

#### Package leaflet: Information for the user

### Dexamethasone 0.5 mg Tablets Dexamethasone 1 mg Tablets Dexamethasone 2 mg Tablets

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

The name of your medicine is Dexamethasone Tablets (called dexamethasone throughout this leaflet). Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone) with an effect on metabolism, electrolyte balance and tissue functions.

Dexamethasone is used for:

#### 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 or acute eczema.

#### Autoimmune disorders/rheumatology

Treatment of rheumatic systemic diseases (rheumatic diseases that 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 infectious diseases with intoxication-like conditions (like tuberculosis, typhoid fever), only in addition to appropriate anti-infective therapy.

#### Oncology

Supportive treatment for malignant tumours.

#### COVID-19

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.

#### Endocrinology

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

#### Various

- Prophylaxis and treatment of nausea and vomiting caused by chemotherapy.
- Prevention and treatment of vomiting after operations, within antiemetic treatment.

#### 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).

#### Warnings and precautions

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

If you are taking other steroid medicines, you should not stop taking any other steroid medications unless your doctor has instructed you to do.

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

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

Treatment with glucocorticoids can lead to underactive adrenal cortex (insufficient endogenous production of glucocorticoids), depending on the dose and duration of treatment, this can last for several months and in individual cases longer 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 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, your doctor should give you a steroid card, which you should always carry with you.

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

By suppressing the body's immune system, treatment with dexamethasone 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. Latent infections can be reactivated.

**In the following illnesses, treatment with dexamethasone 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 (hepatitis B, 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 vaccination with attenuated pathogens (live vaccine)
- Acute and chronic bacterial infections
- Fungal diseases with involvement of internal organs
- Certain diseases caused by parasites (amoebae, worm infections). In patients with suspected or confirmed infection with thread worms (nematodes), dexamethasone may lead to activation and mass proliferation of these parasites.

- Polio
- Lymph node disease after tuberculosis vaccination
- In the case of history of tuberculosis, use only together with medicines for tuberculosis.

**The following diseases should be specifically monitored during concomitant treatment with dexamethasone 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), ophthalmological monitoring and adjunctive therapy are recommended.
- Injuries and ulcers of the cornea of the eye, ophthalmological monitoring and adjunctive therapy are recommended.

If you experience blurred vision or other visual disturbances, contact your doctor.

**Because of the risk of intestinal wall perforation, dexamethasone 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 (diverticulitis).
- After certain intestinal operations (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 severe high blood pressure and/or severe heart failure should be carefully monitored, as there is a risk of deterioration.

High dose can lead to slowing of the heartbeat.

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

The risk of tendon pain, tendon inflammation and tendon rupture is increased when fluoroquinolones (certain antibiotics) and dexamethasone are administered together.

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

#### Vaccinations

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

#### Long-term treatment

- Long-term use of even small quantities of dexamethasone leads to an increased risk of infection, 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 difficult to diagnose an existing or developing infection.
- During long-term therapy with dexamethasone, regular medical (including ophthalmologic) check-ups are required.
- Especially with prolonged treatment with high doses of dexamethasone, sufficient potassium intake (like vegetables, bananas) and a limited salt intake should be ensured. Your 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

Viral diseases (such as measles, chickenpox) can be particularly severe in patients treated with dexamethasone. 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 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 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.

#### Children and adolescents

Due to the risk of growth inhibition, dexamethasone 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 tablets should be of limited duration or it should be carried out alternately (e.g. every other day, but then double dose). Dexamethasone should not be used routinely in preterm neonates with respiratory problems.

#### Elderly

In elderly patients, a special risk-benefit analysis should be carried out because of the increased risk of osteoporosis.

#### Effects in case of misuse for doping purposes

The use of dexamethasone can lead to positive results in doping controls.

#### Other medicines and dexamethasone

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

**What other medicines influence the effect of dexamethasone?**

- 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 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 may be reduced.

**How does dexamethasone influence the effect of other medicines?**

- During concomitant use with certain medicines for lowering blood pressure (ACE inhibitors), dexamethasone may increase the risk of blood count changes.
- Dexamethasone may increase the effect of medicines that strengthen the heart (cardiac glycosides) by potassium deficiency.
- Dexamethasone may increase the potassium excretion by diuretics (saluretics) or laxatives.
- Dexamethasone may decrease the blood glucose lowering effect of oral antidiabetics and insulin.
- Dexamethasone 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.
- If used together with anti-inflammatory and antirheumatic drugs (salicylates, indomethacin, and other NSAIDs), dexamethasone may increase the risk of stomach ulcers and gastrointestinal bleeding.
- Dexamethasone may prolong the muscle-relaxing effect of certain medicines (non-depolarizing muscle relaxants).
- Dexamethasone may enhance the intraocular pressure-increasing effect of certain medicines (atropine and other anticholinergics).
- Dexamethasone may decrease the effect of medicines for worm diseases (praziquantel).
- If used together with medicines for malaria and rheumatic diseases (chloroquine, hydroxychloroquine, mefloquine), dexamethasone may increase the risk of muscle diseases or heart muscle diseases (myopathies, cardiomyopathies).



