PATIENT INFORMATION LEAFLET

DYNACEF SUSPENSION

SCHEDULING STATUS

S4

DYNACEF SUSPENSION (powder for oral suspension)

Cefpodoxime proxetil

DYNACEF SUSPENSION contains sugar (sucrose 2464,67 mg per 5 mL). Contains aspartame 20 mg/5 ml

Read all of this leaflet carefully before you start taking DYNACEF SUSPENSION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DYNACEF SUSPENSION has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DYNACEF SUSPENSION is and what it is used for

DYNACEF SUSPENSION belongs to the antibiotic group of medicines known as ~~the~~ cephalosporins.

DYNACEF SUSPENSION is used for the treatment of:

- Ear infection
- Tonsillitis, throat infection (pharyngitis)
- Pneumonia

2. What you need to know before you take DYNACEF SUSPENSION

Do not take DYNACEF SUSPENSION:

- if your child is hypersensitive (allergic) to other cephalosporin antibiotics, penicillin, any other beta-lactam class of antibiotics or to any of the ingredients of DYNACEF SUSPENSION (see section 6)
- DYNACEF SUSPENSION must not be given to children with phenylketonuria (a rare inherited disorder that causes an amino acid called phenylalanine to build up in your body) since the formulation contains aspartame
- if your child is under 1 year old.

Warnings and precautions

Take special care with DYNACEF SUSPENSION:

- DYNACEF SUSPENSION should be taken with caution in patients who are generally allergic. Please tell your doctor about all allergic reactions your child may have had previously, especially to medicines
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- take care if your child is allergic to penicillin antibiotics, as he/she may have an increased chance of being allergic to cephalosporins (including DYNACEF SUSPENSION) as well
- if your child has or has ever had a condition called colitis (inflammation of the large intestine with symptoms of abdominal pain, diarrhoea and fever) or if your child develops diarrhoea while using DYNACEF SUSPENSION. This may be an indication of inflammation of the large intestine (colitis). Please consult your doctor immediately
- if your child has kidney problems his/her dose may need to be adjusted)

- if your child undergoes certain blood or urine tests as DYNACEF SUSPENSION may interfere with the results.
- if your child experiences symptoms such as seizure, confusion, consciousness disorders or abnormal movements (especially in children with kidney problems or who have been given more medicine than required), contact your doctor or healthcare provider immediately

Other medicines and DYNACEF SUSPENSION

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Certain medicines may interact with DYNACEF SUSPENSION. In these cases it may be necessary to change the dose or interrupt the treatment of one of the medicines.

DYNACEF SUSPENSION works better when taken with food.

Medicines that may interact with DYNACEF SUSPENSION are:

- medicines used to treat ulcers such as ranitidine or cimetidine and antacids (used to treat indigestion such as aluminium hydroxide, sodium bicarbonate) may delay how DYNACEF SUSPENSION works
- pentagastrin (medicine used to stimulate stomach acid secretion) may increase the effects of DYNACEF SUSPENSION
- probenecid (used for the treatment of gout) may increase the blood levels of DYNACEF SUSPENSION and increase the chance of side effects
- anti-coagulants such as warfarin (used to thin the blood) may increase the risk of bleeding
- please ensure that your doctor knows that your child is taking DYNACEF SUSPENSION if he/she is required to take any tests (blood, urine or diagnostic), as this medicine may interfere with the test results
- certain diuretics (water tablets e.g. furosemide) used to increase the amount of urine you pass, may affect your kidneys

- aminoglycoside antibiotics (e.g. gentamicin) (used to treat infections) may affect the way your kidneys work
- as anti-coagulants may increase the risk of bleeding, your doctor may want to monitor increased ratio of the blood clotting time whilst your child is taking DYNACEF SUSPENSION.

DYNACEF SUSPENSION with food and drink

DYNACEF SUSPENSION must be taken after a meal.

Pregnancy, breastfeeding and fertility

Not applicable.

Driving and using machines:

Not applicable.

Important information about some of the ingredients of DYNACEF SUSPENSION:

DYNACEF SUSPENSION contains aspartame (20 mg/5 mL), and sucrose.

Dynacef Suspension should not be taken by patients with phenylketonuria since one of its metabolic products is phenylalanine (see Do not take DYNACEF SUSPENSION).

DYNACEF SUSPENSION should not be given to patients with a history of sucrose intolerance or hereditary sucrose-isomaltase deficiency.

3. How to take DYNACEF SUSPENSION

Do not share medicines prescribed for you with any other person. Always use DYNACEF SUSPENSION exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Children:

The average dose is 8 mg/kg/day administered in two doses every 12 hours with meals. Your doctor will adjust the dose according to the child's weight.

The following may be used as a dosage guide:

- Children weighing between 10 and 15 kg the dose is 5 mL every 12 hours.
- Children weighing 15 kg or more, the dose is 10 mL every 12 hours.

Shake the bottle before use. For reconstitution instructions, refer to section 6.

Kidney disorders:

If your child has a kidney disorder, he/she will receive lower doses that the normal dose. Your doctor will determine the correct dose according to his/her condition.

DYNACEF SUSPENSION must not be given to children with phenylketonuria, since the formulation contains aspartame (see Do not take DYNACEF SUSPENSION).

Administration of DYNACEF SUSPENSION in children under one year of age is currently not indicated safety has not yet been established.

Your doctor will tell you how long your child's treatment with DYNACEF SUSPENSION will last. If you have the impression that the effect of DYNACEF SUSPENSION is too strong or too weak, tell your doctor or pharmacist.

