

Dexamethasone 2 mg/5 ml Oral Solution

Dexamethasone
(as 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 do come into contact with chicken pox or shingles, 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.

The name of the product is Dexamethasone 2mg/5ml Oral Solution but will be referred to as Dexamethasone in this leaflet.

Read all of this leaflet carefully before you are given 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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

Dexamethasone belongs to a group of medicines called corticosteroids. These 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 reduces this inflammation, which could otherwise continue to make your condition worse. You must take this medicine regularly to get the maximum benefit from it.

Dexamethasone can be used to:

- 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 a 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 if you:

- are allergic to dexamethasone or to any of the other ingredients in this medicine, listed in section 6 of this leaflet
- The signs of an allergic reaction include a rash, itching or shortness of breath
- have an infection (including fungal infections) that affects the whole body, unless you are being treated for the infection
- have an ulcer in your stomach (peptic ulcer) or digestive tract area (duodenal ulcer)
- have an infection with tropical worms.
- had vaccination with live vaccines, e.g. chickenpox

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.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Dexamethasone if:

- you have kidney or liver problems
- you have high blood pressure, heart disease or you have recently had a heart attack
- you suffer from diabetes or there is a family history of diabetes
- you have osteoporosis (thinning of the bones), particularly if you are a female who has been through the menopause
- you have suffered from muscle weakness with this or other steroids in the past
- you have glaucoma (raised eye pressure) or there is a

- family history of glaucoma
- you have a condition causing muscle weakness (myasthenia gravis)
- you have a bowel disorder or a stomach (peptic) ulcer
- you have mental problems or you have had a illness which was made worse by this type of medicine
- you have epilepsy
- You have migraines
- you have had an allergy or unusual reaction to corticosteroids
- you have an underactive thyroid gland
- you have an infection with parasites
- you have spent time in the tropics
- you have unexplained diarrhoea
- you have tuberculosis, septicaemia or a viral or fungal infection in the eye
- you have malaria that affects the brain (cerebral malaria)
- you have herpes (cold sores or genital herpes)
- you have 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.

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.

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 following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience these signs.

Talk to your doctor before taking Dexamethasone if you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands).

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.

Other medicines and Dexamethasone

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines

If you are taking any of the following medicines, you should

consult your doctor before taking Dexamethasone:

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).

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

- 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-inflammatories (NSAIDs), such as indometacin, hydrocortisone, cortisone and other corticosteroids. You should be

Continued overleaf

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
- ritonavir, used to treat HIV
- 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 saquinavir
- live vaccines such as MMR, tuberculosis, yellow fever or oral typhoid.

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before using this medicine.

Driving and using machines

Dexamethasone may cause side effects that may affect your ability to drive or use machines (see also section 4. Possible side effects). If you are affected you should not attempt to drive or use machines.

Dexamethasone contains sodium, benzoic acid, sorbitol, maltitol and propylene glycol

- This medicine contains up to 3g sorbitol and 7g liquid maltitol per dose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product. May have a mild laxative effect. Calorific value 2.6kcal/g sorbitol and 2.3 kcal/g maltitol.
- This medicine also contains up to 2.5g propylene glycol per dose. This can be harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children less than 5 years of age and high-risk groups, such as patients with liver or kidney disease.

This medicine contains 5mg of benzoic acid in each 5ml. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks ago)

This product contains 7mg sodium per maximum daily dose. As this product contains less than 1mmol sodium per maximum daily dose, that is to say essentially 'sodium-free'

3. How to take Dexamethasone

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

The usual dose is:

Adults: The usual dose is 0.5mg to 9mg each day. As you get better your doctor may reduce your dose

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

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 doctors instructions.

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

- take 500 micrograms to 2mg for each dose
- you will have this medicine for a short period of time.

If you forget to take Dexamethasone

- If you forget a dose, take it as soon as you remember. 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 take more Dexamethasone than you should

If you take too much of your medicine you should contact your doctor or your nearest hospital casualty department **immediately**.

If you stop taking Dexamethasone

It can be dangerous to stop taking this medicine abruptly. If your treatment is to be stopped you should follow your doctor's advice. They may tell you to reduce the amount of medicine you are taking gradually until you stop taking it altogether. The symptoms that have been reported when treatment has been stopped too quickly have included low blood pressure and in some cases, relapse of the disease for which the treatment was given.

A 'withdrawal syndrome' may also occur, the symptoms of which include fever, muscle and joint pain, inflammation of the nose lining (rhinitis), weight loss, itchy skin and inflammation of the eye (conjunctivitis). Your doctor should gradually reduce the dose.

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

4. Possible side effects

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

Some side effects that have been reported following treatment with Dexamethasone are listed below.

- 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. If any of the following symptoms occur contact your doctor or nearest accident and emergency department **immediately**:
- feeling depressed, including thinking about suicide
 - feeling high (mania), very happy (euphoria) or moods that go up and down
 - feeling anxious, irritable, nervous, 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

It is also possible to experience a severe allergic reaction to medicines like Dexamethasone. If any of the following symptoms occur, contact your doctor or nearest accident and emergency department **immediately**.

- sudden wheeziness and tightness of chest
- swelling of eyelids, face or lips
- skin lumps or hives
- skin rash (red spots), itchiness, fever
- collapse

Other side effects that may occur include:

- **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
- **Heart and blood problems:** congestive 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.
- **Problems with salts in your blood** such as too much sodium or low potassium or calcium. You may have water retention
- **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 eye membranes, worsening of existing eye infections or bulging of the eyeballs
- Frequency rare: blurred vision. Frequency not known: visual disturbances, loss of vision.
- **Hormone problems:** growth of extra body hair (particularly in women), weight gain, unusual fat deposits, 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, worsening of schizophrenia, hallucinations (seeing or hearing things that don't exist), extreme mood swings, feeling restless or worried.
- **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 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 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

Keep this medicine out of the sight and reach of children.

Do not store above 25°C. Store in the original container, in order to protect from light.

Use within 28 days of opening.

Do not use Dexamethasone after the expiry date which is stated on the carton and bottle label after (EXP). 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 to protect the environment.

Always keep the medicine in the bottle in which it was originally given to you.

Do not use this medicine if you notice any defects or any signs of deterioration.

6. Contents of the pack and other information

What Dexamethasone contains:

The active substance is Dexamethasone Sodium Phosphate.

This medicine contains Dexamethasone Sodium Phosphate which is equivalent to 2mg Dexamethasone per 5 ml.

The other ingredients are benzoic acid (E210), propylene glycol (E1520), citric acid monohydrate, sodium citrate, liquid sorbitol (non-crystallising), liquid maltitol, garden mint flavour (contains propylene glycol E1520), citric acid 10% solution (pH adjustment) and purified water.

What Dexamethasone looks like and contents of the pack:

Dexamethasone is a colourless to faint yellow solution with an odour of mint. Each bottle contains 150 ml of solution.

Marketing Authorisation Holder:

Martindale Pharma
Bampton Road, Harold Hill, Romford, Essex RM3 8UG
United Kingdom

Manufacturer:

Martindale Pharmaceuticals
Bampton Road, Harold Hill, Romford, Essex RM3 8UG
United Kingdom

Marketing Authorisation number: PL 00156/0125

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If you would like any more information, or would like the leaflet in a different format, please contact medical information at the above address

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