- Dexamethasone may decrease the effect of growth hormones (somatotropin), particularly if used in high doses or for a long time.
- Dexamethasone 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 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 may increase the concentration of ciclosporin in the blood and thereby increase the risk of seizures.
- Fluoroquinolones, a certain group of antibiotics, may increase the risk of tendon rupture.

#### Effect on investigative methods

Glucocorticoids can suppress skin reactions to 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, medicine should only be used after a careful risk-benefit 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 into breast milk. Harm to infants 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 tablets affect the ability to drive or operate machinery, or work without safe foothold. However, 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 and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### 3. How to take Dexamethasone

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

#### Unless otherwise prescribed by your doctor, the usual doses for the following conditions are:

- **Swelling of the brain:** 16-24 mg (up to 48 mg) per day, divided into 3-4 (up to 6) individual doses over 4-8 days. For this indication, higher dose tablets are preferred.
- **Swelling of the brain due to bacterial meningitis:** 0.15 mg/kg bodyweight, every 6 hours for 4 days  
Children: 0.4 mg/kg body weight every 12 hours for 2 days, starting before the first antibiotic administration.
- **Severe acute asthma attack:** Adults: 8-20 mg as soon as possible, if necessary repeated doses of 8 mg every 4 hours.  
Children: 0.15-0.3 mg/kg bodyweight.
- **Acute skin conditions:** 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 daily.
- **Severely progressive form of rheumatoid arthritis, e.g. forms that quickly lead to joint destruction:** 12-16 mg, when tissues outside the joints is affected: 6-12 mg daily.
- **Severe infectious with intoxication-like conditions:** 4-20 mg per day for a few days, only with appropriate anti-infective therapy.
- **Supportive therapy in malignant tumours:** initially 8-16 mg/day, for longer therapy 4-12 mg/day.
- **For the 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.

- **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 (infections with fever, accidents, surgery or childbirth), the dose should be temporarily increased as instructed by your doctor.
- **Prevention and treatment of vomiting (being sick) when receiving chemotherapy:** 10-20 mg before starting chemotherapy followed by 4-8 mg, 2 to 3 times a day for 1-3 days or up to 6 days if necessary.
- **Prevention and treatment of vomiting (being sick) after surgeries:** Single dose of 8-20 mg before the start of surgery, in children from 2 years of age: 0.15-0.5 mg/kg bodyweight (max. 16 mg).

#### Method of administration

Tablets for oral use.

Take the tablets during or after a meal; swallowed 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 the 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 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 the forgotten dose.

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 tablets must never be discontinued without discussion with your doctor, particularly since long-term treatment can lead to a decrease in the body's production of glucocorticoids (underactive adrenal cortex). This is a highly physically stressful situation without adequate glucocorticoid production and 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.

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, recurrence and worsening of viral, fungal, bacterial infections and parasitic or opportunistic infections, activation of threadworm infection.

#### Blood and lymphatic system disorders

Blood count changes (increase in white blood cells or all blood cells, decrease in certain white blood cells).

#### Immune system disorders

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

#### Endocrine disorders

Cushing's syndrome (typical signs include moon face, central obesity and facial flushing), hypofunction or atrophy of the adrenal cortex.

#### Metabolism and nutrition disorders

Weight gain, elevated blood sugar levels, diabetes, increase in blood lipids (cholesterol and triglycerides), increased sodium levels with swelling (oedema), potassium deficiency due to increased potassium excretion (may lead to heart arrhythmias), 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 a previously unrecognized epilepsy, more frequent occurrence of seizures (fits) 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 inflammations of the cornea, drooping eyelid, pupil dilation, conjunctival swelling, perforation of the white of the eye, visual disturbances, loss of vision and blurred vision.

#### Vascular disorders

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

#### Gastrointestinal disorders

Gastrointestinal ulcers, gastrointestinal bleeding, inflammation of 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 and connective tissue disorders

Muscle disorders, 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, tendonitis, 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 sex hormone secretion (consequently: irregular or absent menstruation (amenorrhoea), 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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the MHRA Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://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.

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 blister and the carton after 'EXP'. The expiry date refers to the last day of that month.

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

Do not throw away 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 tablets contain:

- The active substance is dexamethasone. Each tablet contains 0.5 mg, 1 mg or 2 mg of dexamethasone. The other ingredients are: lactose monohydrate, sorbolac 400, sodium starch glycolate (Type A), magnesium stearate (E572), silica, colloidal anhydrous (E551).

#### What Dexamethasone tablets look like and contents of the pack

Dexamethasone 0.5 mg tablets: White to off white, round, flat bevelled edge tablet approximately 8 mm in diameter, engraved with DX on one side and 500 on the other side.

Dexamethasone 1 mg tablets: White to off white, round, flat bevelled edge tablet approximately 8 mm in diameter, engraved with DX on one side and 1 on the other side.

Dexamethasone 2 mg tablets: White to off white, round, flat bevelled edge tablet approximately 8 mm in diameter, engraved with DX on one side and 2 on the other side.

Packed into Alu/PVC/PVDC blisters.

Pack sizes: 10, 20, 30, 50 or 100 tablets. Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

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