

4. Possible side effects

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

Do not be alarmed by this list of possible side effects. You may not experience any of them. Some side effects only happen after weeks or months.

Seek medical help immediately if you have any of the following **allergic reactions:**

- ▶ difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- ▶ severe itching of the skin, with a red rash or raised lumps.

Also, seek immediate medical attention if you have come in contact with anyone suffering from chickenpox, shingles or measles.

Serious 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.



- ▶ 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.**

Tell your doctor if you get any of the following symptoms:

- ▶ headache
- ▶ acne
- ▶ a feeling of dizziness or spinning
- ▶ increased sweating
- ▶ nausea
- ▶ changes in vision
- ▶ visual disturbance, loss of vision
- ▶ malaise (feeling ill)
- ▶ slow wound healing
- ▶ hiccoughs
- ▶ thinned, delicate skin
- ▶ fits
- ▶ difficulty swallowing, sore throat, a feeling of chest pain (which may be signs of a fungal infection in the oesophagus (gullet))

- ▶ stomach pain and discomfort, swollen abdomen
- ▶ increased appetite
- ▶ raised blood pressure
- ▶ salt imbalances, fluid retention
- ▶ swelling and weight gain of the body and face
- ▶ high blood sugar, with symptoms such as excessive thirst
- ▶ increased requirement for diabetic medication
- ▶ muscle weakness and wasting
- ▶ thinning of bone with an increased risk of fractures
- ▶ pain behind the ribs radiating towards the back, often worse when lying down, nausea, vomiting, fever. This may be due to inflammation of your pancreas
- ▶ bruising and unusual skin markings or rash
- ▶ raised pressure in the eye(s) (glaucoma), cataracts
- ▶ irregular periods or absence of periods in women
- ▶ increase in body and facial hair growth
- ▶ slow growth or development in children and adolescents
- ▶ increased frequency or severity of infections.

Blood or skin tests: tell the doctor or nurse if you are having blood tests for bacterial infection, or skin tests, as the results may be affected.

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 the Yellow Card Scheme Website at: 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 take after the expiry date, which is clearly marked on the carton and bottle label after 'Exp'. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C.
- ▶ Keep the container in the outer carton in order to protect from light.
- ▶ Discard 90 days after first opening.

- ▶ Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.

6. Contents of the pack and other information

What Dexamethasone contains
The active ingredient is Dexamethasone sodium phosphate.

Each 5ml of oral solution contains 2mg dexamethasone (as dexamethasone sodium phosphate).

The other ingredients are propylene glycol (E1520), benzoic acid (E210), citric acid monohydrate (E330), sodium citrate (E331), liquid maltitol (E965), liquid sorbitol (E420), garden mint flavour (containing propylene glycol (E1520)) and purified water.

What Dexamethasone looks like and contents of the pack

Dexamethasone is clear colourless to faint yellow solution with odour of mint supplied in an amber glass bottle, with a tamper evident, child resistant white plastic cap with a 10ml oral syringe having 0.5ml graduation mark and 1ml oral syringe with 0.01ml graduation mark for measuring and an adaptor for the syringe.

Dexamethasone oral solution is supplied in a bottle containing 150ml oral solution.

POM

Marketing Authorisation Holder and Manufacturer:

Thame Laboratories,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 ONU, UK.

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

This leaflet was last revised in 03/2019.



Package leaflet: Information for the users

Dexamethasone 2mg/5ml Oral Solution



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, 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 chickenpox or shingles,** if you have never had them. They could affect you severely. If you do come into contact with chickenpox or shingles, **see your doctor straight away.**

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.

The name of your medicine is Dexamethasone 2mg/5ml Oral Solution but it will be referred to as 'Dexamethasone' throughout this leaflet.

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

Dexamethasone contains dexamethasone sodium phosphate. This belongs to a group of medicines called steroids. Their full name is 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 go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Some of the illnesses and conditions that dexamethasone is used for include:

- ▶ swelling of the brain and increased pressure in the brain caused by a tumour
- ▶ severe allergic reactions
- ▶ blood disorders such as leukaemia and haemolytic anaemia (a reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness)
- ▶ sarcoidosis, an immune disease that can lead to excessive levels of calcium and vitamin D in the body
- ▶ inflammation of the heart in association with heart attack or heart surgery
- ▶ intestinal disorders, e.g. Crohn's disease, ulcerative colitis
- ▶ respiratory disorders such as asthma
- ▶ tuberculosis (together with appropriate chemotherapy)

- ▶ certain inflammatory skin and muscular disorders
- ▶ inflammation of the eye
- ▶ rheumatoid arthritis
- ▶ kidney inflammation caused by SLE, a disease of the immune system.

