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Package leaflet: Information for the user

Dexamethasone 4 mg tablets

Dexamethasone 8 mg tablets

dexamethasone

Read all of this leaflet carefully before you start taking 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 is and what it is used for
2. What you need to know before you take Dexamethasone
3. How to take 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 is a synthetic glucocorticoid. Glucocorticoids are hormones produced by the cortex of adrenal glands. The medicine has anti-inflammatory, analgesic and anti-allergic effects, and suppresses the immune system.

Dexamethasone is recommended for the treatment of rheumatic and autoimmune diseases (e.g. systemic lupus erythematosus, rheumatoid arthritis, juvenile idiopathic arthritis, polyarthritis nodosa), diseases of respiratory tract (e.g. bronchial asthma, croup), skin (e.g. erythroderma, pemphigus vulgaris), tuberculous, meningitis only in conjunction with anti-infective therapy, diseases of blood (e.g. idiopathic thrombocytopenic purpura in adults), cerebral oedema, treatment of symptomatic multiple myeloma, acute lymphoblastic leukemia, Hodgkin's disease and non-Hodgkin's lymphoma in combination with other medicinal products, palliative treatment of neoplastic diseases, prophylaxis and treatment of nausea and vomiting caused by chemotherapy and prevention and treatment of vomiting after operation, within antiemetic treatment.

Dexamethasone 4 mg tablets

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.

2. What you need to know before you take Dexamethasone

Do not take 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 that affects the whole body (unless you are receiving treatment).

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- if you have a stomach or duodenal ulcer.
- if you are going to have a vaccination by live vaccines.

Warnings and precautions

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

Talk to your doctor, pharmacist or nurse before taking Dexamethasone:

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

Mental health problems can happen while taking steroids like Dexamethasone.

- 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.

Talk to your doctor before taking this medicine if:

- you have kidney or liver problems (liver cirrhosis or chronic liver failure),
- you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands),
- you have high blood pressure, heart disease or you have recently had a heart attack (myocardial rupture has been reported),
- you have diabetes or there is a family history of diabetes,

- you have osteoporosis (thinning of the bones), particularly if you are a female who has been through the menopause,
- you have suffered from muscle weakness with this or other steroids in the past,
- you have glaucoma (raised eye pressure) or there is a family history of glaucoma, cataract (clouding of the lens in the eye leading to a decrease in vision),
- you have myasthenia gravis (a condition causing weak muscles),
- you have a bowel disorder or a stomach (peptic) ulcer,
- you have psychiatric problems or you have had a psychiatric illness which was made worse by this type of medicine,
- you have epilepsy (condition where you have repeated fits or convulsions),
- you have migraine,
- you have an underactive thyroid gland,
- you have a parasitic infection,
- you have tuberculosis, septicæmia or a fungal infection in the eye,
- you have cerebral malaria,
- you have herpes (cold sores or genital herpes and ocular herpes simplex because of possible corneal perforation),
- you have asthma,
- you are treated for a blockage of blood vessels by blood clots (thromboembolism),
- you have corneal ulcerations and corneal injuries.

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

Treatment with corticosteroid may reduce your body's ability to fight infection. This can sometimes lead to infections caused by germs that rarely cause infection under normal circumstances (called opportunistic infections). If you get an

infection of any kind during treatment with this medicine, contact your doctor immediately. This is particularly important if you notice signs of pneumonia: cough, fever, shortness of breath and chest pain. You may also feel confused, particularly if you are elderly. You should also tell your doctor if you have had tuberculosis or if you have stayed in regions where roundworm infections are common.

It is important that whilst you are taking this medicine you avoid contact with anybody who has chickenpox, shingles or measles. If you think you may have had exposure to any of these diseases, you should consult your doctor immediately. You should also inform your doctor if you have ever had infectious diseases such as measles or chickenpox and of any vaccinations.

You should tell your doctor if you have any 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.

