



DYNACEF SUSPENSION

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE
DYNACEF SUSPENSION 40 mg/5 mL, powder for oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 mL of suspension contains cefpodoxime proxetil equivalent to cefpodoxime 40 mg.
DYNACEF SUSPENSION contains sugar (sucrose 2,46 g/5 mL). Contains sweetener (aspartame 20 mg/5 mL).
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Powder for oral suspension.
Powder: Almost white to pale yellow coloured powder.
Reconstituted solution: Off-white to pale yellow suspension with characteristic fruity odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In Children:

DYNACEF SUSPENSION is indicated for use in the short-term treatment of upper and lower respiratory tract infections caused by susceptible micro-organisms:

- acute otitis media due to: *Haemophilus influenzae* (non-typeable), *Streptococcus pneumoniae*, *Moraxella catarrhalis*
- tonsillitis and pharyngitis due to: *Streptococcus pyogenes*
- pneumonia due to: *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Moraxella catarrhalis*.

4.2 Posology and method of administration

Posology

Paediatric population

The dosage depends on the weight of the child being treated. The average dose is 8 mg/kg/day. The following may be used as a dosage guide:

- children weighing between 10 and 15 kg the dose is 5 mL (40 mg) every 12 hours
- children weighing 15 kg or more, the dose is 10 mL (80 mg) every 12 hours.

The use of DYNACEF SUSPENSION in children under one year of age has not been established (see section 4.3).

DYNACEF SUSPENSION must not be given to children with phenylketonuria, since the formulation contains aspartame (see section 4.3).

Refer to section 6.6 for reconstitution instructions.

Special populations

Renal insufficiency in children:

When the creatinine clearance is above 40 mL/min, it is not necessary to adjust the dose. For values below 40 mL/min, the daily dosage regimen should be reduced by half. For values 10 - 39 mL/min DYNACEF SUSPENSION should be administered as a single daily dose and every second day for values below 10 mL/min. DYNACEF SUSPENSION should be administered after each dialysis session for haemodialysis patients.

Hepatic insufficiency in children:

No dosage adjustment necessary.

Method of administration

Oral use:

DYNACEF SUSPENSION is administered in two doses at 12 hourly intervals with meals. Shake the bottle before use.

Refer to section 6.6, for reconstitution instructions.

Missed dose:

Medical practitioners should advise patients who forget to take DYNACEF SUSPENSION to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

4.3 Contraindications

DYNACEF SUSPENSION is contraindicated in:

- known sensitivity to cephalosporin antibiotics, penicillin's, any other beta-lactam class of antibiotics, or to any of the ingredients of DYNACEF SUSPENSION (see section 6.1)
- DYNACEF SUSPENSION must not be given to children with phenylketonuria since the formulation contains aspartame.
- children below 1 year of age (see section 4.2).

4.4 Special warnings and precautions for use

Hypersensitivity reactions:

Before initiating therapy with DYNACEF SUSPENSION, careful enquiry should be made concerning an allergic diathesis and previous hypersensitivity reactions to penicillin and other beta-lactam antibiotics.

The use of DYNACEF SUSPENSION is strictly contraindicated in subjects with a previous history of immediate type hypersensitivity to cephalosporins (see section 4.3).

There have been reports of serious and occasionally fatal hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arterio-spasm that can result in myocardial infarction) (see section 4.8). If an allergic reaction occurs, treatment should be stopped immediately.

Clostridium difficile-associated disease:

Prolonged use may result in overgrowth of non-susceptible organisms.

Pseudomembranous colitis may develop. It is important to consider its diagnosis in patients who develop diarrhoea, particularly if severe and/or persistent in association with the use of DYNACEF SUSPENSION. Such colitis may range in severity from mild to life threatening. Treatment should be discontinued if symptoms suggestive of pseudomembranous colitis arise. Mild cases of pseudomembranous colitis usually respond to discontinuance of the medicine alone.

The diagnosis of this possibly fatal condition is confirmed by endoscopy and/or histology. Screening of faeces for this pathogen, and its cytotoxin is the best way to diagnose *Clostridium difficile*-associated disease.

When the colitis or suspected pseudomembranous colitis, does not improve after the medicine has been discontinued, or when it is severe, oral vancomycin or metronidazole therapy should be started without delay.

Clostridium difficile-associated disease can be favoured by faecal stasis.

Renal impairment:

DYNACEF SUSPENSION should be given with caution to patients with renal impairment. In patients with severe renal failure, it may be necessary to adjust the daily dose based on creatinine clearance (see section 4.2).

