



Dexamethasone 3.3 mg/ml, solution for injection

Dexamethasone (as sodium 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.
- 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 is and what it is used for
2. What you need to know before you use Dexamethasone
3. How to use Dexamethasone
4. Possible side effects
5. How to store Dexamethasone
6. Contents of the pack and other information

1. What Dexamethasone is and what it is used for

Dexamethasone 3.3 mg/ml, solution for injection contains the active substance dexamethasone (as sodium phosphate), which belongs to a group of medicines called steroids (specifically known as corticosteroids). Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone).

Corticosteroids occur naturally in the body and help to maintain health and well-being. Synthetic steroids such as dexamethasone work by mimicking some of their actions to treat disease.

Corticosteroids are given to patients for a variety of conditions where their abilities to reduce inflammation and suppress the immune system are valuable. These conditions may include Crohn's disease, asthma, shock, anaphylaxis, tuberculosis, arthritis, osteoarthritis, and skin disorders including acne.

Dexamethasone PANPHARMA 3.3 mg/ml is used as a treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) with difficulty breathing and need of oxygen therapy.

2. What you need to know before you use Dexamethasone

Do not use Dexamethasone:

- If you are allergic to dexamethasone, related substances 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 (e.g. thrush), which is not being treated. However, your doctor may decide to treat you with Dexamethasone under certain circumstances.
- If you are to be vaccinated by live virus vaccines.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before Dexamethasone is used.

- If you have ever had severe depression or manic depression (bipolar disorder). This includes having had depression before while taking steroid medicines like dexamethasone.
- If any of your close family has had these illnesses.

If either of these applies to you, talk to a doctor before taking dexamethasone.

- Mental health problems while taking dexamethasone: Mental health problems can happen while taking steroids like dexamethasone (see also section 4 Possible side effects). These illnesses can be serious. Usually they start within a few days or weeks of starting the medicine. They are more likely to happen at high doses. Most of these problems go away if the dose is lowered or the medicine is stopped. However if problems do happen, they might need treatment.

Talk to a doctor if you (or someone taking this medicine), show any signs of mental health problems.

This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental health problems have happened when doses are being lowered or stopped.

Patients taking Dexamethasone should avoid, if possible, close personal contact with people suffering from chickenpox, shingles or measles. If you think you may have been exposed to either disease, **it is vital that you inform your doctor immediately**. You should also tell your doctor whether or not you have had common infectious diseases such as measles or chickenpox and of any vaccinations you have had. If you develop either disease, you will need specialist treatment from your doctor.

Corticosteroids may mask some signs of infection and new infections may appear during their use. Your doctors will try to use the smallest dose necessary to help you. However there may be times when an increase in dose will be needed. Any reduction in dose will need to be made more slowly than an increase. You should see your doctor if you develop any new infections while taking this medicine.

Take special care when using Dexamethasone if you have:

- Liver, kidney or heart problems (heart attack for example);
- High blood pressure;
- Epilepsy;
- A history of migraines;
- Osteoporosis (thinning of the bones);
- Had tuberculosis in the past;
- An under-active thyroid;
- Had amoebiasis in the past (infection specific to tropical countries which causes diarrhoea);
- A herpes infection of the eye;
- Diabetes (or a family history of diabetes);
- An eye disease called glaucoma (or a family history of glaucoma);
- Stomach ulcers;
- Experienced muscle weakness caused by previous steroid treatment;
- Suffered from myasthenia gravis (a disease causing weak muscles).

Talk to your doctor before taking this medicine if:

- You have a tumour of the adrenal gland (pheochromocytoma).

You should also tell your doctor if you have symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath, in case you suffer from haematological malignancy.

If you have an accident, fall ill, require any surgery (including at the dentist's) or are to have any vaccinations (especially with so-called 'live virus vaccines') during or after treatment with Dexamethasone, you must tell the doctor treating you that you are taking or have taken steroids.

In the case of local injection of Dexamethasone (e.g. injection into a joint), your doctor will take special care to reduce the particular risk of bacterial infection. This medicine should not be injected directly into an infected site.