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

Treatment with this medicine may cause central serous chorioretinopathy, an eye disease that leads to blurred or distorted vision. This happens usually in one of the eyes. Treatment with this medicine may cause tendon inflammation. In extremely rare cases, a tendon may rupture. This risk is increased by treatment with certain antibiotics and by kidney problems. Contact your doctor if you notice painful, stiff or swollen joints or tendons.

Treatment with Dexamethasone can cause a condition called adrenocortical insufficiency. This can cause change in effectiveness of the medicine following stress and trauma, surgery, childbirth or illness and your body may not be able to respond in the usual way to severe stress such as accidents, surgery, childbirth or illness.

If you have an accident, are ill, have other specific physical stress conditions, or require any surgery (even at the dentists)

or you require a vaccination (particularly with 'live virus' vaccines) whilst taking or when you have finished taking Dexamethasone, you should inform the person treating you that you are taking or have taken steroids.

If you have suppression tests (test for the amount of hormone in the body), skin test for allergy or test for bacterial infection you should inform the person performing the test that you are taking dexamethasone as it may interfere with the results.

You may also find that your doctor will reduce the amount of salt in your diet and give you a potassium supplement whilst you are taking this medicine.

If you are elderly, some of the side effects of this medicine may be more serious, especially thinning of the bones (osteoporosis), high blood pressure, low potassium levels, diabetes, susceptibility to infection and thinning of the skin. Your doctor will monitor you more closely.

Children

If a child is taking this medicine, it is important that the doctor monitors their growth and development at frequent intervals. Dexamethasone should not be used routinely in preterm neonates with respiratory problems.

Other medicines and Dexamethasone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- Anticoagulant medicines which thin the blood (e.g. warfarin)
- Acetylsalicylic acid or similar (Non-Steroidal Anti-Inflammatory drugs) e.g. indomethacin
- Medicines used to treat diabetes
- Medicines used to treat high blood pressure
- Medicines used to treat cardiac diseases
- Diuretics (water tablets)
- Amphotericin B injection
- Phenytoin, carbamazepine, primidone (epilepsy medication)
- Rifabutin, rifampicin, isoniazid (antibiotics used to treat tuberculosis)



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- Antacids – particularly those containing magnesium trisilicate
- Barbiturates (medication used to aid sleep and relieve anxiety)
- Aminoglutethimide (anti-cancer treatment)
- Carbenoxolone (used in the treatment of stomach ulcers)
- Ephedrine (nasal decongestant)
- Acetazolamide (used for glaucoma and epilepsy)
- Hydrocortisone, cortisone and other corticosteroids
- Ketoconazole, itraconazole (for fungal infections)
- Ritonavir (for HIV)
- Antibiotics including erythromycin, fluoroquinolones
- Medicines that help muscle movement in myasthenia gravis (e.g. neostigmine)
- Colestyramine (for high cholesterol levels)
- Estrogen hormones including the contraceptive pill
- Tetracosactide used in the test for adrenocortical function
- Sultopride used to calm emotions
- Ciclosporin used to prevent rejection after transplants
- Thalidomide used for e.g. multiple myeloma
- Praziquantel given for certain worm infections
- Vaccination with live vaccines
- Chloroquine, hydroxychloroquine and mefloquine (for malaria)
- Somatotropin
- Protirelin

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. You may be at an increased risk of serious side effects if you take dexamethasone together with these medicines:

- Some medicines may increase the effects of Dexamethasone and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)
- Acetylsalicylic acid or similar (Non-Steroidal Anti-Inflammatory drugs) e.g. indometacin
- Medicines used to treat diabetes
- Medicines used to treat cardiac diseases
- Diuretics (water tablets)

- Amphotericin B injection
- Acetazolamide (used for glaucoma and epilepsy)
- Tetracosactide used in the test for adrenocortical function
- Carbenoxolone (used in the treatment of stomach ulcers)
- Chloroquine, hydroxychloroquine and mefloquine (for malaria)
- Medicines used to treat high blood pressure
- Thalidomide used for e.g. multiple myeloma
- Vaccination with live vaccines
- Medicines that help muscle movement in myasthenia gravis (e.g. neostigmine)
- Antibiotics including fluoroquinolones

You must read the package leaflets of all medicinal products to be taken in combination with Dexamethasone for information related to these medicines before starting treatment with Dexamethasone. When thalidomide, lenalidomide or pomalidomide is used, particular attention to pregnancy testing and prevention requirements is needed.