Changes in renal function have been observed with antibiotics of the same class and particularly when given concurrently with potentially nephrotoxic agents such as aminoglycosides and/or potent diuretics. In such cases renal function should be monitored.

Interactions with laboratory tests:

DYNACEF SUSPENSION may interfere with Jaffe method of measuring creatinine concentrations and may produce falsely high values.

Positive Coombs test:

DYNACEF SUSPENSION may be absorbed onto the surface of red cell membranes and react with antibodies directed against the medicine. This can produce a positive antiglobulin test and haemolytic anaemia. Cross-reactivity may occur with penicillin for this reaction.

Superinfection:

The use of DYNACEF SUSPENSION, especially if prolonged, may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken (see section 4.8).

Encephalopathy:

Beta-lactam antibiotics, including cefpodoxime (as in DYNACEF SUSPENSION), predispose patients to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness or movement disorders), particularly in case of overdose or if they have impaired renal function.

Information on excipients of DYNACEF SUSPENSION:

Aspartame:

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

Excessive use of aspartame should be avoided by patients with phenylketonuria since one of its metabolic products is phenylalanine (see section 4.3).

Sucrose:

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Sodium benzoate:

Increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

4.5 Interaction with other medicines and other forms of interaction

- probenecid slows tubular excretion of DYNACEF SUSPENSION and increases serum levels thereof
- the bioavailability increases if DYNACEF SUSPENSION is administered during meals (acidic pH)
- absorption of DYNACEF SUSPENSION is decreased by concurrent ingestion of antacids or histamine H₂-receptor antagonists such as ranitidine. Therefore, mineral antacids (aluminium hydroxide, sodium bicarbonate) and histamine blocking H₂ blockers, which cause an increase in gastric pH, should be taken 2 or 3 hours after DYNACEF SUSPENSION administration. In contrast, a decrease in gastric pH (caused by pentagastrin) will increase bioavailability
- enhanced nephrotoxicity with a loop diuretic (e.g. furosemide) may occur
- changes in renal function have been observed with antibiotics of the same class, particularly when given concurrently with potentially nephrotoxic medicines such as aminoglycosides (e.g. gentamicin) and/or potent diuretics. In such cases, renal function should be monitored (see section 4.2)
- as with other cephalosporins, isolated cases showing development of a positive Coombs test have been reported (see section 4.4)
- In patients treated with DYNACEF SUSPENSION, a false positive reaction for glucose in the urine may occur with Benedict's or Fehling's solutions or with copper sulphate test tablets, but not with tests based on enzymatic glucose oxidase reactions
- concurrent use with anticoagulants, such as warfarin, may increase the risk of bleeding.

Special international normalised ratio (INR) imbalance issues

Numerous cases of increased oral anticoagulant activity have been reported in patients receiving antibiotics. The severity of the infection or inflammation, age and general health status of the patient appear to be risk factors. Under these circumstances, it seems difficult to determine to what extent the infection itself or its treatment play a role in the INR imbalance. However, certain classes of antibiotics are more involved, particularly fluoroquinolones, macrolides, cyclines, cotrimoxazole and certain cephalosporins.

4.6 Fertility, pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

If adverse effects occur, such as dizziness or encephalopathy (which can include seizure, confusion, consciousness disorders or abnormal movements), (see sections 4.4, 4.8, 4.9), patients should not drive or use machines.

