

On long-term treatment:

- ▶ filling or rounding of the face, neck and body
- ▶ dehydration or weakness
- ▶ hormone deficiency
- ▶ irregular periods or complete absence of periods
- ▶ abnormal hair growth
- ▶ weight gain or weight loss
- ▶ increased or decreased appetite
- ▶ in diabetics: the need for more insulin or antidiabetic tablets
- ▶ recurring infections or mild infections getting worse e.g. chickenpox; being less protected after inoculation; having a decreased response to skin test; recurrence of dormant tuberculosis (TB)
- ▶ brittle bones (osteoporosis) or bone disease (osteonecrosis)
- ▶ muscle weakness
- ▶ fluid retention in the tissues, usually marked by swelling of ankles or feet
- ▶ sodium retention, usually marked by an increase in blood pressure
- ▶ calcium deficiency
- ▶ high blood pressure
- ▶ potassium loss
- ▶ changes of mood (nervousness, depression, euphoria, psychological dependence and schizophrenia)
- ▶ sleeplessness
- ▶ aggravation of epilepsy
- ▶ certain eye diseases (increased pressure in the eye, glaucoma, papilloedema (optic nerve swelling), cataracts (clouding of vision), thinning of the cornea or outer wall (sclera), worsening of a viral or fungal eye disease, visual disturbances or loss of vision)
- ▶ abdominal or stomach pain
- ▶ nausea and vomiting
- ▶ candidiasis (thrush)
- ▶ slower healing of wounds
- ▶ easy bruising; skin problems
- ▶ (spinal) fracture, tendon rupture
- ▶ telangiectasia (spider veins)
- ▶ in children: delayed or stunted growth and increased intracranial pressure (pseudo tumour cerebri)
- ▶ an increase in the amount of white blood cells in your blood
- ▶ a blood clot in your vessels
- ▶ In elderly: symptoms of diabetes (unusual thirst, frequent urination); loss of bone tissue with symptoms such as low back pain, loss of stature and fractures
- ▶ Blurred vision.

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.
- ▶ 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 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:

SyriMed,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK.

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

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Malta: Dexamethasone Thame 2mg/5ml Oral Solution United Kingdom

(Northern Ireland): Dexamethasone 2mg/5ml Oral Solution

This leaflet was last revised in 10/2023

Package leaflet: Information for the patient

Dexamethasone 2mg/5ml Oral Solution

Read all of this leaflet carefully before you start using 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

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. Taking extra corticosteroids, such as Dexamethasone, is used 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 including:
 - ▶ Rheumatism (pain, stiffness or limitation of motion in the joints, muscles and tendons)
 - ▶ Inflammations including inflammation of the joints and tissue around the joint (rheumatoid arthritis), inflammation of the skin (such as contact dermatitis), the eye, blood vessels and other parts of the body

- ▶ Allergic conditions which cause joint pain, skin rashes and fever
- ▶ Hypersensitivity reactions (allergic reactions) to other drugs or insect stings
- ▶ Anaphylactic shock (severe sudden allergic reaction)
- ▶ Asthma
- ▶ Potential rejection of an organ or tissue transplant
- ▶ Disorders of the adrenal gland
- ▶ Swelling of the brain and part of the treatment for some types of cancer
- ▶ Lupus erythematosus

You must talk to a doctor if you do not feel better or if you feel worse. 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 suffering from a stomach or intestinal ulcer
- ▶ If you have a general infection (caused by a virus or a fungus)
- ▶ If you are allergic to dexamethasone or any of the other ingredients in this medicine (listed in section 6). The signs of an allergic reaction include a rash, itching or shortness of breath.
- ▶ If you have a parasitic infection
- ▶ If you have recently had a vaccination with a live vaccine (especially chickenpox)

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.

Tell your doctor if 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.

If you have been using Dexamethasone for a longer period, the therapy may never be stopped abruptly. If during prolonged therapy any intercurrent illness, trauma or surgical procedure occurs, your doctor may decide to temporarily increase the dosage. Dexamethasone may mask symptoms of an infection and new infections may develop during therapy. Vaccines should, in certain circumstances, not be given to you during therapy. Your doctor will decide for you whether or not this is relevant to you. Exposure to chickenpox, shingles or measles should, if you have not had these diseases before, be avoided during therapy. Please contact your doctor if, for some reason, you have been exposed to chickenpox or measles during therapy. The common side effects of Dexamethasone may be associated with more serious consequences in old age, especially osteoporosis, high blood pressure, low potassium levels in the blood, diabetes, susceptibility to infection and thinning of the skin. Extra supervision by your doctor is necessary.

Contact your doctor if you experience blurred vision or other visual disturbances.

Before Dexamethasone is given to you, it is also important to tell your doctor if you have or ever had:

- Brittle bones (osteoporosis);
- High blood pressure or heart disease;
- Mental illness;
- Diabetes (or a family history of diabetes);
- Tuberculosis;
- Certain visual disturbances (glaucoma);
- Disease of the muscles (glucocorticoid-induced myopathy);
- Liver disease (liver failure);
- Kidney disease (renal insufficiency);
- Epilepsy;
- Peptic ulcer.

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

Children

Extra supervision by your doctor is necessary when Dexamethasone is used to treat children since glucocorticoids may affect growth.

Dexamethasone should not be used routinely in preterm neonates 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 used to treat epilepsy such as phenobarbitone, phenytoin, primidone and carbamazepine.
- ▶ Medicines used to treat tuberculosis such as rifampin and rifabutin.
- ▶ Medicines used to treat certain cancers such as aminoglutethimide.
- ▶ Antidiabetic medicines used to control blood sugar levels, including insulin.
- ▶ Medicines used to control blood pressure and diuretics (to stimulate urination).
- ▶ Medicines used to treat myasthenia gravis such as anticholinesterases.
- ▶ Use of certain diuretics (potassium-depleting diuretics such as acetazolamide, loop diuretics, thiazide diuretics or carbenoxolone) during therapy with Dexamethasone may result in hypokalaemia (a shortage of potassium).