Dexamethasone with food, drink and alcohol

Dexamethasone should be taken with or after food to minimise irritation to the gastrointestinal tract. Drinks containing alcohol or caffeine should be avoided. Eating small, frequent meals is recommended, and possibly taking of antacids, if recommended by your doctor.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Dexamethasone should be prescribed during pregnancy and particularly in the first trimester only if the benefit outweighs the risks for the mother and child. If you become pregnant during the use of the product, do not stop using Dexamethasone, but tell your doctor immediately that you are pregnant. Corticosteroids may pass into breast milk. A risk to the newborns/infants cannot be excluded.

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Merilo/Measure: 1:1
Datum/Date: 29.03.2023
Izdelač/Prepared by: A. Mohorič
Pregledal/Checked by: N. Regina
Oddelek za oblikovanje/Packaging Design

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A decision on whether to continue/discontinue breast feeding or to continue/discontinue therapy with dexamethasone should be made taking into account the benefit of breast feeding to the child and the benefit of dexamethasone therapy to the woman.

Driving and using machines

Do not drive, use any tools or machines or carry out any hazardous tasks if you experience side effects, such as confusion, hallucinations, dizziness, tiredness, sleepiness, fainting or blurred vision.

Dexamethasone contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Dexamethasone

Take Dexamethasone 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.

Dexamethasone is in the form of tablets 4 mg, 8 mg, 20 mg and 40 mg. The tablet can be divided into equal halves to provide additional 2 mg and 10 mg strengths or to help swallowing.

Dexamethasone is given in usual doses of 0.5 to 10 mg daily, depending on the disease being treated. In more severe disease conditions doses above 10 mg per day may be required. The dose should be titrated to the individual patient response and disease severity. In order to minimize side effects, the lowest effective possible dose should be used.

Unless otherwise prescribed, the following dosage recommendations apply:

The below mentioned dosing recommendations are given for guidance only. The initial and daily doses should always be determined based on individual patient

response and disease severity.

• **Cerebral oedema:** Initial dose and duration of treatment depending on the cause and severity, 6-16 mg (up to 24 mg) / day orally, divided into 3-4 individual doses.

• **Acute asthma:** Adults: 16 mg / day for two days. Children: 0.6 mg / kg body weight for one or two days.

• **Croup:** Children: 0.15mg/kg-0.6 mg/kg in a single dose.

• **Acute skin diseases:** Depending on the nature and extent of the disease daily doses of 8-40 mg, in some cases up to 100 mg, which should be followed by down titration according to clinical need.

• **Active phase of rheumatic system disorders:** Systemic lupus erythematosus 6-16 mg / day.

• **Active rheumatoid arthritis with severe progressive course form:** running at fast destructive forms 12-16 mg / day, with extra-articular manifestations 6-12 mg / day.

• **Idiopathic thrombocytopenic purpura:** 40 mg for 4 days in cycles.

• **Tuberculous meningitis:** Patients with grade II or III disease received intravenous treatment for four weeks (0.4 mg per kilogram per day for week 1, 0.3 mg per kilogram per day for week 2, 0.2 mg per kilogram per day for week 3, and 0.1 mg per kilogram per day for week 4) and then oral treatment for four weeks, starting at a total of 4 mg per day and decreasing by 1 mg each week. Patients with grade I disease received two weeks of intravenous therapy (0.3 mg per kilogram per day for week 1 and 0.2 mg per kilogram per day for week 2) and then four weeks of oral therapy (0.1 mg per kilogram per day for week 3, then a total of 3 mg per day, decreasing by 1 mg each week).