4.8 Undesirable effects

a. Tabulated list of adverse effects

System Organ Class	Frequency	Side effects
Infections and Infestations	Frequent	Oral and vaginal candidiasis, superinfections, overgrowth of non-susceptible organisms
Blood and lymphatic system disorders	Less frequent	Thrombocytopenia, leucopenia, neutropenia, hypoprothrombinaemia, haemolytic anaemia, reduction of haemoglobin, thrombocytosis and agranulocytosis, aplastic anaemia, pancytopenia, eosinophilia, lymphocytosis, anaemia, leukocytosis eosinophilia,
Immune system disorders	Less frequent	Hypersensitivity reactions, anaphylactic reactions, angioedema, bronchospasm, malaise, shock
Metabolism and nutrition disorders	Frequent	Appetite loss
Nervous system disorders	Frequent Less frequent	Headache Dizziness, paraesthesia, asthenia, seizures, CNS toxicity
Ear and labyrinth disorders	Less frequent	Tinnitus, hearing loss
Cardiac disorders	Frequency unknown	Kounis syndrome
Gastrointestinal disorders	Frequent Less frequent	Diarrhoea, nausea, vomiting and abdominal pain Dyspepsia, flatulence, pseudomembranous colitis, blood in stools, acute pancreatitis, fever
Hepato-biliary disorders	Less frequent	Hepatic dysfunction including cholestasis, elevated liver enzymes (elevations of AST, ALT and alkaline phosphatase), bilirubinaemia, liver injury, hepatitis, cholestatic jaundice
Skin and subcutaneous tissue disorders	Less frequent	Pruritus and urticaria, toxic epidermal necrolysis, erythema multiforme, rash, Stevens-Johnson syndrome, bullous eruptions, cutaneous eruptions, purpura, Linear IgA bullous dermatosis (LABD)
Renal and urinary disorders	Less frequent	Renal dysfunction, toxic nephropathy, increase in blood urea and creatinine
General disorders and administrative site conditions	Less frequent	Fatigue and asthenia
Investigations	Less frequent	Positive response to the Coombs test

b. Description of selected adverse reactions

Beta-lactam antibiotics, including cefpodoxime (as in DYNACEF SUSPENSION, predispose patients to encephalopathy (which can include seizure, confusion, consciousness disorders or abnormal movements), particularly if they have had an overdose or if they have renal failure.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose

Signs and symptoms:

Overdosage with DYNACEF SUSPENSION may manifest in any of the symptoms described under section 4.8. Convulsions and other signs of central nervous system (CNS) toxicity have been associated with high doses, especially in patients with severe renal impairment. There is a risk of encephalopathy, particularly in patients with renal insufficiency.

Management of overdose:

There is no specific antidote for DYNACEF SUSPENSION.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other beta-lactam antibacterials – Third-generation cephalosporins

ATC code: J01DD13

Pharmacological classification: A.20.1.1 Broad and medium spectrum antibiotics.

Mechanism of action

Cefpodoxime proxetil is a semi-synthetic beta-lactam antibiotic belonging to the third-generation oral cephalosporin group. Cefpodoxime proxetil is the prodrug of the bactericidal antibiotic cefpodoxime. Cefpodoxime possesses *in vitro* bactericidal activity against a broad spectrum of Gram positive and Gram-negative bacteria. *In vitro* sensitivity does not necessarily imply *in vivo* efficacy. The antibacterial action of cefpodoxime is through inhibition of bacterial cell wall biosynthesis most likely by acylation of membrane bound transpeptidase enzymes. This prevents cross linkage of peptidoglycan chains, which is necessary for bacterial cell wall strength and rigidity.

The following organisms are not sensitive: Group D streptococci, Methicillin-resistant staphylococci (*S. aureus* and *S. epidermidis*), *Staphylococcus saprophyticus*, Corynebacteria, groups J and K, *Listeria monocytogenes*, *Pseudomonas aeruginosa* and *Pseudomonas* spp., *Acinetobacter baumannii*, *Clostridium difficile*, *Bacteroides fragilis* and related species.

5.2 Pharmacokinetic properties

The bioavailability of cefpodoxime proxetil is increased when the product is administered with meals, or when there is a decrease in gastric pH. Absorption is decreased in conditions of low gastric acidity.

Absorption:

Cefpodoxime proxetil is absorbed orally and rapidly hydrolysed by non-specific esterases in the gastrointestinal wall to cefpodoxime, the active acid.

Paediatric population:

After oral administration of a single 5 mg/kg dose (200 mg maximum) of cefpodoxime to subjects between 4 and 12 years of age, the maximum plasma concentration (C_{max}) is on average 2.6 mg/L. The time taken to reach maximum concentration (T_{max}) is 2 - 4 hours. The average plasma concentrations observed 8 and 12 hours after administration (residual) are 0,39 and 0,08 mg/L respectively.

Diffusion in fluids and tissues:

Cefpodoxime proxetil diffuses well in lung parenchyma, bronchial mucosa, pleural fluid and tonsils.

Metabolism and elimination:

The main metabolite is cefpodoxime, resulting from the hydrolysis of cefpodoxime proxetil. The serum half-life is about 2,4 hours. Clearance is about 2,4 mL/min/kg. Approximately 80 % of cefpodoxime is excreted unchanged in the urine.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous citric acid (for pH adjustment)
Artificial banana flavour spray dry
Aspartame
Hydroxypropyl cellulose
Maize starch
Microcrystalline cellulose & carboxymethyl cellulose sodium
Silica colloidal anhydrous
Sodium benzoate
Spectracol yellow iron oxide
Sucrose.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

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.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal and other handling

Directions for Reconstitution of the Suspension:

Remove the screw cap by simultaneously pushing and turning it. Remove the tear-tab and discard.