2. What you need to know before you take Dexamethasone

Do not take Dexamethasone if:

- ▶ you are allergic to dexamethasone or any other ingredients of this medicine (listed in section 6)
- ▶ you have an untreated infection affecting your whole body
- ▶ you have a fungal infection affecting the whole of your body, e.g. thrush
- ▶ you are to have a 'live virus' vaccination.

If any of the above apply to you, talk to your doctor or pharmacist.

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.**

Warnings and precautions

Talk to your doctor before taking Dexamethasone. You should tell your doctor if you have any of the following conditions:

- ▶ recently suffered from a heart attack
- ▶ tuberculosis
- ▶ kidney or liver problems, including cirrhosis
- ▶ an underactive thyroid
- ▶ high blood pressure
- ▶ diabetes, or a family history of diabetes; your doctor may need to increase your dose of diabetic treatment
- ▶ heart problems
- ▶ thinning of the bones (osteoporosis)
- ▶ raised pressure in the eye(s) (glaucoma) or a family history of glaucoma
- ▶ myasthenia gravis (which causes weakened muscles)



- ▶ intestinal or stomach problems
- ▶ had muscle weakness with steroids in the past
- ▶ an eye infection caused by herpes virus
- ▶ malaria affecting the brain
- ▶ epilepsy
- ▶ severe mental health problems or if you ever had **severe depression** or manic depression (bipolar disorder) or if a family member has or has ever had these problems. This includes having had depression before while taking steroids
- ▶ symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbance and shortness of breath, in case you suffer from haematological malignancy.

Pay attention when using Dexamethasone

Dexamethasone should not be used routinely in preterm neonates with respiratory problems.

Children and adolescents

Long term use of steroids at high doses may cause slowing of growth in children. Your doctor may check your child's height at intervals during treatment and reduce the dose if any effects are seen.

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.

Chickenpox, shingles, measles

These infections will become more serious during treatment with steroids, and you will require urgent specialist care if you become exposed to someone with these infections. DO NOT stop taking the medicine.

If you have not had chickenpox, shingles or measles, you should AVOID contact with anyone who has these illnesses.

If you think that you have been exposed to any of these infections, **seek immediate medical attention**. Do this if you are taking this medicine, or have taken them during the previous 3 months.

Surgery or other treatment by a doctor, dentist or nurse

If you have an accident, become ill, require any surgery (including at the dentist's), or are to have any 'live virus' vaccinations during or after treatment with Dexamethasone, you MUST tell the person treating you that you are taking or have taken steroids.

Other medicines and Dexamethasone

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

Some medicines may be affected by dexamethasone or they may affect how well dexamethasone will work. Tell your doctor or pharmacist if you are taking:

- ▶ aspirin or similar medicines
- ▶ phenytoin (to treat epilepsy)
- ▶ ephedrine (a nasal decongestant)
- ▶ barbiturates (to treat sleeplessness and epilepsy)
- ▶ ketoconazole (for fungal infections)
- ▶ rifampicin and rifabutin (antibiotics used to treat tuberculosis)
- ▶ erythromycin or similar antibiotics
- ▶ anticoagulants (to thin the blood), such as warfarin
- ▶ medicines for diabetes, including insulin; your doctor may need to increase your dose of diabetic treatment
- ▶ diuretics (water tablets)
- ▶ carbamazepine (for epilepsy, pain, manic depression)
- ▶ aminoglutethimide (a cancer medicine)
- ▶ thalidomide (to treat leprosy)
- ▶ indometacin, as this may affect dexamethasone tests for certain diseases.

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).

Pregnancy, breast-feeding and fertility

Dexamethasone may pass to your unborn baby or into breast milk. DO NOT take dexamethasone if you are pregnant, planning to become pregnant or while breast-feeding unless advised to by your doctor.

Steroids may affect sperm count and movement in men. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Dexamethasone is unlikely to affect your ability to operate machinery or to drive.

Dexamethasone contains

This product contains 700mg **sorbitol** (E420) in each 5ml of dose. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This product also contains **maltitol** (E965). 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 2.3 kcal/g maltitol (or isomaltitol).

This medicine contains 2.2275mg sodium (main component of cooking/table salt) in each 5ml dose. This is equivalent to 0.11% of the recommended maximum daily dietary intake of sodium for an adult.

This product also contains 182.2mg **propylene glycol** (E1520) in each 5ml of dose. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

This medicine contains 3 mg **benzoic acid** (E210) in each 5ml of dose. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

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. Your doctor will decide on the appropriate dose to suit your condition.

