DYNACEF

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE
DYNACEF 100 mg film coated tablets
DYNACEF 200 mg film coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
DYNACEF 100 mg
Each film coated tablet contains cefpodoxime proxetil equivalent to cefpodoxime 100 mg.
Each 100 mg tablet contains sugar (lactose monohydrate, 9 mg). Essentially 'sodium free'.

DYNACEF 200 mg
Each film coated tablet contains cefpodoxime proxetil equivalent to cefpodoxime 200 mg.
Each 200 mg tablet contains sugar (lactose monohydrate, 18 mg). Essentially 'sodium free'.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Film coated tablets.
DYNACEF 100 mg: White to off-white, round, biconvex film coated tablets with "100" debossed on one side and plain on the other side.
DYNACEF 200 mg: White to off-white, round, biconvex film coated tablets with "200" debossed on one side and plain on the other side.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
In adults
DYNACEF 100 mg and 200 mg tablets are indicated for use in the short-term treatment of upper and lower respiratory tract infections when caused by susceptible organisms (sensitivity tests must be performed):
- acute bronchitis due to *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Moraxella catarrhalis*
- pharyngitis and tonsillitis due to *Streptococcus pyogenes*
- acute exacerbations of chronic bronchitis due to: *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Moraxella catarrhalis*
- bacterial pneumonia and community acquired bronchopneumonia due to *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Moraxella catarrhalis*
- acute sinusitis due to *Haemophilus influenzae* (non-typeable), *Streptococcus pneumoniae*, Methicillin-sensitive *Staphylococcus aureus*, *Moraxella catarrhalis.*

4.2 Posology and method of administration
Posology
Adults
Each film coated tablet of DYNACEF contains either 100 mg or 200 mg cefpodoxime.
The dosage is dependent on the condition being treated.

Tonsillitis, pharyngitis and acute bronchitis
One DYNACEF 100 mg tablet every 12 hours with meals (200 mg/day).
As is the case with all beta lactam antibiotics in the treatment of beta-haemolytic streptococcal infections, therapeutic doses should be administered for at least ten days.

Acute sinusitis, acute exacerbations of chronic bronchitis, pneumonia
One DYNACEF 200 mg tablets every 12 hours (400 mg/day), to be taken with meals.

Special populations
Elderly patients
No dose adjustments are necessary with normal renal function.

Renal insufficiency in adults
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 tablets should be administered as a single daily dose and every second day for values below 10 mL/min. DYNACEF tablets should be administered after each dialysis session for haemodialysis patients.

Hepatic insufficiency in adults
No dose adjustments are necessary.

Method of administration
DYNACEF tablets are for oral use and must be swallowed whole with half a glass of water and should be taken with meals.

4.3 Contraindications
DYNACEF is contraindicated in:
- hypersensitivity to cefpodoxime proxetil, the cephalosporin group of antibiotics, penicillin's or to any of the ingredients of DYNACEF
- safety in pregnancy and lactation has not been established.

4.4 Special warnings and precautions for use
Prescribers must adhere to the principles of antibiotic stewardship.
Before initiating therapy with DYNACEF, careful enquiry should be made concerning previous hypersensitivity reactions to penicillin and other β-lactam antibiotics.

The use of DYNACEF 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 allergic hypersensitivity reactions which progressed to Kounis syndrome (acute 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:**
Diarrhoea, particularly if severe and/or persistent, occurring during treatment or in the initial weeks following treatment with DYNACEF may be symptomatic of *Clostridium difficile*-associated disease (CDAD), the most severe form of which is pseudomembranous colitis.
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.
It is important to consider its diagnosis in patients who develop diarrhoea in association with the use of DYNACEF. Such colitis may range in severity from mild to life threatening.
Treatment should be discontinued if symptoms suggestive of pseudomembranous colitis arise.

When the colitis does not improve after the medicine has been discontinued, or when it is severe, appropriate specific therapy should be started without delay. *Clostridium difficile*-associated disease can be favoured by faecal stasis.

Renal impairment:
DYNACEF should be given with caution to patients with renal impairment, dosage reduction may be necessary. Renal and haematological status should be monitored, especially during prolonged and high-dose therapy.

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

As with all beta-lactam antibiotics, neutropaenia and less frequently agranulocytosis may develop particularly during extended treatments. For cases of treatment lasting longer than 10 days, blood count should therefore be monitored, and treatment discontinued if neutropaenia is found.