• **Palliative treatment of neoplastic diseases:** Initial dose and duration of treatment depending on the cause and severity, 3-20 mg / day. Very high doses up to 96 mg may also be used for palliative treatment. For optimal dosing and reduction of the number of tablets the combination of lower dose strengths (4 and 8 mg) and higher dose strengths (20 mg or 40 mg) can be used.



• **Prophylaxis and treatment of emesis induced by cytostatics, emetogenic chemotherapy within antiemetic treatment:** 8-20 mg dexamethasone prior to chemotherapy treatment, then 4-16 mg/day on day 2 and 3.

• **Prevention and treatment of postoperative vomiting, within antiemetic treatment:** single dose of 8 mg before the surgery.

• **Treatment of symptomatic multiple myeloma, acute lymphoblastic leukemia, Hodgkin's disease and non-Hodgkin's lymphoma in combination with other medicinal products:** the usual posology is 40 mg or 20 mg once per day.

The dose and administration frequency varies with the therapeutic protocol and the associated treatment(s). Dexamethasone administration should follow instructions for dexamethasone administration when described in the Summary of Product Characteristics of the associated treatment(s). If this is not the case, local or international treatment protocols and guidelines should be followed. Prescribing physicians should carefully evaluate which dose of dexamethasone to use, taking into account the condition and disease status of the patient.

Long term treatment

For the long-term treatment of several conditions, after initial therapy, glucocorticoid treatment should be switched from dexamethasone to prednisone/prednisolone to reduce suppression on the function of the adrenal cortex.

Dexamethasone 4 mg tablets

Treatment of Covid-19

Adult patients are recommended to take 6 mg 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 take 6 mg once a day for up to 10 days.

Use in children

If a child is taking this medicine, it is important that the doctor monitors their growth and development at frequent intervals.

If you take more Dexamethasone than you should

If you take too much medicine contact a doctor or hospital immediately.

If you forget to take Dexamethasone

If you forget to take a dose, take it as soon as you remember unless it is almost time for the next dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Dexamethasone

If your treatment is to be stopped follow your doctor's advice. He may tell you to reduce the amount of medicine you are taking gradually until you stop taking it altogether. The symptoms that have been reported when treatment has been stopped too quickly have included low blood pressure and in some cases, relapse of the disease for which the treatment was given.

A 'withdrawal syndrome' may also occur which includes fever, muscle and joint pain, inflammation of the nose lining (rhinitis), weight loss, itchy skin and inflammation of the eye (conjunctivitis). If you stop treatment too soon and some of the mentioned symptoms occur, you must talk to your doctor as soon as possible.

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.

Tell a doctor straight away if you experience serious mental health problems. They can affect about 5 in every 100 people taking medicines like dexamethasone. These problems include:

- 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 that do not exist. Having

strange and frightening thoughts, changing how you act or having feelings of being alone.

Tell a doctor straight away if you experience:

- severe abdominal pains, nausea, vomiting, diarrhoea, profound muscle weakness and fatigue, extremely low blood pressure, weight loss and fever as these may be signs of adrenocortical insufficiency;
- sudden abdominal pain, tenderness, nausea, vomiting, fever and blood in stool as these may be signs of tearing of the bowel particularly if you have or have had a bowel disease.

This medicine may worsen your existing heart problem. If you experience shortness of breath or ankle swelling, consult your doctor straight away.

Other side effects may be (frequency not known):

- Greater chance of picking up infections, including viral and fungal infections e.g. thrush; recurrence of tuberculosis or some other infections, e.g. eye infections if you have already had it
- Reduction in the number of white blood cells or increased number of white blood cells, abnormal coagulation
- An allergic reaction to the medicine, including serious, potentially life-threatening allergic reaction (which may show as a rash and swelling of the throat or tongue and in severe cases difficulty in breathing or dizziness)
- Impairment of the body's regulation of hormones, swelling and weight gain of the body, full-moon face (Cushingoid state), change in effectiveness of endocrines following stress and trauma, surgery, childbirth or illness, your body may not be able to respond in the usual way to severe stress such as accidents, surgery, childbirth or illness, stunted growth in children and teenagers, irregular and absence of menstrual cycles (periods), development of excess body hair (particularly in women)
- Weight gain, loss of protein and calcium balance, increased appetite, salt imbalances, water retention in the body, potassium loss which can cause rhythm disorder, increased requirement for diabetic medication, unknown diabetes

becomes evident, high levels of cholesterol and triglycerides in the blood (hypercholesterolemia and hypertriglyceridaemia)

