Package leaflet: Information for the patient

Dexamethasone 0.5 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

Dexamethasone 0.5 mg tablets is a synthetic glucocorticoid (adrenocortical hormone) with an effect on metabolism, electrolyte balance and tissue functions.

Dexamethasone 0.5 mg tablets are used in

Diseases that require systemic treatment with glucocorticoids. These include, depending on the type and severity:

Neurology
Swelling of the brain caused by brain tumours, neurosurgery, bacterial inflammation of the lining of the brain (meningitis), brain abscess.

Pulmonary and respiratory diseases
Severe acute asthma attack.

Dermatology
Initial treatment of extensive acute severe skin diseases, such as erythroderma, pemphigus vulgaris, acute eczema.

Autoimmune disorders/rheumatology
Treatment of rheumatic systemic diseases (rheumatic diseases which can affect internal organs), such as systemic lupus erythematosus.
Severely progressive form of active rheumatic joint inflammation (rheumatoid arthritis), e.g. forms that quickly lead to joint destruction and/or when tissue outside the joints is affected.

Infectology
Severe infections with intoxication-like conditions (e.g. in tuberculosis, typhoid fever), only with appropriate anti-infective therapy.

Oncology
Supportive treatment in malignant tumours.

Endocrinology
Hormone replacement therapy: in reduced adrenal function or failure of adrenal function (adrenogenital syndrome) in adulthood.

2. What you need to know before you take Dexamethasone

Do not take Dexamethasone
- if you are allergic to active substance or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Dexamethasone.

Talk to your doctor before taking Dexamethasone if you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands).

Treatment with glucocorticoids can lead to an underactive adrenal cortex (insufficient production of glucocorticoids by the body); depending on the dose and duration of treatment, this can last for several months and in individual cases more than a year after discontinuation of treatment. If you experience particular physical stress (such as illnesses with fever, accidents or surgery, childbirth, etc.) during treatment with glucocorticoids, you should tell your doctor or inform the emergency doctor about your ongoing treatment. A temporary increase in the daily dose of Dexamethasone 0.5 mg tablets may be required. Even in case of continued underactive adrenal cortex after the end of treatment, the administration of glucocorticoids may be necessary in physical stress situations. Therefore, during long-term treatment with Dexamethasone 0.5 mg tablets, your doctor should give you a steroid card, which you should always carry with you.

In order to avoid treatment-related acute adrenal insufficiency, when treatment discontinuation is intended, your doctor will determine a dose-reduction plan, which you should follow strictly.

By suppressing the body's immune system, treatment with Dexamethasone 0.5 mg tablets can lead to an increased risk of bacterial, viral, parasitic, opportunistic and fungal infections. It can mask the signs and symptoms of an existing or a developing infection, making it more difficult to recognize them.

In the following illnesses, treatment with Dexamethasone 0.5 mg tablets should only be started if your doctor considers it essential. If necessary, medications that act against the pathogens should also be taken:
- Acute viral infections (chickenpox, shingles, herpes simplex infections, inflammation of the cornea caused by herpes viruses)
- HBsAG-positive chronic active hepatitis (infectious liver inflammation)
- About 8 weeks prior to 2 weeks after vaccinations with attenuated pathogens (live vaccine)
- Acute and chronic bacterial infections
- Fungal infections with involvement of internal organs
- Certain diseases caused by parasites (amoebic, worm infections). In patients with suspected or confirmed infection with threadworms (nematodes), Dexamethasone 0.5 mg tablets can lead to activation and mass proliferation of these parasites.
- Polio
- Lymph node disease after tuberculosis vaccination
- In case of history of tuberculosis, use only together with medicines for tuberculosis

The following diseases should be specifically monitored during concomitant treatment with Dexamethasone 0.5 mg tablets and treated according to the requirements:
- Gastrointestinal ulcers
- Bone loss (osteoporosis)
- Severe heart failure
- High blood pressure that is difficult to regulate
- Diabetes that is difficult to regulate
- Mental (psychological) disorders (also in the past), including suicidal tendencies. In this case, neurological or psychiatric monitoring is recommended.
- Increased intraocular pressure (narrow- and wide-angle glaucoma); ophthalmologic monitoring and adjunctive therapy are recommended.
- Injuries and ulcers of the cornea of the eye; ophthalmologic monitoring and adjunctive therapy are recommended.