Please tell your doctor if you suffer from complications like a marked increase in pain accompanied by local swelling, further restriction of joint motion, fever or malaise after a local injection of this medicine. Your doctor will have to check if you suffer from blood poisoning and take the appropriate action.

Injection into unstable joints should be avoided.

Please be advised not to over-use joints that are still diseased, even if you do not suffer pain.

IMPORTANT: all patients taking steroids drugs for more than a few days should carry "steroids treatment card", which are available from your pharmacist. These cards carry details of your medicine and your doctor.

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

Talk to your doctor, pharmacist or nurse before you take Dexamethasone PANPHARMA.

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

Preterm neonates (premature babies)

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

There may be an increased risk of the development of cerebral palsy when Dexamethasone is used to treat or prevent chronic lung disease in pre-term infants.

Children and adolescents

If the patient is an infant or a child, it is important that the doctor monitors his/her growth and development at intervals during treatment because this medicine can cause growth retardation.

Other medicines and Dexamethasone

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

Some other medicines do not mix with Dexamethasone. Your doctor is aware of these and will adjust your treatment as necessary. However, it is very important that you tell your doctor all the medicines you are taking, including those obtained without a doctor's prescription.

You should not be vaccinated with a live vaccine while having steroid therapy. Tell your doctor or pharmacist if you are planning to have a vaccination.

If you are taking any of the following medicines you should talk to your doctor before starting treatment with Dexamethasone:

- Aspirin or similar medicines;
- Phenytoin (used to treat epilepsy);
- Ephedrine (a nasal decongestant);
- Barbiturates (sedative drugs used to treat sleeplessness and epilepsy);
- Antibiotics called rifampicin and rifabutin (used to treat tuberculosis);
- Anticoagulant medicines which thin the blood;
- Medicines for diabetes;
- Certain diuretics (water tablets);
- A medicine called carbamazepine, used to treat epilepsy, pain and manic depression;
- An anticancer medicine called aminoglutethimide;
- Antiretroviral medicines e.g. ritonavir, darunavir, indinavir, lopinavir, saquinavir and efavirenz.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding.

If you receive dexamethasone often or over a long period of time during pregnancy there may be a risk that the baby's growth slows down. The baby may need careful observation for a short time after being born.

If you are given dexamethasone for a long time during breast-feeding then the baby's growth may slow down and it may have other side effects (see Section 4). Your doctor will discuss this with you and decide whether you should receive dexamethasone.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Do not drive or use machines if you experience any side effect which may lessen your ability to do so.

Dexamethasone contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg per ampoule), i.e. essentially sodium-free.

3. How to use Dexamethasone

You have been given or are about to be given Dexamethasone by a healthcare professional. This medicine will be given as an injection either intravenously (injection into a vein), intramuscularly (injection into a muscle) or directly into a joint or soft tissue. Your doctor will decide what the appropriate dose for your condition is, and may alter your dose depending on how you respond. The usual initial dose ranges from 0.4 mg-16.6 mg (0.125-5 ml) per day, with repeat dosing depending on your condition.

For some patients the medicine may be given as an injection into the painful area itself, usually once every 3 to 5 days or once every 2-3 weeks depending on your response.

Take Dexamethasone PANPHARMA as only as prescribed by your doctor. Your doctor will decide how long you should take dexamethasone for. Check with your doctor or pharmacist if you are not sure.

For the treatment of Covid-19

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

Use in adolescents

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

If you receive more Dexamethasone than you should

The times at which you are to have your injections will be set by your healthcare professional. Your doctor will monitor your response and condition to determine what treatment is needed. If you are concerned that you may have been given too much Dexamethasone by mistake, contact your doctor or healthcare professional immediately.

If you receive less Dexamethasone than you should

The times at which you are to have your injections will be set by your healthcare professional. Your doctor will monitor your response and condition to determine what treatment is needed. However, if you are concerned that you may have missed a dose, you should notify your healthcare professional as soon as possible.

