxide, water for injections.

What Dexamethasone looks like and contents of the pack
Clear, colourless solution free from visible particles.

1 ml or 2 ml Type I clear colourless glass ampoules with one point cut.
Ampoules are marked with a specific colour ring code.
Ampoules are packed in liners. Liners are packed in outer cartons.

Pack sizes:
3, 10, 25, 50 or 100 ampoules of 1 ml
5, 10, 25, 50 or 100 ampoules of 2 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
AS KALCEKS
Krustpils iela 71E, Rīga, LV-1057, Latvia
Tel.: +371 67083320
E-mail: kalceks@kalceks.lv

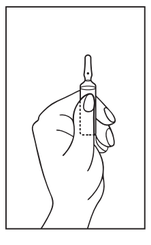
This leaflet was last revised in 05/2022

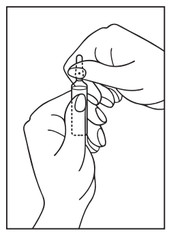
Place for AS Kalceks internal code
Place for manufacturer internal code

Dexamethasone solution for injection/infusion should preferably be administered by the direct intravenous route or injected into the infusion tube. However, the solutions for injection are compatible with the following solutions for infusion (250 ml and 500 ml):
– 9 mg/ml (0.9%) sodium chloride solution
– 50 mg/ml (5%) glucose solution
– Ringer's solution.

When combining with solutions for infusion, information from the respective manufacturers on their solutions for infusion, including data on compatibility, contraindications, undesirable effects and interaction, must be taken into account.

Instruction of ampoule opening
1) Turn the ampoule with coloured point up. If there is any solution in the upper part of the ampoule, gently tap with your finger to get all the solution to the lower part of the ampoule.
2) Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point (see the pictures below).





Any unused medicinal product or waste material should be disposed of in accordance with local requirements.