

Package leaflet: Information for the user

Dexamethasone 2 mg Tablets

Read 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 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.
- **Dexamethasone is a steroid medicine**, prescribed for many different conditions, including serious illnesses
- **You need to take it regularly** to get the maximum benefit.
- **Don't stop taking this medicine** without talking to your doctor - you may need to reduce the dose gradually
- **Dexamethasone can cause side effects in some people** (read Section 4: Possible side effects). Some problems such as mood changes (feeling depressed, or 'high'), or stomach problems can happen straight away. If you feel unwell, in any way, keep taking your medicine, but **see your doctor straight away**.
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, or developing a rounder face (read Section 4: Possible side effects for more information)
- **If you take it for more than 3 weeks, you will get a blue 'steroid card'**: always keep it with you and show any doctor or nurse treating you
- **Keep away from people who have chicken pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, **see your doctor straight away**.

Now read the rest of this leaflet. It includes other important information on the safe and effective use of this medicine that might be especially important for you.

What is in this leaflet

1. What Dexamethasone Tablets is and what it is used for
2. What you need to know before you take Dexamethasone Tablets
3. How to take Dexamethasone Tablets
4. Possible side effects
5. How to store Dexamethasone Tablets
6. Contents of the pack and other information

1. What Dexamethasone Tablets is and what it is used for

Dexamethasone Tablets belong to a group of medicines called corticosteroids.

Corticosteroids are hormones that are found naturally in your body that help to keep you healthy and well. 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 maximum benefit from it. 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.

Ask your doctor to explain why you have been given Dexamethasone Tablets if you are unsure.

2. What you need to know before you take Dexamethasone Tablets

Do not take Dexamethasone Tablets if you:

- are allergic, (hypersensitive) to dexamethasone or any of the other ingredients of this medicine (listed in section 6).
- have an infection that affects the whole body.
- need to have any vaccination, particularly with 'live virus' vaccines.

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

Warnings and precautions

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

Talk to your doctor or pharmacist 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.
- **any of your close family** has had these illnesses.

Check with your doctor before taking your medicine if:

- you have recently had a heart attack
- 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 tuberculosis (TB) or X-ray changes, or have had it in the past
- you have a stomach ulcer or other digestive problem
- you have chickenpox, shingles, measles or any other infection including an eye infection
- you had muscle weakness after taking steroids in the past
- you have bowel problems such as ulcerative colitis
- you have epilepsy
- you suffer from migraines
- you have a history of allergy
- you have stunted growth

- 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 experience blurred vision or other visual disturbances
- you have mental problems or have had a mental illness which was made worse by this type of medicine such as ‘steroid psychosis’
- you have an infection with parasites.

Also, check with your doctor if any of the following problems run in your family, or if you have any of them:

- diabetes
- heart problems
- high blood pressure
- an eye condition called ‘glaucoma’
- kidney or liver problems
- a type of muscle weakening problem called ‘myasthenia gravis’
- thinning of the bones (osteoporosis) particularly if you are a female who has been through the menopause
- low thyroid levels (hypothyroidism).

If you are not sure if any of the above run in your family, or you have them, talk to your doctor or pharmacist **before** taking the tablets.

Important

If you are taking or have recently (within the last 3 months) been taking Dexamethasone and **you become ill, suffer stress, get injured or are about to have surgery**, tell your doctor or other healthcare professional.

If you have been on Dexamethasone for longer than 3 weeks and wish to stop taking it, **do not stop suddenly**.

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.

Taking Dexamethasone for a long time increases your chance of getting infections and these might be worse than normal. Also, dexamethasone treatment can hide the usual symptoms of infection. Amoebic dysentery and an infestation of a gut worm (strongyloidiasis) may be activated or become worse, as may fungal and viral infections of the eye.

It is particularly important to **avoid contact** with people who have **chicken pox, shingles or measles** especially if you have not already had these illnesses or are not sure if you have had them. Go to your doctor immediately if you come in contact with measles. Dexamethasone increases the risk of a severe bout of chicken pox.

You should still take your Dexamethasone, but the dose may need adjusting. If you are about to take dexamethasone, or are already taking it, and you get a rash or other symptoms of an infection, **tell your doctor immediately**.