Because of the risk of an intestinal perforation, Dexamethasone 0.5 mg tablets may only be taken if there are compelling medical reasons and under appropriate monitoring:
- In severe inflammation of the colon (ulcerative colitis) with threatened perforation, with abscesses or purulent inflammation, possibly without peritoneal irritation
- In inflamed pouches in the bowel wall (diverticulitis)
- After certain intestinal surgeries (enteroenterostomy), immediately after surgery

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

In patients with diabetes, metabolism should be checked regularly; the possibility of a higher need for medicines for the treatment of diabetes (insulin, oral antidiabetics) should be taken into consideration.

Patients with severely high blood pressure and/or severe heart failure should be carefully monitored due to the risk of deterioration.

High doses can lead to slowing of the heartbeat.

Severe anaphylactic reactions (overreaction of the immune system) may occur.

The risk of tendon disorders, tendon inflammation and tendon rupture is increased when fluoroquinolones (certain antibiotics) and Dexamethasone 0.5 mg tablets are administered together.

During the treatment of a particular form of muscle paralysis (myasthenia gravis), the symptoms may worsen at the beginning.

Long-term use of even small doses of dexamethasone leads to an increased risk of infections, even by such microorganisms which would otherwise rarely cause infections (opportunistic infections). At the same time, the signs of infection may be masked, making it more difficult to diagnose an existing or a developing infection.

Vaccinations with vaccines from killed pathogens (inactivated vaccines) are generally possible. However, it should be noted that the immune response and thus the vaccine may be compromised at higher doses of corticosteroids.

During long-term therapy with Dexamethasone 0.5 mg tablets, regular medical (including ophthalmologic) checkups are required.

Especially with prolonged treatment with high doses of Dexamethasone 0.5 mg tablets, sufficient calcium intake (e.g. vegetables, bananas) and limited salt intake should be ensured. The doctor will monitor your blood potassium levels.

Depending on the dose and duration of treatment, a negative effect on calcium metabolism can be expected; therefore, the prevention of osteoporosis is recommended. This applies especially to patients with concomitant risk factors, such as familial predisposition, advanced age, insufficient protein and calcium intake, heavy smoking, excessive alcohol consumption, period after menopause and lack of physical activity. Prevention consists of sufficient calcium and vitamin D intake and physical activity.
In already existing osteoporosis, your doctor may also consider treatment with medications.

Upon termination of long-term use of glucocorticoids, the following risks must be taken into account: recurrence or worsening of the underlying disease, acute adrenal insufficiency, cortisone withdrawal syndrome.

Viral diseases (e.g. measles, chickenpox) may be very severe in patients treated with Dexamethasone 0.5 mg tablets. Patients with a compromised immune system who have not had measles or chickenpox yet are particularly at risk. If these patients have contact with people infected with measles or chickenpox during treatment with Dexamethasone 0.5 mg tablets, they should immediately contact their doctor, who will introduce a preventative treatment if necessary.

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 pheochromocytoma crisis, which can be fatal. Pheochromocytoma is a rare tumor of the adrenal glands. Crisis can occur with following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience these signs.

Children and adolescents

Due to the risk of growth inhibition, Dexamethasone 0.5 mg tablets should only be administered in children for compelling medical reasons, and during long-term treatment, growth in height should be controlled regularly. Therapy with Dexamethasone 0.5 mg tablets should be of limited duration or it should be carried out alternatingly (e.g. every other day, but then double dose).
Dexamethasone should not be used routinely in preterm neonates with respiratory problems.

Elderly

Also in the elderly a special benefit-risk assessment should be carried out because of the increased risk of osteoporosis.

Effects in case of misuse for doping purposes

The use of Dexamethasone 0.5 mg tablets can lead to positive results in doping controls.

