

PACKAGE LEAFLET: INFORMATION FOR THE USER

DEXAMETHASONE

0,5 mg Tablets e

DEXAMETHASONE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Dexamethasone is and what it is used for
2. Before you take Dexamethasone
3. How to take Dexamethasone
4. Possible side effects
5. How to store Dexamethasone

1. WHAT DEXAMETHASONE IS AND WHAT IT IS USED FOR

The name of your medicine is Dexamethasone. This belongs 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 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

2. BEFORE YOU TAKE DEXAMETHASONE

Do not take Dexamethasone and tell your doctor if:

- You are allergic (hypersensitive) to dexamethasone or any other ingredients in this medicine. The signs of an allergic reaction include a rash, itching or shortness of breath
- You have an infection that affects the whole body
- You need to have a vaccination, particularly with 'live virus' vaccines
- Do not take this medicine if any of the above apply to you, talk to your doctor or pharmacist before taking Dexamethasone.

Check with your doctor first:

- 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 doctor before taking this medicine.

Mental problems while taking Dexamethasone

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.

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

More important information about taking this kind of medicine

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.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal 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
- Ritonavir, indinavir or saquinavir used to treat HIV
- 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

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Dexamethasone

This medicine 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

Take this medicine as your doctor or pharmacist has told you. Read the label and ask the doctor or pharmacist if you are not sure.

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 (two doses at the same time) 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, Dexamethasone 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

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. Also 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
- 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 has become worse, headache or problems with your vision (including eye pain or swelling)
- General problems: may make you feel generally unwell or tired

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, tell your doctor or pharmacist.

5. HOW TO STORE DEXAMETHASONE

- Keep out of the reach and sight of children
- Do not store above 25°C. Do not store in the fridge
- Do not use after the expiry date which is stated on the pack
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

This leaflet was last revised in February 2014