If you administer more DYNACEF SUSPENSION than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Take this leaflet and any remaining suspension with you, so that the doctor knows what medicine your child has taken.

Symptoms of overdose may include:

- any of the symptoms as described under Side Effects including central nervous system toxicity (with symptoms including anxiety, dizziness, mouth numbness, lightheadedness, ringing or buzzing in the ears and convulsions) and brain function (with symptoms such as memory loss, personality change, seizures and twitching)

If you forget to take DYNACEF SUSPENSION:

If you forget to administer DYNACEF SUSPENSION, administer it as soon as you remember on the same day. If you do not administer a dose on that same day, give the normal dose the next day. Do not administer a double dose to make up for forgotten individual doses.

If you stop taking DYNACEF SUSPENSION

It is important that you continue the course of treatment even if your child begins to feel better after a few days.

4. Possible side effects

DYNACEF SUSPENSION can have side effects.

Not all side effects reported for DYNACEF SUSPENSION are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DYNACEF SUSPENSION, please consult your healthcare provider for advice.

If any of the following happens, stop using DYNACEF SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, shock
- rash or itching
- fainting

These are all very serious side effects. If your child has them, they may have had a serious allergic reaction to DYNACEF SUSPENSION. Your child may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Hepatitis (inflammation of the liver) and other liver problems including jaundice (symptoms may include: nausea, vomiting, stomach pain, loss of appetite, tiredness, yellowing of the skin or whites of your eyes, dark urine), liver injury, increased liver enzymes.
- A severe infection of the lining of the bowel, characterised by diarrhoea, fever and abdominal pain. This may be something called 'Pseudomembranous colitis', blood in stools.
- Blistering, peeling or bleeding on any part of your skin with or without a rash (including your lips, eyes, mouth, nose, genitals, hands or feet), flu-like symptoms (fever, chills or aching muscles) which are symptoms of a serious skin reaction (Steven Johnson Syndrome or toxic epidermal necrolysis (TEN)) which could be fatal.
- Skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious skin allergy called ‘erythema multiforme’.
- Pancreatitis (inflammation of the pancreas) (symptoms may include upper abdominal pain that radiates into the back; swollen and tender abdomen; nausea and vomiting, fever and increased heart rate).
- Your child gets infections more easily than usual. This could be because of a blood disorder and is more likely if he/she taking DYNACEF SUSPENSION for a long time
- Superinfection (a second infection which occurs during the course of the existing infection, by other bacteria or organisms resistant to DYNACEF SUSPENSION), including fungal infections such as oral or vaginal thrush.
- Chills, tiredness, unusually pale skin colour, shortness of breath, fast heartbeat or dark

coloured urine. These could be signs of a serious type of anaemia.

- Blood disorders which may make your child more likely to get infections, get tired very easily, or bruise very frequently.
- Your child bruises more easily than usual, or may have a painful rash of dark red spots under the skin which do not go away when you press on them (purpura). This could be because of a serious blood problem.
- Seizures, central nervous system toxicity (with symptoms including anxiety, dizziness, mouth numbness, lightheadedness, ringing or buzzing in the ears and convulsions).
- Little or no urine when you try to urinate, decreased kidney function (with symptoms such as swelling from fluid retention and high blood pressure).
- Hearing loss.

These are all serious side effects. Your child may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- appetite loss
- nausea, vomiting, diarrhoea, abdominal pain
- headache

Less frequent side effects:

- abnormal blood and/or urine test results
- dizziness, sensations of tingling, burning, pricking (pins and needles), or numbness of the skin, asthenia (unusual tiredness or weakness)
- bloating, excess gas (wind), indigestion
- ringing in the ears
- abnormal liver test results
- skin rashes or other skin conditions

- fatigue
- false positive blood test (direct Coombs' test).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8
By reporting side effects, you can help provide more information on the safety of DYNACEF SUSPENSION. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store DYNACEF SUSPENSION

Store all medicines out of reach of children.

Before reconstitution:

Store at or below 25 °C, protect from light and humidity.

After reconstitution:

Use within 10 days. Store in a refrigerator (2 – 8 °C).

Shake well before use.

Keep the bottle tightly closed. Discard any unused portion. Do not freeze.

Do not use after the expiry date stated on the bottle. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DYNACEF SUSPENSION contains

Each 5 mL of suspension contains cefpodoxime proxetil equivalent to 40 mg cefpodoxime.

The other ingredients are:

Anhydrous citric acid, artificial banana flavour spray dry, aspartame, hydroxypropyl cellulose, maize starch, Microcrystalline cellulose & carboxymethyl cellulose sodium, silica colloidal anhydrous, sodium benzoate (preservative 0,2 % m/v), Spectralol yellow iron oxide, sucrose.

Directions and Reconstitution of the Suspension:

Remove the screw cap by simultaneously pushing and turning it. Remove the desiccant plug by pulling the tear-tab and discard. Add 27,0 mL water in to the dry powder for the 50 mL suspension. Add 54,0 mL water in two equally divided portions to the dry powder for the 100 mL suspension. Shake well after each addition. See section 3. How to use Dynacef Suspension.

What DYNACEF SUSPENSION looks like and contents of the pack

Powder for oral suspension.

Powder: Almost white to pale yellow coloured powder.

Reconstituted solution: Off-white to pale yellow suspension with characteristic fruity odour.

Translucent HDPE bottle with a white polypropylene 28 mm cap (child resistant, with foil seal peelable liner), containing powder for reconstitution up to 50 mL or 100 mL of suspension, contained in a printed outer carton.

Holder of Certificate of Registration

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