Mental Problems while taking Dexamethasone Tablets

Mental health problems can happen while taking steroids like Dexamethasone (see also section 4 Possible side effects).

- 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 problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

Children

If a child is taking this medicine, it is important that the doctor monitors their growth and development regularly. Dexamethasone should not be routinely given to premature babies 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 including those obtained without a prescription. This includes herbal medicines. This is because Dexamethasone can affect the way some medicines work. Also, some other medicines can affect the way Dexamethasone works.

In particular, do not take this medicine and tell your doctor or pharmacist if you are taking any of the following:

- some medicines for fungal infections such as casofungin, amphotericin and ketoconazole
- cough and cold medicines that contain a decongestant called ephedrine
- some medicines may increase the effects of Dexamethasone Tablets and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat, indinavir, lopinavir, saquinavir)
- aprepitant, a drug used to treat sickness and feeling sick
- aspirin
- medicines for fits (epilepsy) such as phenytoin, phenobarbital, carbamazepine and primidone
- medicines used for TB (tuberculosis) called rifabutin or rifampicin
- medicines used to thin the blood such as warfarin
- water tablets (diuretics)
- a medicine for cancer called aminoglutethimide
- some medicines for heart failure such as digoxin, furosemide or bumetanide
- a medicine used for some infections called erythromycin
- oral contraceptive pills and hormone replacement therapy (HRT)
- a type of growth hormone called somatropin
- some medicines for high blood pressure
- some medicines for heart disease such as guanethidine, isosorbide mononitrate, isosorbide dinitrate and theophylline
- carbenoxolone, an ulcer-healing drug

- anti-cancer drugs (cytotoxics)
- mifepristone, a drug used to assist in the medical termination of pregnancy
- medicines sometimes used for asthma, low blood pressure or in cough and cold remedies called sympathomimetics
- calcium supplements
- medicines for pain and inflammation called NSAIDs such as ibuprofen, diclofenac or naproxen
- a medicine for urea cycle disorder called sodium phenylbutyrate (usually started by a specialist doctor or consultant)
- medicines for diabetes
- medicines for heartburn, indigestion or stomach ulcers, called antacids
- medicines used to treat a condition called myasthenia gravis
- medicine for glaucoma such as acetazolamide.

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

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. Dexamethasone can reach your baby and may slow its growth. Small amounts of dexamethasone may get into breast milk; tell your doctor if you are breast-feeding.

Driving and using machines

Steroids may cause a feeling of movement, even while you are still and this can cause you to feel dizzy (vertigo). Changes in your eyesight or muscle weakness may also happen. If you are affected you should not drive or operate machinery.

Important information about some of the ingredients of Dexamethasone

This medicine contains lactose monohydrate. 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 Tablets

Remember always to carry a Steroid Treatment Card. Make sure your doctor or pharmacist gives you this and has filled out the details including the dose and how long you will have treatment.

If you have surgery, an accident or become unwell while taking this medicine, tell whoever is treating you that you are taking Dexamethasone tablets.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

The dose is chosen by your doctor and usually depends on how serious your condition is. Always follow your doctor's instructions and read the pharmacy label. If you are unsure, ask your doctor or pharmacist.

Swallow the tablets whole with some water. Do not chew them.

For the treatment of Covid-19

Adults

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

Adults:

Your doctor will probably ask you to take a total DAILY dose of between 2 mg and 10 mg. Up to 20 mg daily may be given for treating swelling on the brain. Usually, you will take your day's dose of Dexamethasone Tablets as a single dose in the morning.

Children:

- Your child's doctor will decide what dose should be given to your child, depending on the condition that is being treated and the size of your child.
- Children will be prescribed the lowest possible dose.
- The doctor will keep an eye on their growth and development.

Sometimes, you may need blood or urine tests to work out how much you should take.

Do not stop taking Dexamethasone Tablets suddenly. When you no longer need them, your daily dose should be reduced gradually. However, you should speak to your doctor or pharmacist about the best way to safely reduce your daily dose.

If you take more Dexamethasone Tablets than you should

Taking too many tablets will cause much larger effects and you may get any of the side effects described in this leaflet. Tell your doctor who will treat your symptoms and may slowly reduce your dexamethasone dose. Do not stop taking your Dexamethasone Tablets suddenly.