Add 27,0 mL water into 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.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Pharma Dynamics (Pty) Ltd
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8. REGISTRATION NUMBER

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9. DATE OF FIRST AUTHORISATION

30 September 2011

10. DATE OF REVISION OF THE TEXT

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NAM	NS2	12/20.1.1/0173
MOZ	4771	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS [54]

DYNACEF SUSPENSION 40 mg/5 mL powder for oral suspension
Cefpodoxime
DYNACEF SUSPENSION contains sugar (sucrose 2,46 g/5 mL).
Contains sweetener (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 or your 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
2. What you need to know before you administer DYNACEF SUSPENSION
3. How to administer DYNACEF SUSPENSION
4. Possible side effects
5. How to store DYNACEF SUSPENSION
6. Contents of the pack and other information

1. What DYNACEF SUSPENSION is and what it is used for
DYNACEF SUSPENSION belongs to the antibiotic group of medicines known as cephalosporins.

DYNACEF SUSPENSION is used in children for the treatment of:

- ear infection
- tonsillitis, throat infection (pharyngitis)
- pneumonia.

2. What you need to know before you administer DYNACEF SUSPENSION
Do not administer 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
- 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, particularly if severe and/or persistent 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 convulsions, confusion, impairment of consciousness or movement disorders (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
- penicillin (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 administered after a meal.

Pregnancy and breastfeeding
Not applicable.

Driving and using machines
If adverse effects occur, such as dizziness or cephalopathy (which can include seizure, confusion, consciousness disorders or abnormal movements), patients should not drive or use machines.

It is not always possible to predict to what extent DYNACEF SUSPENSION may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DYNACEF SUSPENSION affects them.

DYNACEF SUSPENSION contains aspartame (20 mg/5 mL), sucrose and sodium benzoate.
Aspartame:
DYNACEF SUSPENSION should not be taken by patients with phenylketonuria since one of its metabolic products is phenylalanine (see Do not take DYNACEF SUSPENSION).

Sucrose:
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking DYNACEF SUSPENSION. This should be taken into account in patients with diabetes mellitus.

Sodium benzoate:
DYNACEF SUSPENSION contains 10 mg sodium benzoate in 5 mL suspension, which is equivalent to 0.2 %
Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to administer DYNACEF SUSPENSION
Do not share medicines prescribed for you with any other person. Always administer DYNACEF SUSPENSION exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
DYNACEF SUSPENSION must be taken after a meal.

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 than 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 as 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 overdose, 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, light-headedness, 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 administer 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 the use of 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 doctor, pharmacist or other healthcare professional 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 (Stevens-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

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PASIENTINLIGTINGSBLAD

SKEDULERINGSSTATUS [54]

DYNACEF SUSPENSION 40 mg/5 mL, poeler vir orale suspensie
Kefpodoxiem
DYNACEF SUSPENSION bevat suiker (suukrose 2,46 g per 5 mL).
Bevat versoeter (aspartaam 20 mg/5 mL).

Les hierdie heel inligtingsblad deeglik deur, voordat u begin om DYNACEF SUSPENSION te neem

- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, apteker, verpleegkundige of ander gesondheidsverskaffer.
- DYNACEF SUSPENSION is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Wat hierdie inligtingsblad bevat

1. Wat DYNACEF SUSPENSION is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u DYNACEF SUSPENSION toedien
3. Hoe om DYNACEF SUSPENSION toe te dien
4. Moontlike nuwe-effekte
5. Hoe om DYNACEF SUSPENSION te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat DYNACEF SUSPENSION is en waarvoor dit gebruik word
DYNACEF SUSPENSION behoort aan die antibiotiese groep medisyne, bekend as kefalosporiene.

DYNACEF SUSPENSION word gebruik vir die behandeling van:

- oorinfeksie
- tonsillitis, keelinfeksie (faringitis)
- pneumonie.

