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Important information about some of the ingredients of Dexamethasone Oral Solution

Package leaflet: Information for the user

Dexamethasone 20mg/5ml Oral Solution

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, pharmacist or nurse.
- 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 take this medicine for more than three weeks, you will get a blue 'steroid card': always keep it with you and show it to any doctor, dentist, nurse, midwife or anyone else who is giving you treatment.
- 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.

The name of your medicine is Dexamethasone 20mg/5ml Oral Solution. It will be called Dexamethasone Oral Solution for ease here after.

What is in this leaflet

1. What Dexamethasone Oral Solution is and what it is used for
2. What you need to know before you take Dexamethasone Oral Solution
3. How to take Dexamethasone Oral Solution
4. Possible side-effects
5. How to store Dexamethasone Oral Solution
6. Contents of the pack and other information

1. What Dexamethasone Oral Solution is and what it is used for

Dexamethasone Oral Solution contains the active substance dexamethasone. Dexamethasone belongs to a group of medicines called steroids (the full name is corticosteroids). Corticosteroids occur naturally in the body and help to maintain health and well-being.

Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone).

Boosting your body with extra corticosteroid (such as dexamethasone) is an effective way to treat various illnesses involving inflammation in the body.

Dexamethasone Oral Solution reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Dexamethasone Oral Solution is used for one of the following

- where your natural corticosteroid levels have been reduced and you need to replace them
- where swelling of the brain has occurred
- if you are having tests for diseases which may decrease your natural corticosteroid level, such as Cushing's syndrome (a hormonal disorder)
- to reduce inflammation and suppress the immune system in:
 - allergy (hypersensitivity)
 - polymyalgia rheumatica (chronic inflammation of the larger arteries), polyarteritis nodosa (chronic inflammation of small and medium arteries)
 - blood disorders including haemolytic anaemia (disorder which breaks down red blood cells), leukaemia (cancer of the blood), myeloma (bone marrow tumour)
 - Crohn's disease, ulcerative colitis (inflammation of the bowel), hepatitis
 - polymyositis (inflammation of muscles)
 - increased pressure in the head not linked to tumours, worsening of multiple sclerosis
 - inflammation of the eye
 - inflammation of the kidney
 - breathing problems including chronic bronchial asthma and chronic obstructive pulmonary disease (COPD) which may show as shortness of breath during exercise, difficulty breathing in and out deeply and persistent cough. Disorders where there is inflammation of the lung
 - rheumatoid arthritis (painful joint disease), rheumatism, inflammation of a wide area of the body
 - chronic and severe diseases of the skin (including Stevens-Johnson syndrome and a rare condition known as mycosis fungoides)
 - leukaemia of the lymphatic system, Hodgkin's and Non-Hodgkin's lymphoma, breast cancer that has spread around the body, Kähler's disease (cancer of blood cells) and high calcium levels caused by this disease
- after organ transplants and to prevent nausea and vomiting following chemotherapy.

Dexamethasone Oral Solution 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 Oral Solution

Do not take Dexamethasone Oral Solution:

- if you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6)
- if you have an infection that affects the whole body (unless you are receiving treatment)
- if you have a fungal infection that affects the whole body
- if you have a stomach or duodenal ulcer
- if you have an infection with worms after travelling to a tropical area.

Warning and precautions

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

Talk to your doctor or pharmacist before taking Dexamethasone Oral Solution:

- **if you have ever had severe depression** or manic depression (bipolar disorder). This includes having had depression before or while taking steroid medicines like Dexamethasone.
- **if any of your close family** has had these illnesses.
- **if the treatment is for a premature baby.** Dexamethasone should not be routinely used in preterm neonates with respiratory problems.

General precautions regarding steroid use in specific diseases, masking infection, concomitant medicines etc. in line with current recommendations.

Mental health problems while taking Dexamethasone Oral Solution

Mental health problems can happen while taking steroids like Dexamethasone Oral Solution.

- 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 health problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental health problems have happened when doses are being lowered or stopped.

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Dexamethasone Oral Solution should only be prescribed during pregnancy, particularly in the first trimester, if the benefit outweighs the risks for the mother and child. If you become pregnant during the use of the product, **do not** stop using it, but tell your doctor **immediately** that you are pregnant.

Dexamethasone is excreted in breast milk. There are no known risks to infants. Nevertheless, breast-feeding should be **discontinued** when using higher doses or long-term treatment.