If use of Dexamethasone is stopped

IMPORTANT: It can be dangerous to stop your treatment with Dexamethasone abruptly. How your treatment is stopped will depend on the disease you are being treated for and how much Dexamethasone you have been given. It may be necessary to reduce the amount of Dexamethasone you are given gradually until you stop having it altogether.

The symptoms that have been reported when treatment has been stopped too quickly included low blood pressure and in some cases, relapse of the disease for which the treatment was given.

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.

If you experience any of the following please contact your doctor immediately as you may need urgent medical attention:

- **Severe allergic reaction** which may include a sudden itchy rash, swelling of the extremities (such as your hands and feet) and a swelling of your mouth and throat (which may cause difficulty in breathing);
- Severe infection and/or fever which makes you feel very ill;
- If you experience sudden and (in cases of long-term therapy) unusual effects like a feeling you are going to faint, bleeding, extreme weakness, or a sudden pain in any of your organs.

The following unwanted side effects have been reported for Dexamethasone and are listed below according to the organs that are affected.

Psychiatric disorders (mental health problems)

Steroids including dexamethasone can cause serious mental health problems.

These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like dexamethasone.

- Feeling depressed, including thinking about suicide;
- Feeling high (mania) or moods that go up and down;
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory;
- Feeling, seeing or hearing things which do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone.

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

Carers of patients receiving Dexamethasone should talk to a doctor immediately if the patient shows any signs of mental health problems. This is particularly important if the patient appears to be depressed, or mentions thoughts of suicide.

If you suffer from schizophrenia or epilepsy your symptoms may worsen.

Infections and infestations

You may experience more frequent and severe infections without noticing the symptoms as well as opportunistic infections (caused by a usually harmless microorganism in case of an impaired immune system) or the recurrence of dormant tuberculosis.

Abnormal growth of tissue

You may develop sterile abscesses (enclosed collections of pus, likely to turn into hard solid lumps as they scar).

Blood systems

There may be an abnormal increase in the number of white blood cells.

Hormonal (endocrine disorders)

Menstrual irregularities, lack of menstruation, abnormal hair growth, development of Cushingoid state (symptoms of which include central obesity with thin arms, thinning of the skin with easy bruising, muscle wasting and weakness, high blood pressure, uncontrolled blood sugar, osteoporosis).

Children and adolescents may have suppressed growth. Your response to stress caused by trauma, surgery or illness may be reduced. You may also experience decreased carbohydrate tolerance, onset of latent diabetes mellitus, increased need for insulin or other medicines if you are diabetic.

Metabolism and nutrition disorders

You may notice that you gain weight or have an increased appetite. Your body may also have difficulty in handling nitrogen, calcium, sodium or potassium appropriately.

Nervous system disorders

You may feel increased pressure in your head with impaired vision, vertigo, headache or in preterm infants cerebral palsy (malformation of the brain) may occur.

Eye disorders

You may develop cataracts or feel increased pressure in the eye or notice abnormal bulging out of the eyeballs or thinning of the cornea or the white, outer coat of the eyeball. Your vision may become blurred due to congestion of the optic disc or glaucoma with possible damage to the optic nerves. Secondary eye infections due to fungi or viruses can occur as can rare instances of blindness associated with local therapy around the face and head. Premature babies may suffer retinopathy. You may also develop visual disturbances or loss of vision (chorioretinopathy).

Disorders of the blood vessels or heart

High blood pressure, blood clots in the veins. Susceptible patients may develop heart failure, or the heart tissue may rupture following a recent heart attack. In infants with a low birth weight a heart muscle disease (hypertrophic cardiomyopathy) may occur.

If you are treated for multiple myeloma with dexamethasone in combination with lenalidomide or thalidomide you will have an increased risk of thromboembolic events including: Deep vein thrombosis (a blood clot in the veins of your leg) – a symptom of this is leg pain; Pulmonary embolism (a blood clot in the arteries leading to your lungs) – a symptom of this is chest pain or shortness of breath.

