



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
DEXAMETHASONE 0.5mg, 1mg, 2mg, 4mg TABLET
Dexamethasone

Read all of this leaflet carefully before you start using this medicine. • Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your healthcare provider. • This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your healthcare provider.

In this leaflet:

1. What Dexamethasone Tablets is and what it is used for
2. Before you take Dexamethasone Tablets
3. How to take Dexamethasone Tablets
4. Possible side effects
5. How to store Dexamethasone Tablets
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1. WHAT DEXAMETHASONE TABLETS IS AND WHAT IT IS USED FOR

(a) Take special care with DEXAMETHASONE TABLETS

Talk to a health professional before using Dexamethasone:

- If you have ever had severe depression or manic depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Dexamethasone.
- If any of your close family has had these illnesses
If either of these applies to you, **talk to a health professional before taking this medicine.**

(c) Mental problems while having Dexamethasone

Mental health problems can happen while having steroids like Dexamethasone (see also section 4).

- 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 may need treatment.

Dexamethasone Tablets contain the active substance Dexamethasone. Dexamethasone belongs to a group of medicines called steroids (the full name is corticosteroids). Corticosteroids occur naturally in the body and help to maintain health and well-being. Boosting your body with extra corticosteroid (such as dexamethasone) is an effective way to treat various illnesses involving inflammation in the body. Dexamethasone Tablets reduce this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get the maximum benefit from it.

Dexamethasone Tablets are used for any of the following conditions: • where your natural corticosteroid levels have been reduced and you need to replenish them.

- where swelling of the brain has occurred.
- if you are having tests for diseases which may decrease your natural corticosteroid level, such as Cushing's syndrome (a hormonal disorder)
- to reduce inflammation and suppress the immune system in:

- allergy (hypersensitivity)
- polymyalgia rheumatica (chronic inflammation of the larger arteries), polyarteritis nodosa (chronic inflammation of small and medium arteries)
- blood disorders including haemolytic anaemia (disorder which breaks down red blood cells), leukaemia (cancer of the blood), myeloma (bone marrow tumour) • Crohn's disease, ulcerative colitis (inflammation of the bowel), hepatitis • polymyositis (inflammation of the muscles)
- increased pressure in the head not linked to tumours, worsening of multiple sclerosis. • inflammation of the eye
- inflammation of the kidney
- breathing problems including chronic bronchial asthma and chronic obstructive pulmonary disease (COPD) which may manifest as shortness of breath during exercise, difficulty breathing in and out deeply, as well as persistent cough. (Disorders where there is inflammation of the lung).
- rheumatoid arthritis (painful joint disease), rheumatism, inflammation of a wide area of the body
- chronic and severe diseases of the skin (including Stevens-Johnson syndrome and a rare condition known as mycosis fungoides)
- leukaemia of the lymphatic system, Hodgkin's and Non-Hodgkin's lymphoma,

breast cancer that has spread around the body, Kahler's disease (cancer of blood cells) and high calcium levels caused by this disease after organ transplants and to prevent nausea and vomiting following chemotherapy.

2. BEFORE YOU USE DEXAMETHASONE TABLETS

(a) Do not take DEXAMETHASONE TABLETS

- if you are allergic to dexamethasone or any of the other ingredients of this medicine. The signs of an allergic reaction include a rash, itching or shortness of breath.
- if you have an infection that affects the whole body
- if you have an infection of a joint
- if you have unstable joints (This is a condition where joints, such as the knee, can suddenly give way).

Do not take this medicine if any of the above applies to you.

