PACKAGE LEAFLET

Package leaflet: Information for the patient

Pantadexa 5 mg/ml solution for injection/infusion
dexamethasone sodium 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pantadexa is and what it is used for

Pantadexa is a solution containing dexamethasone sodium phosphate, which is quickly transformed into dexamethasone by the body after injection. The active substance is dexamethasone.

Dexamethasone belongs to a group of medicines called corticosteroids. It is a synthetic glucocorticoid (adrenocortical hormone).
Corticosteroids are hormones that are naturally present in your body. They help you stay healthy and well. Corticosteroids, like Pantadexa, are used for the treatment of various inflammatory conditions. This medicine reduces the inflammation, which otherwise would weaken you. You must be given this medicine regularly in order to get the most benefit from it.

Pantadexa may be used:
- to reduce inflammation
- in the treatment of several conditions of the immune system, including
- rheumatism (pain, stiffness or restricted mobility in joints, muscles and tendons);
- inflammations, including inflammation of joints and tissue around joints (rheumatoid arthritis), inflammation of the skin, inflammation of the eyes, blood vessels and other parts of the body;
- allergic conditions that cause pain, rash and fever;
- hypersensitivity reactions (allergic reactions) to other medicines or mosquito bites;
- anaphylactic shock (serious acute allergic reaction);
- asthma;
- possible organ or tissue transplant rejection;
- adrenal disorders;
- swelling of the brain and as part of the treatment of some types of cancer;
- systemic lupus erythematosus.

Pantadexa 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 are given Pantadexa

Pantadexa must not be given
- If you are allergic (hypersensitive) to dexamethasone or any of the other ingredients of

this medicine (listed in section 6).
Signs of an allergic reaction are e.g. rash, itching or difficulty breathing.
- If you have an infection that affects your whole body.
- If you have a joint infection.
- If you have unstable joints. This is a condition when the joints, such as the knee joint, may suddenly give way.

You must not be given this medicine if any of the above apply to you. Talk to your doctor or pharmacist before receiving Pantadexa.

Warning and precautions
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 are given Pantadexa.
General precautions regarding steroid use in specific diseases, masking infection, concomitant medicines etc. in line with current recommendations.

Talk to your doctor, pharmacist or nurse before you are given Pantadexa, if
- corticosteroid treatment has earlier caused you allergic reactions. In relation to the use of corticosteroids administered as an injection severe allergic reactions (including shock) have occurred;
- you have kidney or liver problems;
- you have high blood pressure or heart problems;
- you have diabetes or a family history of diabetes;
- you have thinning of the bones (osteoporosis), especially if you are a post-menopausal woman;
- you previously have had muscle weakness caused by using this or another steroid medicine;
- you have intraocular pressure (glaucoma) or a family history of glaucoma;
- you have stomach ulcers (peptic ulcer);
- you have a mental health problem or you have had a mental health disorder, which worsened when using this type of medicine, such as 'steroid psychosis';
- you have epilepsy;
- you have migraines;
- you have an infection caused by parasites;
- you have tuberculosis;
- you have slow growth;
- you have Cushing's syndrome;
- you have had a head injury;
- you have had a stroke;
- you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands).

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

If you have used Pantadexa for an extended period of time, treatment cannot be stopped suddenly.
If any concomitant illness, trauma or surgery occurs during prolonged treatment, your doctor may decide to temporarily increase your dose.
Pantadexa can mask the symptoms of an infection and new infections may develop during treatment.

Under certain conditions you should not be vaccinated during treatment. You doctor will decide if the restriction applies to you. Exposure to chickenpox and measles should be avoided during treatment if you have not had them before. Contact your doctor if you, for some reason, have been exposed to chickenpox or measles.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before you are given Pantadexa.

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

Pheochromocytoma crisis
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 the following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience any of these signs.

Children
If your child is receiving Pantadexa, it is important that your doctor monitors his or her growth or development regularly.

Pantadexa should not be used routinely in pre-term neonates with respiratory problems.

