

B. PACKAGE LEAFLET

Package leaflet: Important information for the patient

Dexamethasone 2mg Tablets Dexamethasone

- **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 for more information)**
- **If you take it for more than 3 weeks, in the UK, you will get a blue 'steroid card': always keep it with you and show it to 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.

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.

Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone)

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 lowers inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Dexamethasone can be used to:

- Reduce inflammation
- Treat a number of different diseases of the immune system

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). 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 need to have a 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 while taking steroid medicines like Dexamethasone
- If any of your close family has had these illnesses
- If you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands).

Mental problems while taking Dexamethasone

Mental health problems can happen while taking 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 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.

Take special care with Dexamethasone

Before you take Dexamethasone, tell your doctor if:

- 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 underactive thyroid gland
- You have an infection with parasites
- You have tuberculosis (TB)
- You have stunted growth
- Contact your doctor if you experience blurred vision or other visual disturbances

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

If you develop an infection while you are taking this medicine, you should talk to your doctor. 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.

If you are living in the UK, you should always carry a blue 'steroid card' which gives clear guidance on the special care to be taken when you are taking this medicine. Show this to any doctor, dentist or person who may be giving you treatment. 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 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, particularly with 'live virus' vaccines

If any of the above apply to you, you should tell your doctor or the person treating you even if you have stopped taking this medicine.

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 if you are taking, have recently taken or might take any other medicines. 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 to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone and primidone
- Medicines to treat stomach problems, such as antacids
- Carbenoxolone, sometimes used for ulcers
- Medicines that control pain or lower inflammation, such as aspirin, ibuprofen or similar non-steroidal anti-inflammatories (NSAIDs)
- Medicines used to treat diabetes
- Medicines used to lower potassium levels
- Medicines used to treat myasthenia
- Indinavir or saquinavir used to treat HIV
- 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)
- Oral contraceptives containing oestrogen and progestogen
- Anti-cancer treatments, such as aminoglutethimide
- Methotrexate used for cancer or inflammatory problems
- Ephedrine used to relieve symptoms of a blocked nose
- Acetazolamide used for glaucoma

Talk to your doctor, pharmacist or nurse before you take Dexamethasone.

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

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.

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 or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take Dexamethasone as 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.

For the treatment of Covid-19

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

Taking this medicine

- Your doctor will tell you how many tablets to take. This will depend on your illness and how bad it is
- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- Do not crush or chew the tablets

Usual dose for adults

- The usual dose is 0.5mg to 10mg each day
- As you get better your doctor may then reduce your dose or ask you to take another corticosteroid such as 'prednisolone'

Usual dose for children

- The usual dose is 0.01 to 0.1 milligrams per kilogram of body weight

If you take more Dexamethasone than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. The following effects may happen:

- Swelling of the throat
- Skin reaction
- Difficulty breathing

If you forget to take Dexamethasone

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose
- Do not take a double dose to make up for a forgotten dose

If you stop taking Dexamethasone

It can be dangerous to stop taking this medicine suddenly.

If you need to stop this treatment, follow your doctor's advice. He or she may tell you to lower the amount of medicine you are taking gradually until you stop taking it altogether. If you stop taking this medicine too quickly, your condition may get worse.

You may also feel a 'withdrawal symptom'. These may include headache, problems with your vision (including pain or swelling in the eye), feeling or being sick, fever, pain in your muscles and joints, swelling in the inside of your nose, weight loss, itchy skin and conjunctivitis.

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.

Dexamethasone can also cause side effects when you stop taking it.

- See Section 3: If you stop taking Dexamethasone

Serious side effects: tell a doctor straight away

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 that 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**.

If you have an allergic reaction to Dexamethasone see a doctor straight away

An allergic reaction may include:

- 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)

If you get any of the following side effects see your doctor as soon as possible:

- **Stomach and gut problems:** ulcers in the throat, stomach ulcers, which may perforate or bleed, indigestion, feeling sick (nausea) or being sick (vomiting), a swollen stomach, having more of an appetite than usual, hiccups, diarrhoea
- **Inflamed pancreas:** this may cause severe pain in the back or tummy
- **Problems with salts in your blood** such as too much sodium or low potassium or calcium. You may have water retention
- **Heart and blood problems:** high blood pressure, blood clots, problems with the muscles in your heart after a recent heart attack
- **Bone problems:** thinning of the bones (osteoporosis) with an increased risk of fractures, bone disease
- **Recurring infections** that get worse each time such as thrush and chicken pox
- **Skin problems:** wounds that heal more slowly, bruising, acne
- **Eye problems:** increased pressure in the eye including glaucoma, eye disorders such as cataracts, eye infections, visual disturbances, loss of vision, blurred vision
- **Hormone problems:** irregular or missing periods, stunted growth in children and teenagers, swelling of the face (called 'Cushingoid' or 'moon' face). It may affect your diabetes and you may notice you start needing higher doses of the medicine you take for diabetes. Your body may not be able to respond normally to severe stress such as accidents, surgery or illness, growth of extra body hair (particularly in women), increased appetite or weight gain
- **Nervous system problems:** fits or epilepsy may become worse, severe unusual headache with visual problems, being unable to sleep, feeling depressed, extreme mood swings, schizophrenia may become worse, headache or problems with your vision (including eye pain or swelling)
- **General problems:** may make you feel generally unwell or tired

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:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

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 store above 25°C. Do not store in the fridge

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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 Tablets BP 2mg contain 2mg of dexamethasone per tablet
- The other ingredients in Dexamethasone Tablets BP 2mg are potato starch, propylene glycol, magnesium stearate and lactose.

What Dexamethasone looks like and contents of the pack

- Dexamethasone Tablets BP 2mg are round, flat and white. They are marked with XC/8 on one side and plain on the other side
- Dexamethasone tablets are sold in containers of 100 and 50 tablets. They may also be available in containers of 500 tablets.

Marketing Authorisation Holder and Manufacturer

Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

The Manufacturer is:

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For any information about this product, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in February 2022