Other medicines and Dexamethasone
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

What other medicines influence the effect of Dexamethasone 0.5 mg tablets?
- Medicines that accelerate the breakdown in the liver, such as certain sleeping pills (barbiturates), medicines used to treat seizures (phenytoin, carbamazepine, primidone) and certain medicines for tuberculosis (rifampicin), may reduce the effect of corticosteroids.
- 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).
- Medicines that slow down the breakdown in the liver, such as certain medicines to treat fungal infections (ketoconazole, itraconazole), may increase the effect of corticosteroids.
- Certain female sex hormones, e.g. for the prevention of pregnancy (the pill): The effect of Dexamethasone 0.5 mg tablets may be increased.
- Medicines used to treat excessive stomach acid production (antacids): Concomitant administration of magnesium hydroxide or aluminium hydroxide can cause decreased absorption of dexamethasone. There should be a 2-hour interval between the intake of one and the other medicine.
- Ephedrine (e.g. medicines for hypotension, chronic bronchitis, asthma attacks, medicines used to reduce swelling of the mucous membranes in rhinitis and appetite suppressants can contain ephedrine): Through accelerated breakdown in the body, the effectiveness of Dexamethasone 0.5 mg tablets may be reduced.

How does Dexamethasone 0.5 mg tablets influence the effect of other medicines?
- During concomitant use with certain medicines for lowering blood pressure (ACE inhibitors), Dexamethasone 0.5 mg tablets may increase the risk of blood count changes.
- Dexamethasone 0.5 mg tablets may increase the effect of medicines that strengthen the heart (cardiac glycosides) by potassium deficiency.
- Dexamethasone 0.5 mg tablets may increase the potassium excretion by diuretics (saluretics) or laxatives.
- Dexamethasone 0.5 mg tablets may decrease the blood glucose lowering effect of oral antidiabetics and insulin.
- Dexamethasone 0.5 mg tablets may weaken or increase the effects of medicines that reduce blood clotting (oral anticoagulants, coumarin). Your doctor will decide whether a dose adjustment of the anticoagulant is necessary.
- During concomitant use of anti-inflammatory and antirheumatic drugs (salicylates, indomethacin, and other NSAIDs), Dexamethasone 0.5 mg tablets may increase the risk of stomach ulcers and gastrointestinal bleeding.
- Dexamethasone 0.5 mg tablets may prolong the muscle-relaxing effect of certain medicines (non-depolarizing muscle relaxants).
- Dexamethasone 0.5 mg tablets may enhance the intraocular pressure-increasing effect of certain medicines (atropine and other anticholinergics).

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- Dexamethasone 0.5 mg tablets may decrease the effect of medicines for worm diseases (praziquantel).
- During concomitant use of medicines for malaria and rheumatic diseases (chloroquine, hydroxychloroquine, mefloquine), Dexamethasone 0.5 mg tablets may increase the risk of muscle diseases or heart muscle diseases (myopathies, cardiomyopathies).
- Dexamethasone 0.5 mg tablets may decrease the effect of growth hormones (somatropin), particularly if used in high doses or for a long time.
- Dexamethasone 0.5 mg tablets may reduce the increase in thyroid-stimulating hormone (TSH) after administration of protirelin (TRH, a hormone of the midbrain).
- If used together with medicines that suppress the body's immune system (immunosuppressants), Dexamethasone 0.5 mg tablets may increase the susceptibility to infections and worsen the existing infections which perhaps have not erupted yet.
- Additionally, for ciclosporin (a medicine used to suppress the body's immune system): Dexamethasone 0.5 mg tablets may increase the concentration of ciclosporin in the blood and thereby the risk of seizures.
- Fluoroquinolones, a certain group of antibiotics, may increase the risk of tendon ruptures.

Effect on investigation methods:

Glucocorticoids can suppress skin reactions in allergy tests.

Pregnancy 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.