- ▶ Certain anticoagulants used to prevent blood clots such as coumarins.
- ▶ The clearance of salicylates (e.g. aspirin) is increased during treatment with Dexamethasone. Therefore, if you stop using Dexamethasone, the dosage of salicylates should be lowered to prevent blood levels becoming too high and causing unwanted effects.
- ▶ Combination of corticosteroids with medicines which can cause stomach ulcers (e.g. painkillers like aspirin, ibuprofen) increases the risk of stomach ulcers.
- ▶ Dexamethasone can diminish the effects of medicines which are broken down in the body by an enzyme in the liver (CYP 3A4), for example, HIV protease inhibitors (e.g. indinavir), and certain antibiotics (e.g. erythromycin).
- ▶ 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).

You should not stop taking any other steroid medications unless your doctor has instructed you to do.

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.

Pregnancy

Dexamethasone should not be used for a prolonged period during pregnancy. If you receive Dexamethasone often or over a long period of time during pregnancy there may be a risk that the baby's growth slows down.

Breast-feeding

It is not known whether or not Dexamethasone is excreted into breast milk. Breast-feeding during treatment with Dexamethasone is therefore discouraged.

Driving and using machines

Glucocorticoids may cause mood changes or visual disturbances. If you notice this, caution should be exercised in driving and operating machinery.

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

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 (15 ml) 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 (15ml) once a day for up to 10 days.

Taking this medicine

- ▶ Your doctor will tell you how much to take. This will depend on your illness and how bad it is.
- ▶ Take this medicine by mouth.
- ▶ Take this medicine with plenty of water. Take the medicine at about the same time each day, preferably in the morning.

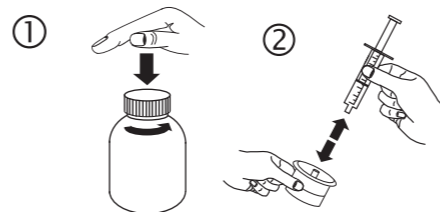
- ▶ Use 1ml measuring syringe for administration of initial dose 1.25ml or for 0.25ml graduation dose required
- ▶ Use 10ml measuring syringe for administration of higher doses.

Usual dose for adults

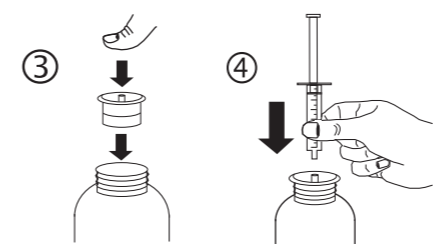
- ▶ The usual dose is 0.5mg (1.25ml) to 10mg (25ml) each day. When you get better the dosage is gradually decreased, preferably to one morning dose on alternate days.

Instructions for the use of syringe:

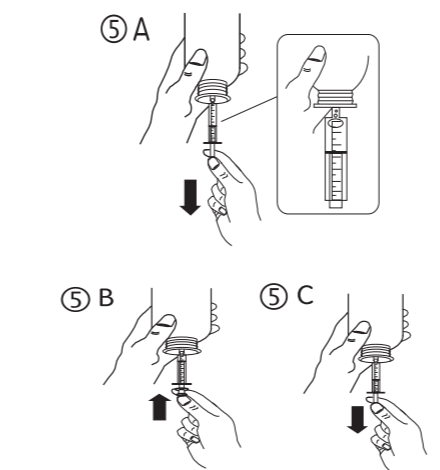
- a) Open the bottle: press the cap and turn it anticlockwise (figure 1). Separate the adaptor from the syringe (figure 2).



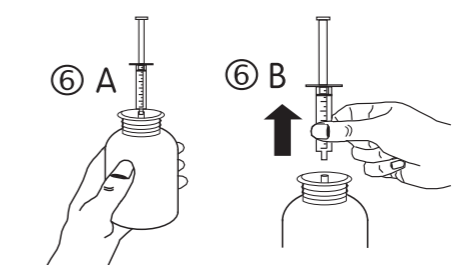
- b) Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



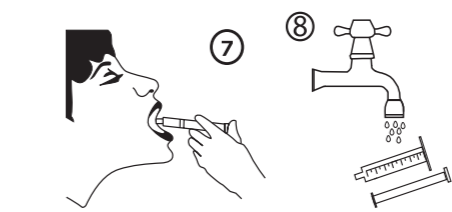
- c) Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed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



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



- e) 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

If you took more Dexamethasone than you should, talk to a doctor or pharmacist immediately.

If you forget to take Dexamethasone

Find the type of dose you take in the chart below and follow the instructions.

Your dose	What to do
One dose several times a day	Take the missed dose as soon as you remember, even if this means taking two doses at once
One dose a day (preferably in the morning)	If you remember on the same day, take the missed dose as soon as possible. If you do not remember until the next day, just skip the missed dose and take only the dose for that day. Do not take a double dose.

One dose every two days (preferably in the morning)	If you remember on the same morning, take the missed dose as soon as possible. If you remember later in the day, wait and take the dose the next morning. Then miss a day and start your regular pattern again in the following morning.
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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.

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.

4. Possible side effects

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

On short-term treatment:

- ▶ gastrointestinal complaints, such as an upset stomach or inflammation of the pancreas, ulcer of the stomach, ulcer of the duodenum, or bleeding ulcer
- ▶ hypersensitivity reactions (allergic reactions) e.g. rash, itch and difficulty in breathing and angioedema (swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing)