Package leaflet: information for the user

Dexamethasone phosphate 4 mg/ml solution for injection/infusion

dexamethasone phosphate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

Dexamethasone phosphate contains the active substance dexamethasone phosphate (further referred to as dexamethasone). Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone). It reduces inflammatory symptoms and intervenes in essential metabolic processes.

Systemic use (affects the entire body)

Dexamethasone phosphate is often used following emergency treatment started at high dose:
- Treatment and prophylaxis of cerebral oedema (swelling of the brain) in brain tumours (after surgery and after X-ray radiation) and after spinal cord trauma.
- State of shock due to a severe allergic reaction called ‘anaphylactic shock’ (e.g. contrast medium reaction).
- States of shock after severe injuries, prevention of post-traumatic ‘shock lung’ (acute respiratory insufficiency).
- Persistent severe symptoms of an asthma attack.
- Initial treatment of some extensive, acute, severe skin conditions (e.g. pemphigus vulgaris, erythroderma).
- Severe blood diseases (e.g. acute thrombocytopenic purpura, haemolytic anaemia, as co-medication as part of leukaemia treatments).
- As second-line treatment in patients with reduced or no adrenal cortex function (adrenocortical insufficiency, Addisonian crisis).

Dexamethasone phosphate 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 (affects restricted part of the body)

- Injection near the joints (periarticular) and treatment that penetrates the tissue (infiltrative), e.g. for inflammation of the shoulder joint (periarthritis scapulohumeralis), elbow joint (epicondylitis), the sacs that cushion the joints (bursitis), tendon sheath (tendovaginitis) and wrist (styloiditis).

- Injection into a joint (intraarticular injection), e.g. in rheumatoid arthritis, when individual joints are affected or respond inadequately to systemic treatment; accompanying inflammatory reactions in degenerative joint disease (rheumatoid arthritis).

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

You should not be given Dexamethasone phosphate
- If you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6).
- Infection affecting the whole body, including one which could have been caused by a fungus (e.g. thrush), which is not being treated with antibiotics.
- Injection into a joint must not be given in the following cases: infections within or in the immediate area of the joint to be treated; joint inflammation caused by bacteria (bacterial arthritis); instability of the joint to be treated; tendency to bleed (spontaneous or due to anticoagulants); calcium deposits near to the joint (periarticular calcification); localised death of bone tissue especially in the head of the humerus and thigh bone (avascular necrosis of the bone); tendon rupture; disease of a joint due to syphilis (Charcot's joint).
- Infiltration without additional treatment of the cause is contraindicated if there are infections within the area of administration.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given this medicine as special care is required, if:
- You have acute or chronic bacterial infection
- You have had tuberculosis
- You have fungal disease that affects internal organs
- You have parasitic disease (e.g. amoeba infection, threadworm infection)
- You have acute viral infection (hepatitis B, herpes infection, chickenpox)
- You (or your child) have been or have to be vaccinated (see "Other medicines and Dexamethasone phosphate"). Particularly tell your doctor if you have not yet had measles or chickenpox or your child's immune system is weakened
- You have stomach or intestinal ulcers
- You have osteoporosis (breakdown of bone tissue). Your doctor may want to determine your bone density before starting long-term treatment. Your doctor may prescribe you supplemental calcium, vitamin D and/or medicines for reduced bone density, if necessary. In patients with severe osteoporosis, this medicine will only be used for life-threatening reasons or over short periods
- You have difficult-to-control high blood pressure
- You have diabetes
- You have a history of psychic illness including risk of suicide
- You have increased pressure inside the eye (closed- and open-angle glaucoma), corneal injury or ulcers of the eye (as close monitoring and treatment by an eye specialist is required)
- You have heart or kidney disorders
- You have myasthenia gravis (a muscle disease) as symptoms may initially get worse after giving dexamethasone; the starting dose needs to be selected with caution;
- You have a tumour of the adrenal gland (pheochromocytoma).

If you are not sure if any of the above applies to you, ask your doctor or pharmacist for advice.

Tell your doctor if you notice any of the following symptoms while treated with this medicine:
- Muscle cramps, muscle weakness, confusion, impaired or loss of vision and shortness of breath, in case you have a malignant blood disease. These may be symptoms of tumour lysis syndrome.
- Blurred vision or other visual disturbances.

Simultaneous use of corticosteroids
You should not stop taking any other steroid medications unless your doctor has instructed you to do. General precautions regarding steroid use in specific diseases, masking infection, concomitant

medicines etc. should be in line with current recommendations.