2. Wat u nodig het om te weet, voordat u DYNACEF SUSPENSION toedien

Moet nie DYNACEF SUSPENSION toedien:

- indien u kind hipersensitief (allergies) is vir ander kefalosporien antibiotika, pensillien, enige ander beta-laktam klas antibiotika, of vir enige van die ander bestandteile van DYNACEF SUSPENSION nie (sien afdeling 6)
- DYNACEF SUSPENSION moet nie aan kinders met fenielketonurie toegedien word nie (‘n skaars oorerflike versterking, wat veroorsaak dat ‘n aminosuur wat fenielalanien genoem word, in u liggaam ophou), aangesien die formule aspartaam bevat
- indien u kind jonger as 1 jaar oud is nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met DYNACEF SUSPENSION:
• DYNACEF SUSPENSION moet omsigtig gebruik word deur pasiënte wie oor die algemeen allergies is. Vertel asseblief u dokter van al die vorige allergies reaksies wat u kind ervaar het, veral teenoor medisyne

- wees versigtig indien u kind allergies is vir pensillien antibiotika, aangesien hy/sy ‘n groter kans het om ook allergies te wees vir kefalosporiene (insluitend DYNACEF SUSPENSION)
- indien u kind ‘n toestand genaamd kolitis het, of ooit gehad het (inflammasie van die dikdarm, met simptome soos abdominale pyn, diarree en koors), of indien u kind diarree ontwikkel, veral indien dit erg of aanhoudend voorkom, terwyl DYNACEF SUSPENSION gebruik word. Dit mag ‘n aanduiding van inflammasie van die dikdarm (kolitis) wees. Raadpleeg asseblief u dokter onmiddellik
- indien u kind nierprobleme het, mag dit nodig wees om sy/haar dosis aan te pas
- indien u kind sekere bloed-, of urientoetse ondergaan, aangesien DYNACEF SUSPENSION met die resultate mag inmeng
- indien u kind simptome soos konvulsies, verwarring, bewussynsversteurings, of abnormale bewegings ervaar (veral by kinders met nierprobleme, of die wie meer medisyne toegedien is as wat benodig word), kontak u dokter of gesondheidsorgverskaffer onmiddellik.

Andere medisyne en DYNACEF SUSPENSION
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem (Dit sluit aanvullende, of tradisionele medisyne in). Sekere medisyne mag ‘n wisselwerking met DYNACEF SUSPENSION toon. In hierdie gevalle, mag dit nodig wees om die dosis te verander, of die behandeling van een van die medisyne te onderbreek. DYNACEF SUSPENSION werk beter, wanneer dit saam met kos geneem word.

Medisyne wat ‘n interaksie met DYNACEF SUSPENSION mag toon is:

- medisyne wat gebruik word om ulkusse te behandel, soos ranitidine, of simetidine en teensuurmiddele (gebruik om indigestie te behandel, soos aluminiumhidroksied, natriumbikarbonaat), mag die werking van DYNACEF SUSPENSION verlaag
- pentagastrien (medisyne wat gebruik word om maagsuurafskieding te stimuleer), mag die effek van DYNACEF SUSPENSION versterk
- probenecid (gebruik vir die behandeling van jg), mag die bloedvlakke van DYNACEF SUSPENSION verhog en die moontlikheid van nuwe-effekte laat toeneem
- teenstoelmiddels soos warfarien (gebruik om die bloed te verdun), mag die risiko vir bloeding verhoog
- maak asseblief seker dat u dokter bewus is van u kind DYNACEF SUSPENSION neem, indien hy/sy enige toetse moet ondergaan (bloed, urine, of diagnosties), aangesien hierdie medisyne met die toetsresultate mag inmeng
- sommige diuretika (water tablette bv. furosemied), wat gebruik word om die volume urine wat u passier te verhoog, mag u niere aantas
- aminoglikosied antibiotika (bv. gentamisien) (gebruik om infeksies te behandel), mag die manier waarop u niere werk, beïnvloed
- aangesien teenstoelmiddels die risiko vir bloeding mag verhoog, mag u dokter dit nodig ag om die verhoogde verhoging van bloedstilstygting te monitor, terwyl u kind DYNACEF SUSPENSION neem.

DYNACEF SUSPENSION saam met kos en drinkgoed
DYNACEF SUSPENSION moet na ‘n maaltyd geneem word.

Swangerskap, borsvoeding en fertiliteit
Nie van toepassing nie.

Bestuur en die hantering van masjien:
Indien ongunstige effekte soos duiseligheid, of ensefalopatie (wat ‘n aanval, verwarring, bewussynsversteurings, of abnormale bewegings mag insluit) voorkom, moet pasiënte nie bestuur, of masjien hanter nie.