If you forget to take Dexamethasone Tablets

If you forget to take your dose, take it as soon as you remember, then continue to take your medicine as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Dexamethasone Tablets

Do not stop taking Dexamethasone Tablets just because you feel better. If you stop too soon or too suddenly you may get withdrawal symptoms which can be severe. Refer to your **Steroid Treatment Card** and always discuss your treatment with your doctor who will tell you if treatment can be stopped and how to reduce the dose gradually.

Sudden withdrawal (after 3 weeks or more of treatment) can cause such a severe drop in blood pressure it may kill you.

Less severe symptoms of withdrawal can include: Fever, muscle pain, joint pain, runny nose (rhinitis), sticky eyes (conjunctivitis), painful itchy skin lumps and weight loss.

Your doctor or pharmacist will give you advice on how to reduce the dose that you take if you need to do this.

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. People taking steroids to replace similar naturally occurring hormones, should be less likely to get side effects than, people taking steroids for other illnesses. Your doctor will want to see you now and then to look out for these effects.

Serious side effects: tell a doctor straight away

- Any kind of skin rash or itching of the skin
- Difficulty in breathing or collapse
- Swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing (angioedema).

These are signs of an allergic reaction and you may need to stop taking the medicine.

Steroids including Dexamethasone can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Dexamethasone. These 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 which do not exist
- Having strange and frightening thoughts, changing how you act or having feelings of being alone.

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

Other side effects can include:

- thinning of the bones (osteoporosis), spontaneous fractures, tendon rupture, muscle wasting
- diabetes, reduced carbohydrate tolerance – increased insulin need
- mental disturbances such as excitability (euphoria), delusions (paranoia), psychological dependence, depression (risk of suicide in patients with a history of mental disorder), being unable to sleep (insomnia), Feeling, seeing or hearing things that do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone, fits or epilepsy may become worse, schizophrenia may become worse.

- stomach ulcers which may perforate or bleed, indigestion, having more of an appetite than usual, diarrhoea, feeling or being sick, thrush (candidiasis)
- irregular or absent monthly periods, weight gain, increased appetite
- moon face, excess body hair (hirsutism), flushing, increased bruising and skin discolouration, acne
- stunted growth (infants, children, teenagers)
- increased liability to infection and severity of infection
- delayed wound healing, skin thinning, dilated capillaries, heart muscle rupture subsequent to recent heart attack, changes in fluid levels and the levels of certain chemicals in your blood called electrolytes, increased concentration of white blood cells, allergic reactions (including anaphylaxis), nausea, malaise, hiccups, increased sweating, increased likelihood of blood clots
- increased pressure within brain
- increased severity of eye infections
- increased pressure in the eye (glaucoma)
- changes in vision including cataract
- headache, vertigo
- congestive heart failure
- rash (urticaria) or red/purple spots (petechiae)
- visual disturbances, loss of vision, blurred vision
- problems with salts in your blood such as too much sodium or low potassium or calcium. You may have water retention.

You are more likely to have side effects if you are on a higher dose.

Your doctor will want to see you now and then to look out for these effects. If you notice any of these, or if you get any other unusual feelings or symptoms, keep taking Dexamethasone but contact your doctor or pharmacist as soon as you can.

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: www.mhra.gov.uk/yellowcard) 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 Tablets

- Keep this medicine out of the sight and reach of children.
- Keep the tablets in the original container in order to protect from light.
- Do not use this medicine after the expiry date which is stated on the carton, blister and bottle after Exp. The expiry date refers to the last day of that month.
- 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 contains

- The active substance is dexamethasone. Each tablet contains 2mg of dexamethasone.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (type A), colloidal anhydrous silica and magnesium stearate (E470b).

What Dexamethasone Tablets look like and contents of the pack

- Dexamethasone 2 mg Tablets are round, white tablets marked DX 2 on one side.
- The tablets are supplied in blister packs of 50 and 100 tablets, and a plastic bottle of 500 tablets (hospital dispensing pack).

Marketing Authorisation holder:

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

Manufacturer:

TioFarma BV, Benjamin Franklinstraat 9, Oud-Beijerland, The Netherlands.

This leaflet was last revised in September 2023.

PL 00289/2269