

DEXAMETHASONE 2 mg/5 ml ORAL SOLUTION

(Dexamethasone Sodium Phosphate)

Important information about this medicine

- **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.

Read all of this leaflet carefully 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. 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 doctor or pharmacist.

In this leaflet:

1. What is DEXAMETHASONE and what is it used for?
2. What you need to know before you take DEXAMETHASONE
3. How to take DEXAMETHASONE
4. Possible side effects
5. Storing DEXAMETHASONE
6. Further information

1. What is DEXAMETHASONE and what is it used for?

The name of this medicine is Dexamethasone 2 mg/5 ml Oral Solution. It contains Dexamethasone sodium phosphate. Dexamethasone 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.

This medicine can be used for:

- Replacing natural corticosteroids when levels have been reduced
- Reducing swelling of the brain which is not caused by a head injury
- Treating swelling (inflammation) and certain allergies
- Treating cancer
- Controlling how well your adrenal glands work. These are glands that are next to your kidneys
- Croup in babies and children. This affects the windpipe and the two airways that branch off from it to the lungs. The top of the airway is slightly blocked causing the barking cough, hoarse voice, a harsh sound (known as 'stridor') and breathing difficulties.

You may be using this medicine for a different reason.

Ask your doctor why this medicine has been prescribed for you.

2. What you need to know before you take DEXAMETHASONE

Do not take DEXAMETHASONE and consult your doctor if:

- You are allergic (hypersensitive) to Dexamethasone or any other ingredients in this liquid (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- You have an infection (including fungal infections) that affects the whole body, unless You are being treated for the infection
- You have an ulcer in your stomach (peptic ulcer) or digestive tract area (duodenal ulcer)
- You have an infection with tropical worms

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 Dexamethasone**.

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.

Warnings and precautions

Check with your doctor or pharmacist before taking your medicine if you have:

- Kidney or liver problems
- High blood pressure, heart disease or you have recently had a heart attack
- Diabetes or there is a family history of diabetes
- Thinning of the bones (osteoporosis), particularly if you are a female who has been through the menopause
- Had muscle weakness with this or other steroids in the past
- Raised eye pressure (glaucoma) or there is a family history of glaucoma
- A condition causing muscle weakness (myasthenia gravis)
- A bowel problem or a stomach (peptic) ulcer
- Mental problems or you have had a mental illness which was made worse by this type of medicine
- Epilepsy
- Migraines
- Had an allergy or unusual reaction to corticosteroids
- An underactive thyroid gland
- An infection with parasites

- Tuberculosis, septicaemia or a fungal infection in the eye
- Malaria that affects the brain (cerebral malaria)
- Herpes, including cold sores or genital herpes
- Asthma
- 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.
- 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 taking Dexamethasone.

More important information about taking this kind of medicine

Taking this medicine can cause problems with your kidneys. This means that you must stop taking this medicine gradually if you have been taking it for a long time.

Tell your doctor if you get ill, injured or have an operation while you are taking this medicine. This is because they may need to increase your dose during this time.

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 'Steroid treatment' 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.

This medicine can cause children to grow more slowly. Because of this, they should take the lowest possible dose for the shortest possible time. Children who use this medicine for any length of time should be carefully monitored by the doctor.

The common side effects of Dexamethasone may be associated with more serious consequences in old age especially thinning of the bones (osteoporosis), high blood pressure, low potassium levels in the blood (hypokalaemia), diabetes, susceptibility to infection and thinning of the skin. Extra supervision by your doctor is necessary.

DEXAMETHASONE and viral infections

While you are taking this kind of medicine, you should not come into contact with anyone who has chickenpox, shingles or measles. 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 immediately. You should also tell your doctor if you have ever had infectious diseases such as measles or chickenpox 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 such as MMR, tuberculosis, yellow fever or oral typhoid.

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

If you have suppression tests or tests for infection, you should tell the person giving you the test that you are taking this medicine as it may interfere with the results of the test.