- Extreme mood swings, schizophrenia (mental disorder) may become worse, depression, inability to sleep
- Severe unusual headache with visual disturbances linked with the withdrawal of treatment, fits and worsening of epilepsy, dizziness
- Increased pressure in the eye, papilloedema, thinning of the eye membranes, increased eye viral, fungal and bacterial infections, worsening of symptoms associated with corneal ulcers, worsening of existing eye infections, protrusion of the eyeballs, cataracts, visual disturbances, loss of vision, blurred vision
- Congestive heart failure in susceptible people, cardiac muscle rupture after a recent heart attack, cardiac decompensation
- High blood pressure, blood clots: formation of blood clots that may clog blood vessels for example in legs or lungs (thromboembolic complications)
- Hiccups

• Nausea, vomiting, stomach discomfort and swollen abdomen, inflammation and ulcers in the oesophagus, peptic ulcers that may split and bleed, inflamed pancreas (which may show as pain in the back and abdomen), flatulence, oesophageal candidiasis

• Thinned delicate skin, unusual marks on the skin, bruising, redness and inflammation of the skin, stretch marks, visible swollen capillaries, acne, increased sweating, skin rash, swelling, thinning of the hair, unusual fat deposits, excessive hair growth, water retaining in the body, pigment disorders, weakened capillaries that rupture easily, observed as bleeding under the skin (increased capillary fragility), skin irritation around the mouth (perioral dermatitis)

• Thinning of the bone with an increased risk of fractures (osteoporosis), bone necrosis, tendinitis, ruptured tendons, muscle wasting, myopathy, muscle weakness, early stoppage of bone growth (premature epiphyseal closure)

- Changes to the number and movement of sperm, impotence
- Impaired reaction to vaccination and skin tests, slow wound healing, discomfort, malaise
- A 'withdrawal syndrome' may also occur which includes fever, muscle and joint pain, inflammation of the nose lining (rhinitis), weight loss, painful itchy skin nodules and inflammation of the eye (conjunctivitis)

Reporting of side effects

If you get any side effects, talk to your doctor or 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. For COVID-19 products/treatments report side effects directly via Yellow Card Scheme website: <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. Please do not report the same adverse event(s) to both systems as all reports will be shared between KRKA, d. d., Novo mesto and MHRA (in an anonymised form) and dual reporting will create unnecessary duplicates.

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

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light and moisture.

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.
 - **Dexamethasone 4 mg tablets**
Each tablet contains 4 mg dexamethasone.
 - **Dexamethasone 8 mg tablets**
Each tablet contains 8 mg dexamethasone.
- The other ingredients are lactose monohydrate, pregelatinised maize starch, colloidal anhydrous silica, and magnesium stearate (E470b). See section 2 "Dexamethasone contains lactose".

What Dexamethasone looks like and contents of the pack
4 mg tablets: White or almost white, round tablets with bevelled edges and scored on one side (Thickness: 2.5-3.5 mm; Diameter: 5.7-6.3 mm). The tablet can be divided into equal doses.
8 mg tablets: White or almost white, oval tablets, scored on one side (Thickness: 3.5-5.5 mm; Length: 8.7-9.3 mm). The tablet can be divided into equal doses.

Dexamethasone 4 mg tablets are available in boxes containing 10, 20, 28, 30, 50, 56, 60, 100, 10 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1 and 100 x 1 tablets, in blisters.
Dexamethasone 8 mg tablets are available in boxes containing 10, 20, 30, 50, 60, 100, 10 x 1, 20 x 1, 30 x 1, 50 x 1, 60 x 1 and 100 x 1 tablets in blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

This leaflet was last revised in March 2023.



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