**FRONT** 

Important information about some of the ingredients of Dexamethasone Oral Solution
Package leaflet: Information for the user

You should tell your doctor if you have any of the

Dexamethasone 20mg/5ml Oral Solution Read all of this leaflet carefully before you start taking this medicine because it contains important information

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 keen 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 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 to a group of medicines called steroids (the full name is

Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone) Boosting your body with extra corticosteroid (such as dexamethasone) is an effective way to treat various

body and help to maintain health and well-being.

corticosteroids). Corticosteroids occur naturally in the

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

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 allergy (hypersensitivity)

polymyalgia rheumatica (chronic inflammation of the larger arteries), polyarteritis nodosa (chronic inflammation of small and medium arteries)

blood disorders including haemolytic anaemic (disorder which breaks down red blood cells), leukaemia (cancer of the blood), myeloma (bone

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 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

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

after organ transplants and to prevent nausea

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

if you have a stomach or duodenal ulcer

• if you have an infection with worms after travelling to
• medicines used to treat diabetes

Warning and precautions

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

Talk to your doctor or pharmacist before taking

• 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

 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 Ask your doctor or pharmacist for advice if you are might be thinking about suicide. In a few cases, mental pregnant, planning to get pregnant or breast-fee health problems have happened when doses are being lowered or stopped.

Symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath, in case you suffer

m haematological malignancy. Contact your doctor if you experience blurred vision of other visual disturbances.

Talk to your doctor before taking this medicine if: you have a bacterial or viral infection (such as

hepatitis, poliomyelitis) vou have kidney or liver problems

 you have high blood pressure, heart disease or you have recently had a heart attack

· you have diabetes or there is a family history of 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 c

other steroids in the past you have glaucoma (raised eye pressure) or there is a

family history of glaucoma you have myasthenia gravis (a condition causing weak muscles)

· you have a bowel disorder (ulcerative colitis of diverticulitis), have recently had an operation on your bowel or a stomach (peptic or gastrointestinal) ulcer you have psychiatric problems or you have had a psychiatric illness which was made worse by this type of medicine

· you have epilepsy (condition where you ha repeated fits or convulsions)

 vou have miaraines you have an underactive thyroid gland

 vou have an infection with parasites (worms) or an internal fungal infection you have tuberculosis (TB) or have recently had a

reaction to a vaccination for TB you have septicaemia you have a fungal infection in the eye, an injury to

your eye or an ulcer on the surface of your eye (corneal ulceration)

you have cerebral malaria

• you have herpes (cold sores or genital herpes) vou have asthma

This may affect the dose you are given or your doctor may want you to take other medicines at the same 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 vhen 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 aetting an infection from a 'live' vaccine.

If you have a doping test when taking this medicine

Your doctor may want to perform regular check ups on you while you are taking Dexamethasone Oral

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

• They may be more frequent if you have other

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 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

Dexamethasone and Viral Infections

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

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

Taking other medicines and Dexamethasone Oral

Tell your doctor or pharmacist if you are taking or have recently taken 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.

 aspirin or similar (non-steroidal anti-inflammatory) drugs) e.g. indometacin

 medicines used to treat high blood pressure diuretics (water tablets) amphotericin B injection

 phenytoin, carbamazepine, (epilepsy medication) rifabutin, rifampicin (antibiotics used to treat

 antacids or charcoal barbiturates (medication used to aid sleep and

 aminoglutethimide (anti-cancer treatment) · carbenoxolone (used in the treatment of stomach

 ephedrine (nasal decongestant) acetazolamide (used for glaucoma and epilepsy)

• ketoconazole (for fungal infections) ritonavir (for HIV)

· antibiotics including erythromycia colestyramine (for high cholesterol levels) estrogen hormones including the contraceptive pill

 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 or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

155 mm

BACK

Dexamethasone Oral Solution should only be blood pressure and sometimes, relapse of the disease prescribed during pregnancy, particularly in the first for which the medicine was given. A 'withdrawal

immediately that you are pregnant known risks to infants. Nevertheless, breast-feeding should be **discontinued** when using higher doses or

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 4. Possible side-effects 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 eatment 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 treatmen

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

 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

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 push the tip of the syringe into the hole in the top of

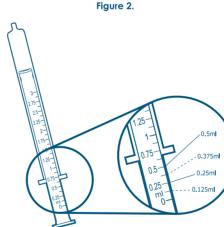
the adaptor and ensure that it is secure. • hold the syringe in place and then turn the bottle upside down (refer to Figure 1). still holding the syringe in place, pull the plunger

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



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



Adults: initially 0.125ml to 2.25ml daily, then a Do not use this medicine after the expiry date which is maintenance dose of 0.375ml daily. The total dose can stated on the bottle label and carton after EXP. The be split into two or three smaller doses to be taken expiry date refers to the last day of that month.

throughout the day. Use in children and adolescents: a single dose on

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

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 Paediatric 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

**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 vou 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 ember unless it is almost time for the next 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

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

mester, if the benefit outweighs the risks for the mother — syndrome' may also occur which includes fever, muscle and child. If you become pregnant during the use of and joint pain, inflammation of the nose lining (rhinitis) the product, do not stop using it, but tell your doctor weight loss, itchy skin and inflammation of the eye (conjunctivitis). If your treatment is to be stopped follow Dexamethasone is excreted in breast milk. There are no 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.

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

Tell a doctor straight away if you:
• experience serious mental health problems. The affect people taking medicines like

dexamethasone. These problems include:

• feeling depressed, including thinking about • feeling high (mania) or moods that go up and

• feeling anxious, having problems sleeping difficulty in thinking or being confused and losing

your memory feeling, seeing or hearing things that do not exis 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 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

 mental health problems: a feeling of dependence, severe headache with visual disturbances (linked to withdrawal of treatment), worsening of schizophrenic (where you may sense, see or hear things that do no exist, become withdrawn or have mistaken beliefs of

stomach and bowel problems: nausea, vomitin hiccups, increased appetite, stomach discomfor 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 you have inflammatory bowel disease, unusual far

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, congesti 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

face (Cushingoid state)

Reporting of side effects

• hormonal problems: impairment of the body regulation of hormones, slow growth in children and eenagers, swelling and weight gain of the body and

• reproductive system problems: irregular or lack of

• nervous system problems: fits and worsening • other general effect: a change in the effectiveness of the medicine following stress and trauma, surgery or Illness, withdrawal effects (fever, muscle and join

pain, inflammation of the eye or nose, itchy skin and

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side ects 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

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

After first opening, use within 3 months. Do not throw away any medicines via wastewater of 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

Not all pack sizes may be marketed. **Marketing Authorisation Holder** 

Attiki TK 19002, Greece

treatment has been stopped too quickly include low This leaflet was last revised in December 2023.

Synchrony Pharma Limited, 3 Bunhill Row, London, EC1Y 8YZ, United Kingdom RAFARM S.A., Thesi Pousi-Xatzi, Agiou Louka, Paiania,

Item Code Number | SYNC063 Printing Colour(s) P302u Proof Number & Date P1 23 November 2023 Pharmacode/Data matrix NA Description | Dexamethasone 20mg/5ml Oral Solutions 50ml | Market | UK Specification Leaflet 155x x450mm Synchrony Pharma Limited 3 Bunhill Row, London, EC1Y 8YZ, United Kingdom