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Taking some medicines together can be harmful.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to treat heart and blood problems, such as warfarin, high blood pressure medicines, a cholesterol lowering medicine called colestyramine and water tablets (diuretics)
- Medicines to treat infections, such as amphotericin B iv injection, rifabutin, rifampicin, a medicine for fungal infections called ketoconazole, antibiotics including erythromycin, a medicine for worm infections called praziquantel and a medicine for tuberculosis called isoniazid
- Medicines to treat epilepsy, such as phenytoin, carbamazepine, primidone, phenobarbital and acetazolamide, also used for glaucoma
- Medicines to treat stomach problems, such as antacids, charcoal and carbenoxolone. You should leave at least two hours between taking these medicines and Dexamethasone
- Medicines that calm emotions or for sleeping, such as barbiturates or sulpiride
- Medicines that control pain or lower inflammation, such as aspirin or similar non-steroidal anti-inflammatory drugs (NSAIDs), such as indometacin, hydrocortisone, cortisone and other corticosteroids. You should be carefully monitored if you are taking NSAIDs at the same time as taking Dexamethasone because you are more likely to get stomach or gut ulcers
- Medicines used to treat diabetes such as insulin, metformin or sulfonylureas such as chlorpropamide

- Medicines that help muscle movement in myasthenia gravis, such as neostigmine
- 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)
- Oestrogen tablets including the contraceptive pill
- Ciclosporin used to stop the rejection of organs after transplants
- Anti-cancer treatments, such as aminoglutethimide and thalidomide, also used for leprosy
- Ephedrine which helps to tighten blood vessels
- Tetracosactide
- Methotrexate
- Medicines to treat viral infections such as indinavir and aquinavir
- Live vaccines such as MMR, tuberculosis, yellow fever or oral typhoid

If you are unsure of the types of medicines you are taking, ask your doctor or pharmacist.

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

You may experience dizziness when taking this medicine (see section 4: possible side effects). This may affect your ability to drive. If this happens, do not drive or use tools or machinery.

Important information about some of the ingredients of DEXAMETHASONE

This medicine contains liquid maltitol (E965) and sorbitol (E420). 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. You should check with them if you are not sure.

Taking this medicine

- This medicine contains 2mg of dexamethasone in each 5ml
- Take this medicine by mouth. Some people may be given a dexamethasone injection at the same time
- You may also find that your doctor will tell you to lower the amount of salt in your diet
- You may also need to take potassium supplements whilst taking this medicine. Your prescriber will advise you if this is necessary since patients should not routinely be taking potassium without medical supervision
- If your daily dose is very small, ask your pharmacist for a device to help you measure these amounts, such as an oral syringe.

The usual dose is:

Adults and older people:

- Take 0.5mg to 9mg each day as a single dose preferably in the morning
- If you are going to take the medicine for a long time your doctor will give you a 'maintenance dose' of 1.5mg each day

Children:

- A single dose on alternate days (every other day).

Croup in babies and children:

- Your doctor will work out the right dose in millilitres (mls) based on your child's weight. This is normally taken once, however sometimes your doctor will recommend that a second dose is also taken after 12 hours. Make sure you follow the doctor's instructions.

If you are taking this medicine as part of hospital tests:

- Take 500 micrograms to 2 mg per dose
- You will have this medicine for a short period of time.

If you take more DEXAMETHASONE than you should:

Do not take more Dexamethasone than stated on the label of your medicine. If you take too much medicine you should **seek** medical attention immediately, either by calling your doctor, or going to the nearest casualty department. Always take the labelled medicine container with you, even if there is no medicine left.

If you forget to take DEXAMETHASONE:

If you forget to take a dose, take it as soon as you remember unless it is almost time for the next one then carry on as before. Never take two doses together.

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, you may have low blood pressure and, in some cases, your illness could come back.
- You may also feel a **'withdrawal symptom'**. This may include fever, pain in your muscles and joints, swelling in the inside of your nose, weight loss, itchy skin and conjunctivitis.