Severe allergic reactions
Severe allergic reactions and even anaphylaxis (potentially life-threatening reaction) with symptoms such as irregular heartbeat, constriction of the respiratory muscles, decrease or increase in blood pressure, circulatory failure or cardiac arrest, can occur.

Adrenocortical insufficiency
Abrupt discontinuation of treatment that has lasted for more than 10 days can cause development of acute adrenocortical insufficiency. The dose should therefore be reduced slowly if discontinuation is intended. Depending on the dose and duration of therapy, adrenocortical insufficiency caused by glucocorticoid therapy may still persist for several months and, in individual cases, for more than one year after treatment has stopped.

If specific physical stress situations occur during treatment, such as feverish illness, accidents or surgery, the doctor must be informed immediately or the emergency doctor must be told about the ongoing treatment with dexamethasone. It may be necessary to temporarily increase the daily dexamethasone dose. Administration of glucocorticoids may also be required in physical stress situations if adrenocortical insufficiency persists after the end of therapy.

Risk of infection
Dexamethasone at doses higher than these required for maintenance therapy is associated with a higher risk of infection, possible worsening of a pre-existing infection and possible activation of a hidden infection. The anti-inflammatory effect can mask symptoms of infection until the infection has reached a higher level.

Gastrointestinal disorders
Due to the risk of bowel wall perforation with peritonitis (inflammation of peritoneum), this medicine will be used if there are compelling medical grounds, together with appropriate monitoring, in the following cases:
- severe inflammation of the colon (ulcerative colitis) with imminent perforation;
- abscesses or purulent (pus-filled) infections;
- diverticulitis (inflammation of bulges [known as diverticula] on the colon wall);
- after certain types of bowel surgery (intestinal anastomosis) immediately after surgery.

The signs of peritoneal irritation after perforation of a stomach or intestinal ulcer may be absent in patients receiving high glucocorticoid doses.

Long-term treatment
In long-term therapy, regular medical check-ups (including follow-up eye tests at 3-monthly intervals) are indicated; at comparatively high doses, adequate potassium intake (e.g. vegetables, bananas) and limited sodium (salt) intake should be ensured and blood potassium levels must be monitored. Careful monitoring is also indicated in patients with severe heart failure (inability of the heart to provide the required amount of ejected blood for metabolism, during exertion or even at rest).

Warnings related to specific methods of administration
- Into a vein, the medicine will be injected slowly (2-3 minutes) as too rapid injection may result in temporary unpleasant tingling or abnormal skin sensations lasting for up to 3 minutes. These effects are harmless in themselves.
- Injection into a joint of glucocorticoids increases the risk of joint infections. Prolonged and repeated use of glucocorticoids in weight-bearing joints can lead to a worsening of degenerative changes within the joint. One possible cause is overloading of the affected joint after pain or other symptoms have worn off.

Other warnings
- At high doses, decreased heart rate can occur.
- The risk of tendon disorders, tendon inflammation and tendon rupture increases when fluoroquinolones (antibiotics) are used at the same time as dexamethasone.

- In principle, vaccinations with dead (inactivated) vaccines are possible. However, it should be remembered that the immune response and hence successful vaccination may be compromised at higher doses.
- In elderly patients, the doctor will carefully outweigh the benefits and risks and look out for side effects such as osteoporosis (breakdown of bone tissue).
- If dexamethasone is given to a prematurely born baby, monitoring of heart function and structure is needed.

Children and adolescents
Dexamethasone should not be used routinely in premature babies with breathing problems.
In children and adolescents, treatment should only be given if there are compelling medical reasons, due to the risk of delayed growth. Where possible, intermittent therapy should be aimed for during long-term treatment.

Other medicines and Dexamethasone phosphate
Tell your doctor or pharmacist if you using, have recently used or might use any other medicines. Some medicines can increase the effects of dexamethasone and your doctor may want to carefully monitor you if you are using these medicines (including medicines for HIV: ritonavir, cobicistat).