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

If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

Other medicines and Pantadexa
Tell your doctor if you are taking, have recently taken or might take any other medicines. Some medicines may cause side effects, and the effect of some medicines may change, or they may change the effect of dexamethasone if used concomitantly.

This is especially the case with:
- medicines used to treat cardiac and blood circulation problems, such as warfarin, medicines used to treat high blood pressure and water pills (diuretics);
- antibiotics, such as rifampicin and rifabutin;
- Dexamethasone may reduce the effects of medicines that are eliminated from the body by the liver enzyme (CYP3A4), for example HIV protease inhibitors (such as indinavir) and certain antibiotics (erythromycin);
- Some medicines may increase the effects of Pantadexa and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat);
- medicines to treat epilepsy, such as phenytoin, carbamazepine, and primidone;
- medicines for treating pain and inflammation, such as aspirin;
- medicines, used to treat diabetes;
- medicines to reduce potassium levels;
- medicines to treat myasthenia;
- anti-cancer medicines, such as aminoglutethimide;
- ephedrine, used as a nasal decongestant;
- acetazolamide used for treatment of glaucoma;
- Dexamethasone may influence the effect of certain anticoagulants (coumarins used to prevent blood clots);
- carbenoxolone, used sometimes for wound care.

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 you are given this medicine.
Newborn babies of mothers who received Pantadexa near the end of pregnancy may have low blood sugar levels after birth.

Driving and using machines
Glucocorticoids can cause mood swings or vision problems. If you experience any of these, caution should be exercised when driving or using machines.

Pantadexa contains propylene glycol and sodium
This medicine contains 20 mg propylene glycol in each ampoule.
This medicine product contains less than 1 mmol sodium (23 mg) per ampoule, i.e. is practically "sodium-free".

3. How Pantadexa is given

Pantadexa is normally given by your doctor. Pantadexa is given only as prescribed by your doctor. Your doctor will decide how long you should be given this medicine for. Check with your doctor or pharmacist if you are not sure.
It is given as an injection into a muscle or under the skin. The medicine may also be given as an injection in a vein. The dose depends on your illness and its severity. The usual dose for adults is 0,5-24 mg daily and for children 0,2-0,4 mg/kg daily. Your doctor will decide on the dose.

For the treatment of Covid-19:
Adult patients are recommended to be given IV 7,89 mg (which is equivalent to 6 mg of dexamethasone base) 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 7,89 mg (which is equivalent to 6 mg of dexamethasone base) once a day for up to 10 days.

If you are given more Pantadexa than you should
Tell your doctor immediately if you think you have been given too much Pantadexa. The following side effects may occur:
- swelling of the throat
- skin reaction
- breathing difficulties

If you stop receiving Pantadexa
Do not stop receiving this medicine suddenly as this might be dangerous. Please follow the instructions of your doctor if you need to stop the treatment with this medicine. The doctor may order a gradual reduction in the amount of medicine you receive until you stop the treatment completely. If you stop receiving this medicine too soon your condition may get worse.

You may also experience some withdrawal symptoms. This are, among others, headache, vision problems (including pain and swelling in the eye) feeling sick or nausea, fever, muscle and joint pain, swelling inside the nose, loss of weight, itchy skin, and conjunctivitis.

If you have any 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.

Pantadexa may also cause side effects when you stop receiving it.
- See section 3 'If you stop receiving Pantadexa'

Serious side effects: tell your doctor immediately
Steroids, including Pantadexa may cause serious mental health problems. These are common in both adults and children. Mental health problems can affect about 5 in every 100 people taking medicines like Pantadexa. They include:
- feeling depressed, including suicidal thoughts;
- feeling high (mania) or moods that go up and down;
- feeling anxious, having problems sleeping, problems with thinking, or confusion and memory loss;
- feeling, seeing or hearing things, which do not exist;

- having strange and frightening thoughts that change how you act or having feelings of being alone.

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

If you are having an allergic reaction to Pantadexa, see a doctor straight away.
An allergic reaction may include:
- any rash or itchy skin
- breathing difficulties or fainting
- angioedema (swelling of the face, lips, tongue and/or throat or difficulty breathing).