Dit is nie altyd moontlik om te voorspel tot watter mate DYNACEF SUSPENSION met die daaglikse aktiwiteite van ‘n pasiënt sal inmeng nie. Pasiënte moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is tot watter mate DYNACEF SUSPENSION hulle beïnvloed nie.

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DYNACEF SUSPENSION bevat aspartaam (20 mg/5 mL) en suukrose en natriumbensoaat.

Aspartaam:
DYNACEF SUSPENSION moet nie deur pasiënte met fenielketonurie geneem word nie, aangesien een van die metabolisme produkte, fenielalanien is (sien Moet nie DYNACEF SUSPENSION neem).

Suukrose:
Indien u dokter u inliging het dat u ‘n onverdraagsaamheid teenoor sommige suikers toon, kontak u dokter voordat u hierdie medikasie neem. Bevat suukrose. Dit moet in ag geneem word by pasiënte met diabetes mellitus.

Natriumbensoaat:
DYNACEF SUSPENSION bevat 10 mg natriumbensoaat per 5 mL suspensie, wat gelykstaande is aan 0.2 %
Natriumbensoaat mag geelsg by pasgebore babas vererger (tot en met 4 weke oud).

3. Hoe om DYNACEF SUSPENSION te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Gebruik DYNACEF SUSPENSION altyd presies soos deur u dokter aanbeveel word. U moet u dokter of apteker raadpleeg indien u onseker is.
DYNACEF SUSPENSION moet na ‘n maaltyd geneem word.

Kinders:
Die gemiddelde dosis is 8 mg/kg/dag, toegedien as twee doserings elke 12 uur, saam met maaltye. U dokter sal die dosis aanpas, in ooreenstemming met die kind se gewig.

Die volgende mag gebruik word as ‘n doseringsriglyn:

- kinders wat tussen 10 en 15 kg weeg, is die dosis 5 mL elke 12 uur
- kinders wat 15 kg of meer weeg, is die dosis 10 mL elke 12 uur.

Skud die bottel voor gebruik. Vir hersamstelling/aanwysings, verwys na afdeling 6.

Nierversteurings:
Indien u kind ‘n nierversteuring het, sal hy/sy ‘n laer dosis as normaal ontvang. U dokter sal die gepaste dosis, in ooreenstemming met sy/haar toestand, bepaal.

DYNACEF SUSPENSION moet nie aan kinders met fenielketonurie toegedien word nie, aangesien die formule aspartaam bevat (kyk Moet nie DYNACEF SUSPENSION neem).

Toediening van DYNACEF SUSPENSION aan kinders jonger as een jaar oud, word tans nie aanbeveel nie, aangesien veiligheid nog nie vasgestel is nie.

U dokter sal u vertel vir hoe lank u kind se behandeling met DYNACEF SUSPENSION sal duur. Indien u onder die indruk is dat die effek van DYNACEF SUSPENSION te sterk, of te swak is, vertel u dokter of apteker.

Indien u meer DYNACEF SUSPENSION toedien as wat u moes: In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal, of gifbeheersentrum.
Neem hierdie inligtingsblad en die oorblywende suspensie saam met u, sodat die dokter weet watter medisyne u kind geneem het.

Simptome van oordosering mag die volgende insluit:

- enige van die simptome soos beskryf onder Nieuwe-effekte, insluitend sentrale senuweestelseltoekiliteit (met simptome wat angstigheid, duiseligheid, mondgevoelloosheid, ligthoofdigheid, gelul, of gepens in die ore en konvulsies, insluit) en breinfunksieprobleme (met simptome soos geheueverlies, persoonlikheidsveranderinge, aanvalle en spierrekkings)

Indien u vergeet om DYNACEF SUSPENSION toe te dien: Indien u vergeet om DYNACEF SUSPENSION toe te dien, doen dit so gou as wat u onthou, op dieselfde dag. Indien u nie die dosis op dieselfde dag toegedien nie, gee die normale dosis die volgende dag. Moet nie ‘n dubbeldose toedien, om op te maak vir die vergeete, individuele doserings nie.

Indien u die gebruik van DYNACEF SUSPENSION staak
Dit is belangrik dat u die behandelingskursus volhou, selfs al begin u kind beter voel na ‘n paar dae.