Tell your doctor of pharmacist if you use any of the following medicines:
- medicines to treat heart failure (cardiac glycosides);
- medicines used to increase urine output;
- medicines to lower blood sugar levels (antidiabetics);
- medicines to prevent blood clots/blood thinners (coumarin derivatives);
- ephedrine (used for asthma and poor circulation);
- rifampicin (used to treat tuberculosis);
- medicines to treat seizures and epilepsy (phenytoin, carbamazepine, primidone);
- barbiturates (medicines to help you sleep);
- ketoconazole, itraconazole (used to treat fungal infections);
- medicines to treat infections (macrolide antibiotics e.g. erythromycin, or fluoroquinolones e.g. ciprofloxacin);
- pain relievers and anti-inflammatory/antirheumatic agents (e.g. salicylates and indometacin);
- contraceptives containing oestrogen;
- a medicine to treat intestinal parasite infestation (praziquantel);
- medicines to treat high blood pressure and some heart diseases (ACE inhibitors);
- antimalarial agents (chloroquine, hydroxychloroquine, mefloquine);
- somatropin (a growth hormone);
- laxatives;
- atropine and other anticholinergics (medicines that block the action of a certain brain neurotransmitter);
- medicines to relax the muscles;
- medicines that weaken the immune system (ciclosporin);
- bupropion (a smoking cessation aid).

Effect on testing methods: Skin reactions to allergy tests may be suppressed. Interactions are possible with a medicine used in thyroid tests (protirelin: the rise in TSH when protirelin is administered may be reduced).

If treatment with dexamethasone is carried out 8 weeks before and up to 2 weeks after active prophylactic vaccination, it can be expected that the effectiveness of such vaccination may be reduced or absent.

Pregnancy, breast-feeding and fertility
Pregnancy
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.
Dexamethasone crosses the placenta. During pregnancy, especially in the first three months, it should

only be used after a careful benefit/risk assessment. Therefore, women should inform the doctor if they are or become pregnant. During long-term treatment 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 in the newborn, which has to be slowly reduced. Newborn babies of mothers who received Dexamethasone phosphate near the end of pregnancy may have low blood sugar levels after birth.

Breast-feeding
Glucocorticoids are excreted in human milk. No harm to the infant has been reported to date. Nevertheless, they should be used only when strictly indicated during breast-feeding. If higher doses have to be used, breast-feeding should be stopped.

Fertility
No fertility studies have been performed.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.

Dexamethasone phosphate 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 phosphate will be given

This medicine should be used as only as prescribed by your doctor. Your doctor will decide how long you should use dexamethasone for. Check with your doctor or pharmacist if you are not sure.

This medicine may be given into a vein, into a muscle, into a joint or by soft tissue infiltration.

The dosage depends on the indication, severity of symptoms, the patient's individual response and, in case of injection into a joint, the size of the joint.

Glucocorticoids should only be used for as long – and only at such low doses – as absolutely necessary to achieve and maintain the desired effect. Duration of use is guided by the indication. Prolonged use of dexamethasone must not be stopped suddenly, but rather the dose must be reduced gradually, as directed by the doctor.

For the treatment of COVID-19
Adult patients are recommended to be given 6 mg into a vein once a day for up to 10 days.

Use in adolescents: Paediatric patients (adolescents of 12 years of age or older with body weight at least 40 kg) are recommended to be given 6 mg into a vein once a day for up to 10 days.

Renal impairment
No dose adjustment is necessary.

Hepatic impairment
In patients with severe liver disease dose adjustment may be necessary.

Children and adolescents
In children up to 14 years of age, a 4-day treatment-free interval should be inserted after each 3-day course of treatment, during long-term treatment, due to the risk of growth disorders.

If you are given more Dexamethasone phosphate than you should
There are no known cases of acute poisoning with dexamethasone. In case of overdose, increased side

effects are to be expected. If you think you have been given too much of this medicine, tell your doctor straight away.

If you stop using Dexamethasone phosphate
The treatment must not be interrupted or stopped abruptly, unless instructed by a doctor. Nevertheless, if you decide to stop the treatment on yourself, e.g. due to side effects that occur or because you feel better, not only will you be putting the success of your treatment at risk, you will also be exposing yourself to significant risks. In particular, after prolonged period of treatment, you must never stop this medicine by yourself. You must always consult your doctor first.

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.

In short-term treatment with dexamethasone, the risk of side effects is low. The following side effects are possible:
- stomach or duodenal ulcers;
- reduction in the body's defences against infections;
- increased blood sugar level (decrease in glucose tolerance).

The following side effects may occur, which are highly dependent on the dose and duration of therapy and whose frequency is therefore not known (frequency cannot be estimated from the available data):

Infections and infestations
Masking of infections, fungal, viral and other infections (opportunistic infections) encouraged to develop or get worse, threadworm activation (see section 2, "Warnings and precautions").