Pregnancy

Dexamethasone crosses the placenta. During pregnancy, especially in the first three months, the medicine should only be used after careful benefit-risk assessment. Therefore, women should inform the doctor if they are already pregnant or if they become pregnant. During long-term treatment with glucocorticoids during pregnancy, growth disorders in the unborn child cannot be excluded. If glucocorticoids are administered towards the end of pregnancy, there is a risk of underactive adrenal cortex in the newborn, which may necessitate replacement therapy that has to be slowly reduced.

Breast-feeding

Glucocorticoids, including dexamethasone, are excreted in breast milk. Harm to the infant is not yet known. Nevertheless, the need for treatment during lactation should be closely examined. If the disease requires higher doses, breast-feeding should be discontinued. Please contact your doctor immediately.

Driving and using machines

To date there is no evidence that Dexamethasone 0.5 mg tablets affect the ability to drive or operate machinery, or work without safe foothold.

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

Always take this medicine exactly as your doctor has told you. The doctor will determine your dose individually. Please follow the instructions in order for Dexamethasone 0.5 mg tablets to have the proper effect. Check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the usual doses are:

- Swelling of the brain: 16–24 mg (up to 48 mg) daily, divided into 3–4 (up to 6) individual doses for 4–8 days. For this indication, higher dose tablets are preferred.
- Swelling of the brain due to bacterial meningitis: 0.15 mg/kg body weight every 6 hours for 4 days, children: 0.4 mg/kg body weight every 12 hours for 2 days, starting before the first antibiotics.
- Severe acute asthma attack: Adults: 8–20 mg as soon as possible, if necessary repeated dose of 8 mg every 4 hours. Children: 0.15–0.3 mg/kg body weight.
- Acute skin diseases: Depending on the nature and extent of the disease, daily doses of 8–40 mg. Followed by treatment with decreasing doses.
- Systemic lupus erythematosus: 6–16 mg.
- Severely progressive form of rheumatoid arthritis, e.g. forms that quickly lead to joint destruction: 12–16 mg, when tissue outside the joints is affected: 6–12 mg.
- Severe infections with intoxication-like conditions: 4–20 mg a day, for a few days, only with appropriate anti-infective therapy.
- Supportive treatment in malignant tumours: initially 8–16 mg/day, during longer lasting treatment 4–12 mg.
- Hormone replacement therapy: Congenital adrenogenital syndrome in adulthood: 0.25–0.75 mg/day as a single dose. If necessary, addition of a mineralocorticoid (fludrocortisone). In particular physical stress (such as infections with fever, accidents, surgery or childbirth), the dose should be temporarily increased by your doctor.

The tablets should not be split to adjust doses. If patients need a dose that cannot be provided by one or more tablets of 0.5mg, other appropriate formulations should be used.

Method of administration

Tablets for oral use.

Take the tablets during or after a meal; swallow them whole, with a sufficient amount of liquid. If possible, the daily dose should be taken as a single dose in the morning. In diseases that require a high-dose therapy, multiple daily dosing is often required to achieve maximum effect.

Duration of use

The duration of treatment depends on the underlying disease and the course of the disease. Your doctor will specify a treatment regimen, which you should strictly follow. Once a satisfactory treatment result is achieved, the dose will be reduced to a maintenance dose or treatment terminated. In principle, the dose should be reduced gradually.

In underactive thyroid or liver cirrhosis, low doses may be sufficient or a dose reduction may be necessary.

If you take more Dexamethasone than you should

Even if taken for a short time in large quantities, Dexamethasone 0.5 mg tablets is generally tolerated without complications. There are no special measures required. If you notice increased or unusual side effects, you should talk to your doctor.

If you forget to take Dexamethasone

A missed dose may be taken on the same day and the next day the dose prescribed by your doctor should be taken as usual. Do not take a double dose to make up for a forgotten tablet.

If you forget to take several doses, this can lead to a recurrence or worsening of the disease being treated. In such cases, you should talk to your doctor, who will review the treatment and adjust it, if needed.