Driving and using machines

Dexamethasone Oral Solution has no influence on your ability to drive or use machines.

Important information about some of the ingredients of Dexamethasone Oral Solution

Carrying your steroid card

If you take this medicine for more than three weeks, your doctor or pharmacist will give you a Steroid Treatment Card with your prescription or medicine.

- Keep this card with you always
- Show it to any doctor, dentist, nurse, midwife or anyone else who is giving you treatment

Even after your treatment is finished, tell any doctor, dentist, nurse, midwife or anyone else who is giving you treatment that you have taken steroids.

Dexamethasone contains sorbitol, maltitol, propylene glycol and sodium:

- Your medicinal product contains **liquid maltitol** and **sorbitol**. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- This medicine contains less than 1 mmol sodium (23 mg) per 2.25 ml, that is to say essentially 'sodium-free'.
- This medicine contains 90 mg propylene glycol in each ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

3. How to take Dexamethasone Oral Solution

Dexamethasone Oral Solution is only to be taken by mouth.

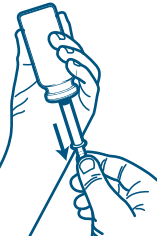
Take Dexamethasone Oral Solution only as prescribed by your doctor. Your doctor will decide how long you should take dexamethasone for. Check with your doctor or pharmacist if you are not sure. These instructions will have been added to the dispensing label by your pharmacist.

Using the syringe

A 3ml graduated syringe and a syringe/bottle adaptor is provided with your medicine. Use the syringe to withdraw from the bottle, the amount of Dexamethasone Oral Solution that has been prescribed for you by your doctor.

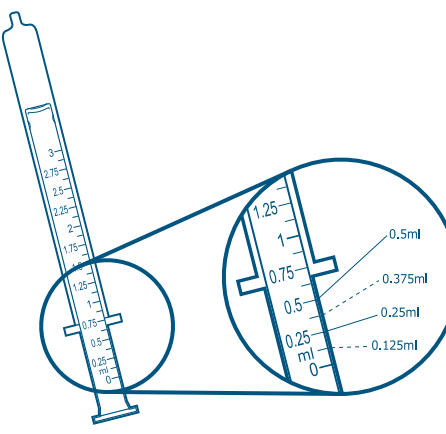
- insert the bottle adaptor firmly into the neck of the bottle.
- push the tip of the syringe into the hole in the top of the adaptor and ensure that it is secure.
- hold the syringe in place and then turn the bottle upside down (refer to **Figure 1**).
- **still** holding the syringe in place, pull the plunger down to the correct mark on the syringe (refer to **Figure 1** and **Figure 2**).
- turn the bottle the right way up.
- remove the syringe from the adaptor, by holding onto the bottle and gently twisting the syringe.
- after use replace the bottle cap and wash the syringe in warm water. Allow to dry.
- **do not** remove the adaptor from the bottle.

Figure 1.



Each graduation on the syringe provided is equivalent to 0.125ml of solution (refer to Figure 2).

Figure 2.



The recommended dose is:

Adults: initially 0.125ml to 2.25ml daily, then a maintenance dose of 0.375ml daily. The total dose can be split into two or three smaller doses to be taken throughout the day.

Use in children and adolescents: a single dose on alternate days.

If Dexamethasone Oral Solution is being given to you as part of some hospital tests, the range given will be: 0.125ml to 0.5ml per dose, given for a short period of time.

For the treatment of Covid-19

Adult patients are recommended to be given 1.5ml once a day for up to 10 days.

Use in adolescents:

Pediatric patients (adolescents of 12 years of age or older) are recommended to be given 1.5ml once a day for up to 10 days.

Important: If you are unsure how much medicine to take, please contact your doctor or pharmacist for advice.

Do not exceed or take less than the stated dose.

Do not take it more or less often than prescribed.

If you take more Dexamethasone Oral Solution than you should

If you take too much medicine contact a doctor or hospital immediately.