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

Interference with laboratory testing:
Positive results to the antiglobulin direct Coombs test and haemolytic anaemia have been found during treatment with cefpodoxime, such as in DYNACEF, and these can interfere with blood-cross-matching. Cross-reactivity may occur with penicillin for this reaction. The urine of patients being treated with DYNACEF may give false-positive reactions for glucose using copper-reduction reactions.
DYNACEF may interfere with Jaffè method of measuring creatinine concentrations and may produce falsely high values.

Encephalopathy:
Beta-lactams, including cefpodoxime, predispose the patient to encephalopathy risk (which may include convulsions, confusion, impairment of consciousness, movement disorders), particularly in case of overdose or renal impairment.

Lactose:
DYNACEF 100 mg and 200 mg tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Sodium:
DYNACEF 100 mg and 200 mg tablets contain sodium. DYNACEF contains less than 1 mmol (0,023 g) sodium per tablet, that is to say essentially 'sodium free'.

Paediatric population
Safety and efficacy of DYNACEF have not been established in children under one year of age.

Missed dose
Medical practitioners should advise patients who forget to take DYNACEF 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.

4.5 Interaction with other medicines and other forms of interaction
The bioavailability of cefpodoxime is increased if DYNACEF is administered during meals (acid pH).

Absorption of cefpodoxime is decreased by concurrent ingestion of antacids and histamine H_2-receptor antagonists such as ranitidine. Therefore, mineral antacids and histamine blocking H_2 blockers, which cause an increase in gastric pH, should be taken 2 or 3 hours after DYNACEF administration. In contrast, a decrease in gastric pH (pentagastrin) will increase bioavailability.

Probenecid slows tubular excretion of DYNACEF and increases serum levels thereof.

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. Enhanced nephrotoxicity with a loop diuretic (e.g. furosemide) may occur. In such cases, renal function should be monitored (see section 4.4).

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, 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 warfarin may increase resulting in an enhanced anticoagulant effect.

DYNACEF may reduce the contraceptive effect of oestrogens.

4.6 Fertility, pregnancy and lactation
Pregnancy
Safety and efficacy in pregnancy have not been established (see section 4.3).

Breastfeeding
Cefpodoxime is excreted into breast milk. It is recommended that either breastfeeding should be ceased, or treatment of the mother should be discontinued.

Fertility
There is no data on fertility with DYNACEF.

4.7 Effects on ability to drive and use machines
DYNACEF tablets can lead to dizziness and patients should be aware how they react to DYNACEF tablets and exercise caution before driving, operating hazardous machinery or performing hazardous tasks.

4.8 Undesirable effects
a. Summary of the safety profile
The most frequently reported adverse effects of DYNACEF are gastrointestinal disturbances, especially diarrhoea.

b. Tabulated list of adverse reactions

System organ class	Frequency	Side effects
Infections and infestations	*Frequent*	Oral and vaginal candidiasis, superinfections, overgrowth of non-susceptible organisms
	Less frequent	*Clostridium difficile*
Blood and lymphatic system disorders	*Less frequent*	Thrombocytopaenia, leukopaenia, neutropaenia, hypoprothrombinaemia, haemolytic anaemia, reduction of haemoglobin, thrombocytosis, agranulocytosis, aplastic anaemia, pancytopenia, eosinophilia, lymphocytosis, anaemia, leukocytosis
Immune system disorders	*Less frequent*	Hypersensitivity reactions, anaphylactic reactions, angioedema, bronchospasm, malaise, shock
Metabolism and nutrition disorders	*Frequent*	Appetite loss
Nervous system disorders	*Less frequent*	Headache, dizziness, paraesthesia
	Frequency unknown	Asthenia, convulsions and signs of central nervous system (CNS) toxicity especially in patients with severe renal impairment
Ear and labyrinth disorders	*Less frequent*	Tinnitus, hearing loss
Cardiac disorders	*Frequency unknown*	Kounis syndrome
Gastrointestinal disorders	*Frequent*	Diarrhoea, nausea, vomiting, abdominal pain
	Less frequent	Dyspepsia, flatulence, enterocolitis, pseudomembranous colitis, blood in stools, acute pancreatitis
Hepatobiliary disorders	*Less frequent*	Bilirubinaemia, liver injury, acute hepatitis, cholestatic jaundice
	Frequency unknown	Hepatic dysfunction including cholestasis
Skin and subcutaneous tissue disorders	*Less frequent*	Pruritus and urticaria, bullous eruptions (erythema multiforme, rash, Stevens-Johnson syndrome, toxic epidermal necrolysis), cutaneous eruptions, purpura, linear IgA bullous dermatosis (LABD)
Renal and urinary disorders	*Less frequent*	Renal dysfunction, toxic nephropathy, acute renal insufficiency, increase in blood urea and creatinine
General disorders and administrative site conditions	*Less frequent*	Asthenia, fatigue, malaise
Investigations	*Less frequent*	Positive response to the Coombs test, elevations of aspartate aminotransferase (AST), alanine transaminase (ALT) and alkaline phosphatase, increase of blood urea and creatinine

