

## **Package Leaflet: Information for the user**

### **Dexamethasone 2mg/5ml Oral Solution**

dexamethasone

**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 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 2mg/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). Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone). 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 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, Kahler'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

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

### Warnings and precautions

Talk to your doctor, pharmacist or nurse 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.**
- if you have a bacterial or viral infection (such as hepatitis, poliomyelitis)
- if you have kidney or liver problems
- if you have high blood pressure, heart disease or you have recently had a heart attack
- if you have diabetes or there is a family history of diabetes
- if you have osteoporosis (thinning of the bones), particularly if you are a female who has been through the menopause
- if you have suffered from muscle weakness with this or other steroids in the past
- if you have glaucoma (raised eye pressure) or there is a family history of glaucoma
- if you have myasthenia gravis (a condition causing weak muscles)
- if you have a bowel disorder (ulcerative colitis or diverticulitis), have recently had an operation on your bowel or a stomach (peptic or gastrointestinal) ulcer
- if you have psychiatric problems or you have had a psychiatric illness which was made worse by this type of medicine
- if you have epilepsy (condition where you have repeated fits or convulsions)

- if you have migraines
- if you have an underactive thyroid gland
- if you have an infection with parasites (worms) or an internal fungal infection
- if you have tuberculosis (TB) or have recently had a reaction to a vaccination for TB
- if you have septicaemia
- if you have a fungal infection in the eye, an injury to your eye or an ulcer on the surface of your eye (corneal ulceration)
- if you have cerebral malaria
- if you have herpes (cold sores or genital herpes)
- if you have asthma

This may affect the dose you are given or your doctor may want you to take other medicines at the same time.

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

Dexamethasone should not be routinely used in preterm neonates with respiratory problems. Contact your doctor if you experience blurred vision or other visual disturbances.

You should tell your doctor if you have any of the following:

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.

### **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.

### **More Important Information about taking this medicine**

- taking this medicine may increase your risk of getting an infection. It may also mask the symptoms of an existing or developing infection and make it harder to find out what is wrong. If you develop an infection whilst on this medicine you should talk to your doctor.
- if you have an accident, are ill, require surgery (even at the dentists) or you require a vaccination (particularly with 'live virus' vaccines) whilst taking or when you have finished taking Dexamethasone Oral Solution, you should inform the person treating you that you are taking or have taken steroids.
- if you have an allergy test, a suppression test (test for hormone levels) or a test for an infection, you should inform the person performing the test that you are taking dexamethasone as it may interfere with the results.
- if you need a vaccination tell your doctor as it may not be effective or you may have a greater chance of getting an infection from a 'live' vaccine.
- if you have a doping test when taking this medicine you may get a positive result.

- your doctor may want to perform regular check ups on you while you are taking Dexamethasone Oral Solution

- they may be more frequent if you have other health problems (such as diabetes or kidney problems) or if you are elderly as any side effects may be more serious for you.
- if a child is taking this medicine, it is important that their growth and development is checked at frequent intervals as dexamethasone can cause children to grow more slowly.
- if you are taking this medicine for a long time, regular (every 3 months) checks of your vision are recommended.
- if you are taking high doses your doctor may monitor the levels of potassium in your blood. You may also find that your doctor will reduce the amount of salt in your diet and give you a potassium supplement whilst you are taking this medicine.

Dexamethasone and Viral Infections

- **it is important** that whilst you are taking this medicine you avoid contact with anybody who has chickenpox, shingles or measles. If you think you may have had exposure to any of these diseases, you should consult your **doctor immediately**.

- you should also inform your doctor if you have ever had infectious diseases such as measles or chickenpox and if you have had any vaccinations for these diseases in the past.

### **Other medicines and Dexamethasone Oral Solution**

Tell your doctor or pharmacist 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:

- anticoagulant medicines which thin the blood (e.g. warfarin, coumarin)
- aspirin or similar (non-steroidal anti-inflammatory drugs) e.g. indometacin
- medicines used to treat diabetes
- medicines used to treat high blood pressure
- diuretics (water tablets)
- amphotericin B injection
- phenytoin, carbamazepine (epilepsy medication)
- rifabutin, rifampicin (antibiotics used to treat tuberculosis)
- antacids or charcoal
- barbiturates (medication used to aid sleep and relieve anxiety)
- aminoglutethimide (anti-cancer treatment)
- carbenoxolone (used in the treatment of stomach ulcers)
- ephedrine (nasal decongestant)
- acetazolamide (used for glaucoma and epilepsy)
- hydrocortisone, cortisone and other corticosteroids
- ketoconazole (for fungal infections)
- ritonavir (for HIV)
- antibiotics including erythromycin
- colestyramine (for high cholesterol levels)
- estrogen hormones including the contraceptive pill
- tetracosactide (used in the test for adrenocortical function)
- sultopride (used to calm emotions)
- ciclosporin (used to prevent rejection after transplants)
- thalidomide
- praziquantel (given for certain worm infections)
- isoniazid for tuberculosis

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may increase the effects of Dexamethasone Oral Solution 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**

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.

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.

### **Dexamethasone Oral Solution contains**

- 0.14 g sorbitol in each ml. When taken according to the dosage recommendations each dose supplies up to 3.15 g of sorbitol.
- 0.275 g maltitol in each ml. When taken according to the dosage recommendations each dose supplies up to 6.2 g of maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- 0.09 g propylene glycol in each ml. When taken according to the dosage recommendations each dose supplies up to 2 g of propylene glycol. If your baby is less than 4 weeks old or 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. If you are pregnant or breast-feeding or suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- 1 mg benzoic acid in each 1 ml of oral solution (i.e. 1mg/ml benzoic acid). May increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

### **Important information on sodium content:**

- This medicine contains less than 1mmol sodium (23 mg) per ml, that is to say essentially sodium free.

### **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 that you have taken steroids
- 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.

## **3. How to take Dexamethasone Oral Solution**

Dexamethasone Oral Solution is only to be taken by mouth.

Take Dexamethasone Oral Solution 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.

The recommended dose is:

**Adults:** initially 0.5 – 9mg daily, then a maintenance dose of 1.5mg 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: 0.5 mg to 2mg per dose, given for a short period of time.

**Do not** exceed or take less than the stated dose.

**Do not** take it more or less often than prescribed.

For the treatment of Covid-19

Adult patients are recommended to take PO 6 mg 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 once a day for up to 10 days.

#### **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 Website: [www.mhra.gov.uk/yellowcard](http://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 Oral Solution**

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

**Do not** store above 25°C. Do not refrigerate.

**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** use this medicine if you notice solid particles inside the solution.

**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 ml of solution contains 0.4 mg of dexamethasone (as dexamethasone sodium phosphate).
- the other ingredients are benzoic acid (E210), propylene glycol (E1520), citric acid monohydrate (E330), liquid maltitol (E965), liquid sorbitol (non-crystallising) (E420), sodium citrate dihydrate (E331), mint flavour, purified water.

### **What Dexamethasone Oral Solution looks like and contents of the pack**

Dexamethasone Oral Solution is a colourless to faint yellow oral solution with mint flavour. It comes in an amber glass bottle, holding 150 ml of solution, with child resistant screw-cap.

### **Marketing Authorisation Holder**

**Focus Pharmaceuticals Ltd.**

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### **Manufacturer**

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