Effects when treatment with DEXAMETHASONE is stopped:

After therapy with Dexamethasone for a longer period, the dose should be gradually decreased in order to prevent a relapse of your disease and to allow your adrenal gland to recover its normal function. The doctor will give you advice on how to do this.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

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

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), very happy (euphoria) or moods that go up and down
- Feeling anxious or irritable, having problems sleeping, difficulty in thinking or being confused and losing your memory
- Feeling, seeing or hearing things that do not exist or believing in things that are not real (delusions). Having strange and frightening thoughts, changing how you act or having feelings of being alone
- Schizophrenia becoming worse.

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

If you have an allergic reaction to Dexamethasone stop taking and seek medical help immediately.

An allergic reaction may include:

- Any kind of skin rash, flaking skin, boils or sore lips and mouth
- Sudden wheezing, fluttering or tightness of the chest or collapse.

If you get any of the following side effects, stop taking Dexamethasone and see your doctor as soon as possible:

- **Stomach and gut problems:** inflamed food pipe (oesophagus), ulcers in the food pipe or gut that may split and bleed, feeling sick (nausea) or being sick (vomiting), stomach ache or a swollen stomach, having more of an appetite than usual, hiccups, diarrhoea, tearing of the bowel, particularly if you have inflammatory bowel disease
- **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:** heart failure in people who are likely to have heart problems, high blood pressure, blood clots (signs of this may include redness, pain or numbness, throbbing, a burning feeling or swelling). There could also be a large rise in the number of white cells in your body. Some types of blood tests will show this affecting you
- **Bone problems:** thinning of the bones with more of a risk of fractures, also hip, arm and leg bone problems, ruptured tendons, muscle wasting and muscle weakness
- **Recurring infections:** that get worse each time. This may be a sign that your immune system is low. Recurrence of TB (tuberculosis) if you have already had it before. You may also get thrush
- **Skin problems:** wounds that heal more slowly, thinned, delicate skin unusual purple spots on the skin or bruising, redness and inflammation of the skin, weaker reaction to skin tests, stretch marks, acne, sweating more than usual, skin rash or swollen small veins under the skin, thinning of hair
- **Eye problems:** cataracts, increased pressure in the eye including glaucoma swelling inside the eye, blurred vision, thinning of the covering of the eyeball, eye infections that you may already have can become worse, bulging of the eyeballs, visual disturbances, loss of vision
- **Hormone problems:** growth of extra body hair (particularly in women), weight gain, irregular or missing periods, changes in the levels of protein and calcium in your body (which would be detected by a blood test), stunted growth in children and teenagers and swelling and weight gain of the body and face (called 'Cushingoid state')
Dexamethasone may affect your diabetes and you may notice you start needing higher doses of the medicine you take for diabetes. While taking dexamethasone your body may not be able to respond normally to severe stress such as accidents, surgery or illness
- **Nervous system problems:** fits or epilepsy may become worse, feeling dizzy, headache, severe unusual headache with visual problems usually in children (normally after treatment has been stopped), a feeling that you are addicted to the medicine, being unable to sleep, feeling depressed, extreme mood swings
- **Other side effects:** may make you feel generally unwell. If you are a man, this medicine can affect the amount of sperm and their movement.

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). By reporting side effects you can help provide more information on the safety of this medicine.

5. Storing DEXAMETHASONE

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

This medicinal product does not require any special storage conditions.

The label on the bottle shows an expiry date (month & year). Do not use this product after this date. The expiry date refers to the last day of that month.

Use within 3 months of opening.

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.

6. Further Information

What DEXAMETHASONE contains:

Each 5 ml of Dexamethasone Oral Solution contains 2 mg of the active substance dexamethasone as dexamethasone sodium phosphate.

The medicine also contains benzoic acid (E210), propylene glycol (E1520), citric acid monohydrate (E330), liquid maltitol (E965), garden mint flavour (containing isopropanol and propylene glycol), liquid sorbitol (non-crystallising) (E420), sodium citrate (E331) and purified water.

What DEXAMETHASONE looks like and contents of the pack:

Dexamethasone Oral Solution is a clear, colourless solution with an odour of mint.

Dexamethasone Oral Solution is available in a 150 ml pack.

Marketing authorisation holder:

Auden Mckenzie (Pharma Division) Ltd.
Mckenzie House
Bury Street
Ruislip
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