c. Description of selected adverse reactions
Increased liver enzymes (AST, ALT and alkaline phosphatase) and/or bilirubin are less frequently observed; however, these laboratory abnormalities exceed twice the upper limit of the normal range and elicit a pattern of drug-induced hepatitis, usually cholestatic.
Changes in renal function have been observed with antibiotics from the same group as DYNACEF, particularly when co-prescribed with aminoglycosides and/or potent diuretics (see section 4.4).
Diarrhoea may sometimes be a symptom of enterocolitis, which may, in some cases, be accompanied by blood in stools. A particular form of enterocolitis that can occur with antibiotics is pseudomembranous colitis (in most cases due to *Clostridium difficile*) (see section 4.4).

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 asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the 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 may manifest in any of the symptoms described under undesirable side effects (see section 4.8). Convulsions and other signs of CNS toxicity and encephalopathy have been associated with high doses, especially in patients with severe renal impairment.

Management of overdose:
There is no specific antidote for DYNACEF. Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: 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 β-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. Therefore, sensitivity tests must be performed. Cefpodoxime is stable in the presence of the majority of beta-lactamases. The antibacterial action of cefpodoxime is through inhibition of bacterial cell wall synthesis.

Resistance:
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 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 in the gastrointestinal tract when taken orally, and rapidly hydrolysed by non-specific esterases in the gastrointestinal wall to cefpodoxime, the active acid.

Distribution:
Adults:
After oral administration of a single dose of 100 mg of cefpodoxime, the maximum plasma concentration (C_{max}) obtained is 1 - 1,2 mg/L and after administration of a dose of 200 mg of cefpodoxime, the maximum plasma concentration (C_{max}) obtained is 2,2 - 2,5 mg/L. In both cases the time taken to reach the maximum concentration (T_{max}) is 2 - 3 hours.
Following administration of 100 mg twice daily for 14,5 days, the pharmacokinetic parameters of cefpodoxime remain unchanged, indicating that there is no accumulation of the active principle.
The binding of cefpodoxime to plasma proteins is about 40 %. This binding is principally to albumin and is of the non-saturable type.
Cefpodoxime diffuses well in lung parenchyma, bronchial mucosa, pleural fluid and tonsils.

Biotransformation 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
Cores:
Carmellose calcium
Hydroxypropyl cellulose
Lactose monohydrate
Magnesium stearate
Sodium lauryl sulphate

Coating:
Opadry White (as the colourant) 03A28718 which includes:
Hypromellose
Titanium dioxide
Talc

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
DYNACEF 100 mg: 24 months
DYNACEF 200 mg: 24 months

6.4 Special precautions for storage
DYNACEF 100 mg and DYNACEF 200 mg:
Store at or below 25 °C, protected from light and humidity.
Keep blister strip in the carton until required for use.

6.5 Nature and contents of container
DYNACEF 100 mg: One silver aluminium/aluminium lidding foil blister strip containing 10 tablets in a printed outer carton.
DYNACEF 200 mg: One or two silver aluminium/aluminium lidding foil blister strip containing 10 or 20 tablets in a printed outer carton.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa
Tel: +27 21 707 7000
or 0860-PHARMA (742 762)

8. REGISTRATION NUMBERS
DYNACEF 100 mg: A44/20.1.1/0012
DYNACEF 200 mg: A48/20.1.1/0583

9. DATE OF FIRST AUTHORISATION
DYNACEF 100 mg: 05 August 2011
DYNACEF 200 mg: 23 February 2021

10. DATE OF REVISION OF THE TEXT
14 August 2025

NAMIBIA:
DYNACEF 100 mg: NS2 12/20.1.1/0058

pharma dynamics

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DYNACEF 100 mg film coated tablets
DYNACEF 200 mg film coated tablets
Cefpodoxime
Contains sugar, lactose monohydrate (9 mg for DYNACEF 100 mg and 18 mg for DYNACEF 200 mg).
Essentially 'sodium free'.