Blood and lymphatic system disorders
Changes in blood counts (moderate leukocytosis, lymphocytopenia, eosinopenia, polycythaemia).

Immune system disorders
Hypersensitivity reactions (e.g. rash), weakening of the immune system, allergic reactions and even anaphylaxis (an acute allergic life-threatening reaction), with symptoms such as irregular heartbeat, constriction of the respiratory muscles, decrease or increase in blood pressure, circulatory failure, cardiac arrest.

Hormone system disorders
Cushing's syndrome (e.g. moon face, obesity of the upper body), adrenocortical inactivity or shrinkage (atrophy).

Metabolism and nutrition disorders
Sodium retention in the body with water accumulation in tissue, increased potassium excretion (caution: heart rhythm disorders possible), weight gain, increased blood sugar levels (reduced glucose tolerance), diabetes, increased blood fat levels (cholesterol and triglycerides), increased appetite.

Psychiatric disorders
Psychosis, depression, irritability, euphoria (excessive happiness), sleep disorders, lability, anxiety, mania, hallucinations, suicidal thoughts.

Nervous system disorders
Pseudotumor cerebri ("false" tumour in the brain), first-time appearance of epilepsy promoted in patients with latent (previously "dormant") epilepsy and increased susceptibility to seizures in pre-existing epilepsy (fits).

Eye disorders
Glaucoma, cataracts, worsening of corneal ulcer symptoms, promotion of viral, fungal and bacterial eye inflammation; worsening of bacterial inflammation of the cornea, drooping eyelid (ptosis), dilated pupils, oedema of the conjunctiva in the eye, iatrogenic scleral perforation (doctor-induced injury to the sclera [white wall of the eye]), impaired or loss of vision, blurred vision. In rare cases, reversible eyeball protrusion (exophthalmos).

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 (change in the blood vessel wall) and thrombosis (blood vessel blockage by a blood clot), inflammation of the blood- and lymphatic vessels (vasculitis, also as a withdrawal syndrome after long-term treatment), fragility of the blood vessel wall (capillary fragility).

Gastrointestinal disorders
Stomach complaints, gastrointestinal ulcers, gastrointestinal bleeding, inflamed pancreas, risk of bowel perforation in ulcerative colitis (severe inflammation of the large bowel).

Skin and subcutaneous tissue disorders
Stretch marks, thinning of the skin, pinpoint bleeding under the skin, bruising, steroid acne, inflammation of the skin around the mouth, dilation of superficial blood vessels, excessive body hair, changes in skin pigmentation.

Musculoskeletal and connective tissue disorders
Muscle weakness, muscle wasting, inflammatory muscle disease, tendon disorders, tendon inflammation, tendon rupture, breakdown of bone tissue (osteoporosis), delayed growth in children, aseptic bone necrosis (death of bone tissue with no germ involvement), increased fatty tissue in the spinal canal.

Reproductive system and breast disorders
Disorders of sex hormone secretion, such as absent monthly periods, excess male-pattern hair growth in women, impotence.

General disorders and administration site conditions
Delayed wound healing.

Local use
Local irritation and signs of intolerability are possible (sensations of heat, prolonged pain), especially when used in the eye. The development of tissue wasting cannot be ruled out if dexamethasone is not carefully injected into the joint 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexamethasone phosphate

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 phosphate contains
- The active substance is dexamethasone phosphate.

Each 1 ml ampoule contains 3.32 mg of dexamethasone (as dexamethasone sodium phosphate) which is equivalent to 4 mg of dexamethasone phosphate or 4.37 mg dexamethasone sodium phosphate.
Each 2 ml ampoule contains 6.64 mg of dexamethasone (as dexamethasone sodium phosphate) which is equivalent to 8 mg of dexamethasone phosphate or 8.74 mg dexamethasone sodium phosphate.