The recommended dose is: Adults and the elderly

The usual starting dose is 1.25ml (0.5mg) to 22.5ml (9mg) per day. Your doctor will tell you the correct dose and when to take it depending on your condition, and may give you the lowest dose to reduce side effects and to control your condition. Your doctor may change the dose during treatment. Elderly patients will be monitored more frequently.

Use in children and adolescents:

Usually 1.25ml (0.5mg) single dose on alternate days will be given. The doctor will also monitor growth and development at intervals during treatment.

During treatment: because of possible side effects, your doctor may monitor you at intervals during your treatment.

Taking dexamethasone long term

You may be given a blue 'steroid treatment card': always keep it with you and show it to any doctor, pharmacist or nurse treating you.

See your doctor if you develop any new infections while taking Dexamethasone.

Prolonged use may lead to eye problems e.g. cataracts or glaucoma.

Withdrawal symptoms, such as fever, muscle weakness or pain, aching joints or malaise (feeling ill), may occur after stopping long term treatment with dexamethasone.

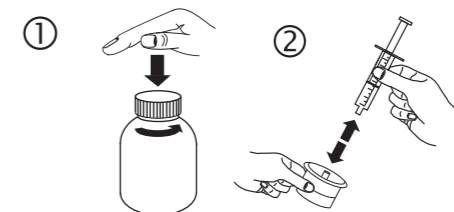
Route and method of administration

- ▶ this medicinal product must be taken orally
- ▶ take this medicine with plenty of water, with or immediately after a **meal** to prevent upset stomach
- ▶ Take this medicine **regularly** as advised by your doctor to obtain the maximum benefit
- ▶ use the measuring syringe provided in the pack to deliver the required dose.
- ▶ use 1ml measuring syringe for administration of initial dose 1.25ml or for 0.25ml graduation dose required

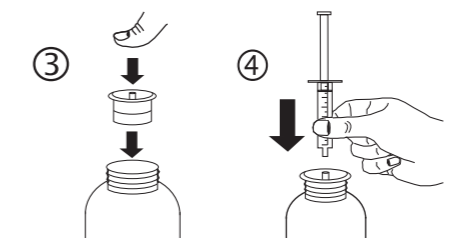
- ▶ use 10ml measuring syringe for administration of higher doses.

Instructions for the use of syringe:

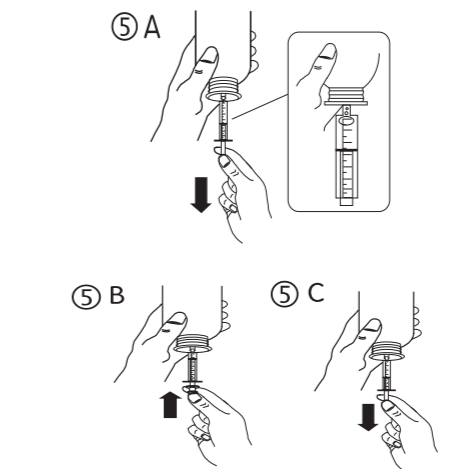
- Open the bottle: press the cap and turn it anticlockwise (figure 1). Separate the adaptor from the syringe (figure 2).



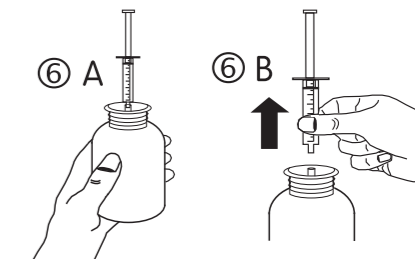
- Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



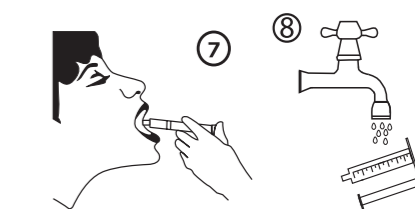
- Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



If you take more Dexamethasone than you should

- ▶ Tell your doctor, pharmacist or nearest hospital casualty department immediately.
- ▶ Take the container and any remaining medicine with you so that people can see what you have taken.
- ▶ Do this even if you feel well.

If you forget to take Dexamethasone

- ▶ If you forget to take a dose, take it as soon as you remember, but if it is almost time for your next dose, skip the missed and continue as usual.
- ▶ Do not take a double dose to make up for a forgotten dose.

If you stop taking Dexamethasone

Stopping this medicine suddenly can be dangerous, and may cause:

- ▶ low blood pressure
- ▶ a relapse of the disease for which treatment was given.

Keep taking the medicine until your doctor tells you how and when to stop.

Do not let yourself run out of medicine, especially over the weekends or on holidays.

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

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