If you get any of the following side effects, contact your doctor as soon as possible:
- **Gastrointestinal problems**: stomach ulcers that may burst or bleed, indigestion, diarrhoea, feeling sick or nausea.
- **Pancreatitis**.
- **Problems with electrolytes,** such as too much sodium or too little potassium or calcium. Water retention in your body.
- **Cardiac and circulatory problems**: high blood pressure, blood clots, thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies, that generally returns to normal after stopping treatment (frequency not known).
- **Skeletal problems**: thinning of bones (osteoporosis), including increased risk of fractures, skeletal disease, tendon damages, tendon damage at the injection site.
- **Recurring infections**, which get worse every time, like chicken pox. Also yeast infection.
- **Skin problems**: wounds healing more slowly, bruising, acne, sweating more than usual. Burning sensation and swelling at injection site. This will not last long.
- **Eye problems**: increased eye pressure, including glaucoma, eye disorders, such as cataracts, eye infections, vision impairment, loss of vision, blurred vision.
- **Hormonal problems**: irregular or absence of periods, slow growth in children or adolescents, swelling of face ('Cushingoid' or 'lunar face'); this may have an effect on your diabetes and you may find that you might start to need higher doses of antidiabetic medicine, your body may not be able to respond normally to severe stress, such as accidents, surgeries or illness, increased growth of extra body hair (especially in women), increased appetite or weight gain.
- **Nervous system problems**: worsening of seizures or epilepsy, severe unusual headache with vision problems, insomnia, feeling depressed, extreme mood swings, worsening of schizophrenia, headache or visual disturbances (including eye pain or swelling).
- Increased number of **white blood cells** in the blood.

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 (see Appendix V)

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pantadexa

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

Store below 25°C.
Store in the original package in order to protect from light.

After first opening the product must be used immediately.

Chemical and physical in-use stability has been demonstrated for 24 hours when stored at 2°C to 8°C or when stored at room temperature (15°C to 25°C) when diluted in solutions for infusions.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior the 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 placed in controlled and validated aseptic conditions.

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 Pantadexa contains

- The active substance is dexamethasone (as sodium phosphate). Each ml contains 5 mg of dexamethasone sodium phosphate (equivalent to 4,6 mg dexamethasone phosphate, equivalent to 3,8 mg dexamethasone base).
- The other ingredients are sodium chloride, disodium edetate, sodium hydroxide (for pH adjustment), propylene glycol, water for injections.

What Pantadexa looks like and contents of the pack
Pantadexa is a clear, colourless to almost colourless solution. It is supplied in brown glass ampoules. 10 x1 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
PANPHARMA
Z.I. du Clairay
35133 Luitré
France

Manufacturer
Panpharma GmbH
Bunsenstrasse 4
22946 Trittau
Germany

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

Finland	Pantadexa 5 mg/ml, injektio-/infuusioneste, liuos
Portugal	Dexametasona Panpharma 5 mg/ml, solução injetável ou para perfusão

This leaflet was last revised in 09/2023.

INFORMATION FOR HEALTHCARE PROFESSIONALS

The following information is intended for medical or healthcare professionals only.
Pantadexa may be administered intravenously, intramuscularly, or intra-articularly.
Pantadexa is a clear, colourless to almost colourless solution.

Incompatibilities
Pantadexa must not be mixed with other medicinal products except those listed below under 'Instructions for use and handling'.

Instructions for use and handling
Pantadexa can be diluted up to a concentration of 0,4 mg/ml in one of the following infusions:
- sodium chloride 0,9%
- glucose 5%
- Ringer's lactate

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.

In-use storage precautions
After first opening the product must be used immediately.
Chemical and physical in-use stability has been demonstrated for 24 hours when stored at 2°C to 8°C or when stored at room temperature (15°C to 25°C) when diluted in solutions for infusions listed under 'Instructions for use and handling'.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior the 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 placed in controlled and validated aseptic conditions.