4. Moontlike nuwe-effekte
DYNACEF SUSPENSION kan nuwe-effekte hê.
Nie alle nuwe-effekte wat vir DYNACEF SUSPENSION aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongewenste effekte ervaar, terwyl u DYNACEF SUSPENSION gebruik, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgeskundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van DYNACEF SUSPENSION en vertel u dokter onmiddellik, of gaan na die ongevallende-afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk of aasemhaling mag bemoeilik, skok
- uitslag, of gejeuk
- flouite.

Hierdie is alles baie ernstige nuwe-effekte. Indien u kind dit ondandig, kon hulle ‘n ernstige allergies reaksie teenoor DYNACEF SUSPENSION ervaar het. U kind mag dringende mediese aandaag, of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevallende-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:

- hepatitis (lewerinflammasie) en ander lewerprobleme, insluitend geelsg (simptome mag die volgende insluit: naarheid, braking, maagpyn, apytyverlies, moegheid, vergeling van die vel of wit gedeeltes van u oë, donker urine), leverbesering, verhoging in lewerensiens

- ‘n erge infeksie van die dermwand, gekenmerk deur diarree, koors en buikpyn. Dit mag iets soos “Pseudomembraneuse kolitis” wees, bloed in die stoolgang.
- blaasvorming, afskierling, of bloeding op enige gedeelte van u vel, gepaardgaande met, of sonder ‘n uitslag (insluitend u lippe, oë, mond, neus, geslagsdele, hande, of voete), grip-soortige simptome (koors, koue rillings, of seer spiere), wat simptome van ‘n ernstige verkiesie is (Stevens-Johnson-Sindroom of toksiese epidermale nekrolise (TEN)). Dit mag noodlottig wees
- veluitslag, of velletseis met ‘n pienk/rooi ring en ‘n bleek kern, wat jeukerig, skubberig, of met vloeistof ge vul mag wees. Die uitslag mag veral op u palms of voetsole voorkom. Hierdie mag tekens van ‘n ernstige verkiesie, wat ‘n erythema multiforme’ genoem word, wees.
- pankreatitis (inflammasie van die pankreas) (simptome mag goeie abdominale pyn, wat na die rug uitstraal; gewelde en gevoelige abdomen; naarheid en braking, koors en ‘n vinniger hartklop, insluit).
- u kind kry infeksies makliker as gewoonlik. Dit kan wees weens ‘n bloedversteuring en is meer waarskynlik indien hy/sy DYNACEF SUSPENSION langdurig gebruik

- superinfeksie (‘n tweede infeksie wat voorkom tydens die van die bestaande infeksie deur ander bakterieë of organis wat weerstandig is teenoor DYNACEF SUSPENSION, insluit swaminfeksies, soos orale, of vaginale sporel)
- koue rillings, moegheid, ongewone breek vlekke, asemnóg vinnige hartklop, of donkerkleurige onder die vel toon, wat nie verdw u daarpodruk nie (purpura). Dit mag voorkom weens ‘n er bloedprobleem
- aanvalle, sentrale senuweestelseltoekiliteit (met simptome angstigheid, duiseligheid, mondgevoelloosheid, ligthoofdig gelul of gepens in die ore en konvulsies, insluit)
- min of geen urine, wanneer u probeer urineer nie, afname i nierfunksie (met simptome soos swelling weens vloeistofre en hoes bloedtoek)
- gehoerverlies
- ‘n allergies reaksie wat Kounis-sindroom genoem word (u mag simptome soos borsongemak, akute borspyn, duiselig hoofpyn, naarheid en asemnood ervaar).

Hierdie is alles ernstige nuwe-effekte. U kind mag dringende mediese aandaag benodig.

Vertel u dokter indien u enige van die volgende opmerk:
Nieuwe-effekte wat dikwels voorkom:

- apytyverlies
- naarheid, braking, diarree, buikpyn
- hoofpyn.

Minder algemene nuwe-effekte:

- abnormale bloed en/of urientoetsresultate
- duiseligheid, sensasie van tinteling, branderigheid, prikkelir (speide en naalde), of gevoelloosheid van die vel, astenie (ongewone moegheid of swakheid)
- voel opgeblase, oormaat windrigheid (wind), slegte spysv
- gelul in die ore
- abnormale lewer-toetsresultate
- veluitslag, of ander veltoestande
- velblase in ‘n toetsangskikking op die gesig en moontlik pe wat mag versprei na die ledemate, bolyf, hande, voete en k (lineêre lga bullose siekte)
- uilputting en astenie
- vals positiewe bloedtoets (direkte Coombs toets).