If you stop taking Dexamethasone

Always follow the dosing schedule prescribed by the doctor. Dexamethasone 0.5 mg tablets must never be discontinued without authorization, particularly since long-term treatment can lead to a decrease in the body's production of glucocorticoids (underactive adrenal cortex). A highly physically stressful situation without adequate glucocorticoid production can be fatal.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects

In hormone replacement therapy, the risk of side effects is low with the use of recommended doses. With prolonged use, especially of high doses, however, side effects of varying degrees can be expected regularly, but their frequency cannot be clearly specified.

Infections and infestations:
Masking of infections, occurrence and worsening of viral, fungal, bacterial infections and parasitic or opportunistic infections, activation of threadworm infection.

Blood and lymphatic system disorders:
Blood count changes (increased number of white blood cells or all blood cells, decreased number of certain white blood cells).

Immune system disorders:
Hypersensitivity reactions (e.g. drug eruption), severe anaphylactic reactions, such as heart rhythm disorders, bronchospasm (spasm of the bronchial smooth muscle), high or low blood pressure, circulatory collapse, heart arrest, weakening of the immune system.

Endocrine disorders:
Cushing's syndrome (typical signs include moon face, central obesity and flushing).

Metabolism and nutrition disorders:
Weight gain, elevated blood sugar, diabetes, increased blood lipids (cholesterol and triglycerides), increased sodium levels with swelling (oedema), potassium deficiency due to increased potassium excretion (may lead to heart rhythm disorders), increased appetite.

Psychiatric disorders:
Depression, irritability, euphoria, increased drive, psychoses, mania, hallucinations, mood swings, anxiety, sleep disorders, suicidal tendencies.

Nervous system disorders:
Increased intracranial pressure, occurrence of previously unrecognized epilepsy, more frequent seizures in already known epilepsy.

Eye disorders:
Increase in intraocular pressure (glaucoma), clouding of the lens (cataract), worsening of corneal ulcers, increased occurrence or worsening of eye inflammation caused by viruses, bacteria or fungi; worsening of bacterial inflammation of the cornea, drooping eyelid, pupil dilation, conjunctival swelling, perforation of the white of the eye, visual disturbances, loss of vision, blurred vision.

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

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

Skin and subcutaneous tissue disorders:
Stretch marks on the skin, thinning of the skin ("parchment skin"), enlargement of skin blood vessels, tendency to bruising, skin bleeding in dots or patches, increased body hair, acne, inflammatory skin changes on the face, especially around the mouth, nose and eyes, changes in skin pigmentation.

Musculoskeletal, connective tissue and bone disorders:
Muscle diseases, muscle weakness and wasting, bone loss (osteoporosis) are dose-related and possible even with only short-term use, other forms of bone death (osteonecrosis), tendon disorders, tendinitis, tendon ruptures, fat deposits in the spine (epidural lipomatosis), growth inhibition in children.

Note:
Too rapid dose reduction after long-term treatment may cause a withdrawal syndrome with symptoms such as muscle and joint pain.

Reproductive system and breast disorders:
Disorders of sexual hormone secretion (consequently: irregular or absent menstruation (amenorrhea), male-like body hair in women (hirsutism), impotence).

General disorders and administration site conditions:
Delayed wound healing.

Measures

Please talk to your doctor or pharmacist if you notice any of the listed side effects or other unwanted effects during treatment with Dexamethasone 0.5 mg tablets. Never stop treatment on your own.

If gastrointestinal discomfort, pain in the back, shoulder or hip area, psychological disorders, abnormal blood sugar fluctuations (in diabetics) or other disturbances occur, please inform your doctor immediately.

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 the Yellow Card Scheme, Website: https://yellowcard.mhra.gov.uk/ 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 packaging after EXP. The expiry date refers to the last day of that month.

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

- The active substance is dexamethasone. Each tablet contains 0.5 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

Tablets are white or almost white, round with bevelled edges; tablet diameter: 4.8-5.2 mm, thickness: 1.4-2.2 mm.

Dexamethasone is available in boxes containing 10, 20, 28, 30, 50, 56, 60, 90, 100, 10 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 90 x 1 and 100 x 1 tablets in blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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