Disorders of the stomach or the digestive system

You may suffer nausea, hiccups, heartburn or reflux or infection or inflammation of the tube that leads to your stomach. Peptic ulcer may occur with possible bleeding or perforation of the small and large bowel (particularly if you have inflammatory bowel disease). Your pancreas may become inflamed (pancreatitis) or your stomach may swell.

Skin disorders

Your skin may become thin or fragile with red or blood spots or bruising or it may become lighter or darker (hypo- or hyperpigmentation). Your face may become unusually red or you may have acne, swelling around the eyes, mouth and hands, hives, allergic dermatitis or stretch marks. Wounds may take longer to heal, skin tests may be affected and you may sweat more. After injection into a vein you may feel a burning or tingling sensation especially in the perineal area (skin between anus and genital organs).

Muscle and bone disorders

You may suffer muscle weakness, loss of muscle mass, osteoporosis (loss of bone density) especially if you are postmenopausal, vertebral compression fractures (collapsing of a bone in the spine), aseptic necrosis of femoral and humeral heads (severe knee and hip joint problem, possibly requiring replacement joints), fracture of long bones, tendon rupture, post-injection flare (following local injection e.g. into a joint).

Reproductive system

The number and activity of spermatozoa may be affected in men.

General disorders

You may have a general ill feeling.

Many of these side effects are serious therefore please tell your doctor about your symptoms as soon as possible.

Please note that it is very important that you do not suddenly stop taking this medicine (even if you are suffering from a side effect) unless your doctor tells you to.

If you think this injection is causing you any problems, or you are at all worried, talk to your doctor, nurse or pharmacist.

Because of these potential side effects, your doctor will want to monitor you at intervals during your treatment.

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 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 use this medicine after the expiry date which is stated on the ampoule and carton as "EXP". The expiry date refers to the last day of that month.

Store in the outer pack to protect from light.

Chemical and physical in-use stability has been demonstrated for 48 hours at 25°C protected from light when diluted with the infusion fluids listed in 6.6. 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 to 8°C, unless reconstitution and dilution have taken place in controlled validated aseptic conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any 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 (as sodium phosphate).

Each 1 ml contains 3.3 mg dexamethasone (as sodium phosphate) which is equivalent to 4 mg dexamethasone phosphate or 4.37 mg dexamethasone sodium phosphate. Each 2 ml contains 6.6 mg dexamethasone (as sodium phosphate) which is equivalent to 8 mg dexamethasone phosphate or 8.74 mg dexamethasone sodium phosphate.

The other ingredients are: creatinine, sodium citrate, citric acid hydrate, sodium hydroxide, water for injection.

What Dexamethasone looks like and contents of the pack
Solution for injection in 1 ml or 2 ml colourless glass ampoules.

Boxes of 5 or 10 ampoules of 1 ml and 2 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

PANPHARMA

Z.I. du Clairay

35133 Luitré

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Manufacturer

PANPHARMA GmbH

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INFORMATION FOR HEALTHCARE PROFESSIONALS

The following information is intended for medical or healthcare professionals only.

Dexamethasone may be administered intravenously, intramuscularly or intraarticularly.

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

Incompatibilities

Dexamethasone (as sodium phosphate) is physically incompatible with daunorubicin, doxorubicin and vancomycin and should not be admixed with solutions containing these drugs. It is also incompatible with doxapram hydrochloride and glycopyrrolate in a syringe.

Instructions for use and handling

Dexamethasone can be diluted with the following infusion fluids:

- sodium chloride 0.9%

- anhydrous glucose 5%

Using these infusion fluids, Dexamethasone can also be injected into the infusion line without causing precipitation of the ingredients.

For single use only.

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

In-use storage precautions

Diluted solution: should be used immediately.

Chemical and physical in-use stability has been demonstrated for 48 hours at 25°C protected from light when diluted with the infusion fluids listed in 6.6. 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 to 8°C, unless reconstitution and dilution have taken place in controlled validated aseptic conditions.