If you forget to take Dexamethasone Oral Solution

If you forget to take a dose, take it as soon as you remember unless it is almost time for the next dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Dexamethasone Oral Solution

It can be dangerous to stop taking this medicine abruptly. The symptoms that have been reported when treatment has been stopped too quickly include low blood pressure and sometimes, relapse of the disease for which the medicine was given. A 'withdrawal syndrome' may also occur which includes fever, muscle and joint pain, inflammation of the nose lining (rhinitis), weight loss, itchy skin and inflammation of the eye (conjunctivitis). If your treatment is to be stopped follow your doctor's advice. He may tell you to reduce the amount of medicine you are taking gradually until you stop taking it altogether.

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

4. Possible side-effects

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

Tell a doctor straight away if you:

- **experience serious mental health problems.** They can affect people taking medicines like dexamethasone. These problems 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.
- **have an allergic reaction to Dexamethasone Oral Solution.** Talk to your doctor immediately or go to hospital straight away if you experience any of the following side effects:
 - red and lumpy skin rash
 - difficulty in breathing
 - swelling of the face, mouth, lips or eyelids

Other side effects may include:

Not known; frequency cannot be estimated from the available data

- **mental health problems:** a feeling of dependence, a severe headache with visual disturbances (linked to withdrawal of treatment), worsening of schizophrenia (where you may sense, see or hear things that do not exist, become withdrawn or have mistaken beliefs or suspicions)
- **stomach and bowel problems:** nausea, vomiting, hiccups, increased appetite, stomach discomfort, swollen abdomen, inflammation and ulcers in the oesophagus, heartburn, stomach ulcers that may bleed, inflamed pancreas (causing pain in the back and abdomen), tearing of the bowel particularly if you have inflammatory bowel disease, unusual fat deposits
- **metabolism and problems with salt levels:** weight gain, salt imbalances, water retention in the body, potassium loss due to low carbon dioxide levels (hypokalaemic alkalosis), loss of protein and calcium balance, increased need for diabetic medication, increased cholesterol levels
- **heart and blood problems:** blood clots, congestive heart failure in susceptible people, heart muscle rupture (especially if you have recently had a heart attack), high blood pressure, raised or lowered levels of red and white blood cells, inflammation and thickening of the veins or arteries
- **muscle, bone and skin problems:** thinning of the bones with an increased risk of fractures, bone disease, ruptured tendons, muscle wasting, weakness, excess body hair (particularly in women), slow wound healing, thinned delicate skin, unusual marks on the skin, bruising, redness and inflammation of the skin, stretch marks, visible swollen capillaries, acne, increased sweating, impaired reaction to skin tests, skin rash, thinning of the hair
- **immune system problems:** thrush, greater chance of picking up infections, recurrence of tuberculosis if you have already had it, blood disorders due to infection
- **eye problems:** cataracts, increased pressure in the eye, swelling of the eye, thinning of the eye membranes, worsening of existing eye infections, protrusion of the eyeballs, visual disturbances, loss of vision and blurred vision
- **reproductive system problems:** irregular or lack of menstruation (periods), impotence
- **hormonal problems:** impairment of the body's regulation of hormones, slow growth in children and teenagers, swelling and weight gain of the body and face (Cushingoid state)
- **nervous system problems:** fits and worsening of epilepsy, dizziness, headache
- **other general effect:** a change in the effectiveness of the medicine following stress and trauma, surgery or illness, withdrawal effects (fever, muscle and joint pain, inflammation of the eye or nose, itchy skin and weight loss).

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 at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dexamethasone Oral Solution

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

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

Do not use this medicine after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month.

After first opening, use within 3 months.

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 Oral Solution contains

- the active substance is dexamethasone. Each 5ml of solution contains 20mg of dexamethasone (as dexamethasone sodium phosphate)
- the other ingredients are: propylene glycol (E1520), liquid maltitol (E965), liquid sorbitol (non-crystallising) (E420), sodium citrate dihydrate (E331), EDTA disodium, sucralose, sodium hydroxide (as a pH adjuster), mint flavour, purified water.

What Dexamethasone Oral Solution looks like and contents of the pack

Dexamethasone Oral Solution is a colourless to yellowish oral solution with a mint odour. It comes in an amber glass bottle, holding 30 or 50ml of solution, with a child resistant screw-cap. The pack also contains a 3ml plastic oral dosing syringe and a bottle/syringe adaptor.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Synchrony Pharma Limited, 3 Bunhill Row, London, EC1Y 8YZ, United Kingdom

Manufacturer

RAFARM S.A., Thesi Pousi-Xatzil, Agiou Louka, Pafosia, Attiki TK 19002, Greece

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