Talk to a health professional if you (or someone taking this medicine), show any sign of mental problems. This is particularly important if you are depressed or may be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Take special care with Dexamethasone

Before you take Dexamethasone, tell your health provider if:

- You have had allergic reactions with a corticosteroid treatment. Severe allergic reactions (including shock) have been seen with injected corticosteroids. • You have a cancer of the blood because you may be at risk of a very rare, potentially life-threatening condition resulting from a sudden breakdown of tumour cells.
- You have symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath, in case you suffer from haematological malignancy • You have kidney or liver problems
- You have high blood pressure or heart disease
- You have diabetes or there is a family history of diabetes
- You have thinning of the bones (osteoporosis), particularly if you are a female who has been through the menopause
- You have had muscle weakness with this or other steroids in the past • You have raised eye pressure (glaucoma) or there is a family history of glaucoma • You have a stomach (peptic) ulcer
- You have mental problems, or you have had a mental illness which was made worse by this type of medicine such as 'steroid psychosis'
- You have epilepsy
- You have migraines
- You have an infection with parasites
- You have tuberculosis (TB)
- You have stunted growth
- You have 'Cushing's syndrome'
- You have had a head injury
- You have had a stroke

Contact your health care provider if you experience blurred vision or other visual disturbances.

If you are not sure if any of the above applies to you, talk to your health care provider before taking Dexamethasone.

If you develop an infection while you are taking this medicine, you should talk to your health care provider. Please tell any doctor, dentist or person who may be giving you treatment that you are currently taking steroids or have taken them in the past.

Even after your treatment has finished you must tell anyone who is giving you treatment that you have taken steroids in the past.

Do not use Dexamethasone for the treatment of Acute Respiratory Distress Syndrome (ARDS; a serious lung disease) if you have been diagnosed with this condition for over 2 weeks.

Dexamethasone and viral infections

While you are taking this kind of medicine, you should not come into contact with anyone who has chicken pox, shingles or measles if you have not had these



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illnesses. This is because you may need specialist treatment if you get these diseases. If you think you may have had exposure to any of these diseases, you should talk to your doctor **straight away**. You should also tell your doctor if you have ever had infectious diseases such as measles or chicken pox and if you have had any vaccinations for these conditions in the past.

Please tell a doctor or anyone giving you treatment, such as at a hospital, if:

- You have an accident

- You are ill
 - You need any surgery. This includes any surgery you may have at your dentist's.
 - You need to have a vaccination
- If any of the above applies to you, you should tell your doctor or the person treating you even if you have stopped having this medicine.

Taking other medicines

Please tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Other medicines can affect the way Dexamethasone works or

Dexamethasone can affect the way they work. In particular:

- Medicines to treat heart and blood problems, such as warfarin, high blood pressure medicine, and water tablets (diuretics)
- Antibiotics such as rifampicin and rifabutin
- Medicines that are broken down in the body by an enzyme in the liver (CYP 3A4) such as HIV protease inhibitors (e.g. indinavir) or certain antibiotics (e.g. erythromycin)
- 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, zalcitabine)
- Medicines to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone and primidone
- Medicines that control pain or lower inflammation, such as aspirin or phenylbutazone
- Medicines used to treat diabetes
- Medicines used to lower potassium levels
- Medicines used to treat myasthenia
- Anti-cancer treatments, such as aminoglutethimide
- Ephedrine used to relieve symptoms of a blocked nose
- Acetazolamide used for glaucoma
- Carbenoxolone sometimes used for ulcers

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 for advice before taking this medicine.

Driving and using machines

Dexamethasone is not likely to affect you being able to drive or use any tools or machines.

3. HOW TO TAKE DEXAMETHASONE TABLETS

Always take Dexamethasone Tablets exactly as your health care provider has told you. You should check with your health care provider if you are not sure. The usual dose is a **single dose each morning** unless your health provider has told you otherwise. Always take this medicine exactly as your doctor has told you. These instructions will have been added to the dispensing label by your pharmacist. You should check with your doctor or pharmacist if you are not sure.

Adults: The usual dose of Dexamethasone is 0.5 mg to 10 mg each day. If your health care provider wishes you to take less than 2 mg per day, you will be prescribed a different Dexamethasone product.

Use in children

A single dose on alternate days.

If Dexamethasone tablets are being given to you as part of some hospital tests, the dose given will be 2 mg, for a short period of time.

Important: If you are unsure how much medicine to take, please contact your doctor or pharmacist for advice.

Do not exceed or take less than the stated dose.

If you take more DEXAMETHASONE TABLETS than you should if you take too much medicine, contact a health care professional immediately.

If you forget to take DEXAMETHASONE TABLETS

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 dose.

If you stop taking DEXAMETHASONE TABLETS

It can be dangerous to stop taking this medicine abruptly. The symptoms that have been reported when treatment has been stopped too quickly include low blood pressure and sometimes, relapse of the disease for which the medicine 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 your treatment is to be stopped follow your health care provider's advice. He/she may tell you to reduce the amount of medicine you are taking gradually until you stop taking it altogether.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dexamethasone Tablets can cause side effects, although not everybody gets them.

Tell a health care professional straight away if you experience serious mental health problems. They can affect 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.

Talk to your health care provider immediately or go to hospital straight away if you experience any of the following side effects:

- red and lumpy skin rash
- difficulty breathing
- swelling of the face, mouth, lips or eyelids
- **mental health problems:** a feeling of dependence, a severe headache with visual disturbances (linked to withdrawal of treatment), worsening of schizophrenia (where you may sense, see or hear things that do not exist, become withdrawn or have mistaken beliefs or suspicions).
- **stomach and bowel problems:** nausea, vomiting, hiccups, increased appetite, stomach discomfort, swollen abdomen, inflammation and ulcers in the oesophagus, heartburn, stomach ulcers that may bleed, inflamed pancreas (causing pain in the back and abdomen), tearing of the bowel particularly if you have inflammatory bowel disease, unusual fat deposits.
- **metabolism and problems with salt levels:** weight gain, salt imbalances, water retention in the body, potassium loss due to low carbon dioxide levels (hypokalaemic alkalosis), loss of protein and calcium balance, increased need for diabetic medication, increased cholesterol levels.
- **heart and blood problems:** blood clots, congestive heart failure in susceptible people, heart muscle rupture (especially if you have recently had a heart attack), high blood pressure, raised or lowered levels of red and white blood cells, inflammation and thickening of the veins or arteries.
- **muscle, bone and skin problems:** thinning of the bones with an increased risk of fractures, bone disease, ruptured tendons, muscle wasting, weakness, excess body hair (particularly in women), slow wound healing, thinned delicate skin, unusual marks on the skin, bruising, redness and inflammation of the skin, stretch marks, visible swollen capillaries, acne, increased sweating, impaired reaction to skin tests, skin rash, thinning of the hair.
- **immune system problems:** thrush, greater chance of picking up infections, recurrence of tuberculosis if you have already had it, blood disorders due to infection.
- **eye problems:** cataracts, increased pressure in the eye, swelling of the eye, thinning of the eye membranes, worsening of existing eye infections, protrusion of the eyeballs.
- **reproductive system problems:** irregular or lack of menstruation (periods), impotence.
- **hormonal problems:** impairment of the body's regulation of hormones, slow growth in children and teenagers, swelling and weight gain of the body and face (Cushingoid state).
- **nervous system problems:** fits and worsening of epilepsy, dizziness, headache.



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• **other general effects:** a change in the effectiveness of the medicine following stress and trauma, surgery or illness, withdrawal effects (fever, muscle and joint pain, inflammation of the eye or nose, itchy skin, and weight loss)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE DEXAMETHASONE TABLETS

Keep all medicines out of the reach and sight of children.

Store below 30°C, in a dry place.

Do not use Dexamethasone Tablets after the expiry date "Exp. Date" which is stated on the carton. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION

What DEXAMETHASONE TABLETS contains:

The active pharmaceutical ingredient is Dexamethasone.

What DEXAMETHASONE TABLETS looks like and contents of the pack:

3x10 and 10x10 tablets in sachet, placed in an outer carton with insert.

Supplier and Manufacturer

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[PMN059-0920-01]