Indien u enige nuwe-effek opmerk, wat nie in hierdie inligting genoem word nie, raadpleeg asseblief u dokter of apteker.

Aanmelding van nuwe-effekte
Indien u nuwe-effekte opmerk, praat met u dokter, apteker, of verpleegkundige. U kan ook nuwe-effekte by SAHPRA via die Safety bypassing (Medisality X SAHPRA) en eReporting platf (who-umc.org) wat op die SAHPRA webtuiste gevind kan won anmeld. U kan help om meer inligting aangaande die veilighe van DYNACEF SUSPENSION te bekom, deur nuwe-effekte aan te meld. U kan ook ‘n e-pos direk aan die maatskappy stuur b pharmacovigilance@pharmadynamics.co.za, om die veilighe die medisyne te versker.

5. Hoe om DYNACEF SUSPENSION te bewaar
Bewaar alle medisyne buite die bereik van kinders.

Voor heramstelling:
Bewaar teen of benede 25 °C, beskerm teen lig en humiditeit

Na heramstelling:
Gebruik binne 10 dae. Bewaar in ‘n ykas (2 - 8 °C).
Skud goed voor gebruik.
Hou die bottel dig gesels. Gooi enige ongebruikte gedeelte we Moenie gebruik nie.
Moet nie verbruik na die vervaardigingsdatum wat op die bottel aangee word nie.
Neem alle ongebruikte medisyne na u apteker terug. Moet nie ongebruikte medisyne in afvoertype of rioolstelsels toeliet), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat DYNACEF SUSPENSION bevat:
Elke 5 mL suspensie bevat kefpodoxiemprokateel, gelykstaar kefpodoxiem 40 mg.

Die ander bestanddele is:
Aspartaam, hidroksiapropiellulose, kunsmatige piesanggeu (spirodronol), mellesytsel, mikrokristallien selullose & natriumkarboksimetielcellulose, natriumbensoaat, Spectracol geel ysteroksiet, suukrose, waterterrye kolloïdale silika, watervr siltreusuur (vir pH-aanpassing).

Aanwysings en Heramstelling van die Suspensie:
Verwyder die skroefopspie, deur dit gelyktydig te druk en te d Verwyder die skroefopspie en goot dit weg. Voeg 27,0 mL wat die droë poeler vir die 50 mL suspensie. Voeg 54,0 mL water gelyke dele by die droë poeler vir die 100 mL suspensie. Skur na elke byvoeging.
Sien afdeling 3 – Hoe om DYNACEF SUSPENSION te gebruik.

Hoe DYNACEF SUSPENSION lyk en die verpakkingsinhoud
Poeler vir orale suspensie.
Poeler: Naaswit, tot liggeel-keurige poeler.
Hersaamstellende oplossing: Naaswit tot liggeel suspensie, kenmerkende vrugetruke.

Deurskynende HDPE bottel, met ‘n wit polipropileen 28 mm d (peuterbestand, met ‘n foelie atrekbare bedekking). Bevat po vir heramstelling tot en met 50 mL of 100 mL suspensie, in ‘n gedrukte buitenste kartonhouer.

Elenaar van die Registrasiesertifikaat
Pharma Dynamics (Edms.) Bpk.
1^{ste} Vloer Grapevine House, Stenenberg Office Park Silverwood Close Westlake, 7945 Kaapstad, Suid-Afrika Tel: +27 21 707 7000 of 0860-PHARMA (742 762)

Hierdie inligtingsblad was voorheen hersien
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pharma  dynamics

180 mm

284739 LFLT DYNACEF CFPDXM SUS50-100ML PD SA R5 (BACK)

Customer/Market :	Pharmadynamics/South Africa	Location :	Mandideep
Prepared On :	30/07/2026	Tracking No. :	02
Product Name :	LFLT DYNACEF CFPDXM SUS50-100ML PD SA R5		
Material Code :	284739	Supersedes Material code :	280381
Open Size :	180 x 585 mm (W x H)	Pharma Code :	11147
Folded Size :	180 x 30 mm (W x H)	Gluings :	NA
Substrate :	GSM : 40 gsm, Paper : Bible Paper	Component :	Pack Insert
		Perforation :	NA
Pantone Colours :	 Black  Dieline		
Reason for Change :	Date of Authorisation updated		
Unicorn Creation			
D/Lupin/Regulatory/South Africa/Dyna cefpo Suspension PD/			