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

What Dexamethasone phosphate 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
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This medicine is authorised in the Member States of the European Economic Area under the following names:

Estonia	Dexamethasone Kalceks
Austria, Germany	Dexamethason Kalceks 4 mg/ml Injektions-/Infusionslösung
Croatia	Deksametazon Kalceks 4 mg/ml otopina za injekciju/infuziju
Czech Republic, Poland	Dexamethasone Kalceks
Denmark, Norway	Dexamethasone phosphate Kalceks

Finland	Dexalcex 4 mg/ml injektio-/infuusioneste, liuos
France	DEXAMETHASONE KALCEKS 4 mg/1 mL, solution injectable/pour perfusion
Hungary	Dexamethasone Kalceks 4 mg/ml oldatos injekció vagy infúzió
Ireland	Dexamethasone phosphate 4 mg/ml solution for injection/infusion
Italy	Desametasone Kalceks
Latvia	Dexamethasone Kalceks 4 mg/ml šķīdums injekcijām/infūzijām
Lithuania	Dexamethasone Kalceks 4 mg/ml injekcinis ar infuzinis tirpalas
The Netherlands	Dexamethasonfosfaat Kalceks 4 mg/ml oplossing voor injectie/infusie
Portugal	Dexametasona Kalceks
Slovenia	Deksametazon Kalceks 4 mg/ml raztopina za injiciranje/infundiranje
Spain	Dexametasona Kalceks 4 mg/ml solución inyectable y para perfusión EFG
Sweden	Dexalcex

This leaflet was last revised in 01/2022

The following information is intended for healthcare professionals only:

Posology and method of administration

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

All dosage recommendations are given in units of dexamethasone phosphate

1. Systemic use

For **treatment and prophylaxis of cerebral oedema in brain tumours (postoperatively and after X-ray radiation) and after spinal cord trauma**
Depending on cause and severity the initial dose is 8-10 mg (up to 80 mg) IV, then 16-24 mg (up to 48 mg)/day divided into 3-4 (6) single doses IV over 4-8 days. Long-term, lower-dose administration of dexamethasone phosphate may be necessary during radiation therapy and in the conservative treatment of inoperable brain tumors.

For **anaphylactic shock**, first adrenaline injection IV, then 40-100 mg (children 40 mg) IV injection, repeated as necessary.

Polytraumatic shock / prophylaxis of post-traumatic shock lung
Initially 40-100 mg (children 40 mg) IV, repetition of the dose after 12 hours, or every 6 hours 16-40 mg for 2-3 days.

For **severe exacerbations of asthma**, 8-40 mg IV as early as possible; if needed, repeated injections of 8 mg every 4 hours.

For **acute severe dermatosis** and **severe blood diseases**, initial treatment with 20-40 mg dexamethasone phosphate IV and further treatment depending on the severity of the case, with the same daily dose or lower doses within the first few days and switch to oral therapy.

For treatment of **acute adrenocortical insufficiency** (Addisonian crisis), initiation of therapy with 4-8 mg dexamethasone phosphate IV.

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

Elderly, renal impairment, hepatic impairment (at low dose (6 mg daily) and short duration): No dose adjustment is needed.

Paediatric population: Paediatric patients (adolescents aged 12 years and older with body weight at least 40 kg) are recommended to use 6 mg IV, once a day for up to 10 days.
Duration of treatment should be guided by clinical response and individual patient requirements.

2. Local use

For local infiltrative, periarticular and intraarticular therapy under strictly aseptic conditions, injection of 4 mg or 8 mg dexamethasone phosphate. For injection into a small joint, 2 mg dexamethasone phosphate is sufficient. Depending on the severity of the disease, no more than 3-4 infiltrations or 3-4 injections per joint should be performed. The interval between injections should be not less than 3-4 weeks.

Method of administration
For intravenous, intramuscular, intraarticular or local use (infiltration).
Dexamethasone phosphate solution for injection/infusion is usually administered slowly (2-3 minutes) intravenously in acute diseases, by injection or infusion. However, it can also be administered intramuscularly (only in exceptional cases), as a local infiltration or intraarticularly.

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

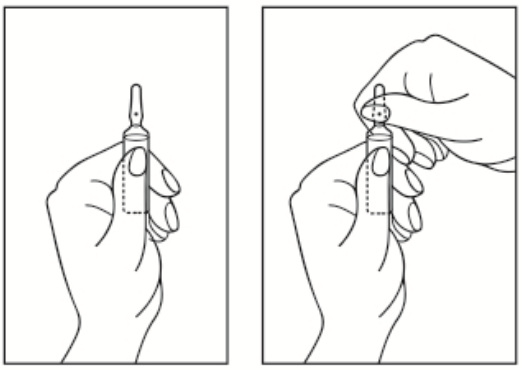
Inspect the ampoule visually prior to use. Only clear solutions free from particles should be used.
pH of solution between 7.0 – 8.5

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

Dexamethasone phosphate 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.