Read all of this leaflet carefully before you start taking DYNACEF
- 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 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 is and what it is used for
DYNACEF contains cefpodoxime proxetil and belongs to the antibiotic group of medicines known as cephalosporins.
DYNACEF tablets are used in adults for a variety of bacterial infections of the tonsils, throat (pharyngitis), lungs (bronchitis, pneumonia) and sinus cavities.

2. What you need to know before you take DYNACEF
Do not take DYNACEF:
- if you are hypersensitive (allergic) to cefpodoxime, cephalosporin antibiotics, penicillin or any of the other ingredients of DYNACEF (see section 6)
- if you are pregnant or breastfeeding.

Warnings and precautions
Take special care with DYNACEF:
- if you are allergic to certain antibiotics. Please tell your doctor about all allergic reactions you have had previously, especially to medicines
- if you are allergic to penicillin antibiotics, as you may have an increased chance of being allergic to cephalosporins (including DYNACEF) as well
- if you develop diarrhoea, particularly if severe and/or persistent, occurring during treatment or in the initial weeks following treatment with DYNACEF. This may be signs of a serious disease called pseudomembranous colitis (an inflammatory disease affecting the colon, caused by the bacterium, *Clostridium difficile*)
- if you have kidney problems (your dose may need to be adjusted)
- if you take DYNACEF for longer than 10 days your doctor may want to do regular blood tests
- if you undergo certain blood or urine tests as DYNACEF may interfere with the results
- if you experience side effects including convulsions (fits), confusion, impairment of consciousness or movement disorders, especially if you have kidney problems.

Children
Safety and efficacy of DYNACEF have not been established in children under one year of age.

Other medicines and DYNACEF
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Certain medicines may interact with DYNACEF. In these cases, it may be necessary to change the dose or interrupt the treatment of one of the medicines.

Medicines that may interact with DYNACEF are:
- medicines used to treat ulcers such as ranitidine and antacids (used to treat indigestion) may delay how DYNACEF works
- probenecid (used for the treatment of gout) may increase the blood levels of DYNACEF and increase the chance of side effects
- aminoglycoside antibiotics (e.g. gentamicin) (used to treat infections) may affect the way your kidneys work
- certain diuretics (water tablets e.g. furosemide) (used to increase the amount of urine you pass) may affect your kidneys
- anticoagulants such as warfarin (used to thin the blood) may increase the risk of bleeding
- birth control pills (oral contraceptive) may not be effective.

DYNACEF with food and drink
DYNACEF must be taken after a meal.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using DYNACEF.

Safety in pregnant women has not been established.
You should either not breastfeed or not take DYNACEF if you are a mother who is breastfeeding your baby. This is because small amounts of DYNACEF may pass into mothers' milk. This can be harmful to your baby.

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Driving and using machines
DYNACEF tablets can lead to dizziness.
It is not always possible to predict to what extent DYNACEF 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 affects them.

DYNACEF 100 mg and 200 mg contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

DYNACEF 100 mg and 200 mg contains sodium
DYNACEF contains less than 1 mmol (0,023 g) sodium per tablet, that is to say essentially 'sodium free'.

3. How to take DYNACEF
Do not share medicines prescribed for you with any other person.
Always take DYNACEF exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose of DYNACEF will be different for each patient even if their symptoms are the same as yours.
The dose may depend on the following factors:
- what the medicine is being used for
- other medical conditions that you may have
- whether or not other medicines are also being taken.

If you have a kidney disorder, you will receive lower doses than the normal adult dose. Your doctor will determine the correct dose according to your condition.

Your doctor will tell you how long your treatment with DYNACEF will last. Do not stop treatment early because your condition may reoccur or get worse.
If you have the impression that the effect of DYNACEF is too strong or too weak, tell your doctor or pharmacist.

If you take more DYNACEF 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 as soon as possible.

Symptoms of overdose may include:
Seizures/fits and abnormal brain function (especially in patients with kidney disease). These symptoms will disappear after the medicine levels in your system have reduced.

If you forget to take DYNACEF
If you forget to take DYNACEF, take a dose as soon as you remember, then continue to take DYNACEF at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DYNACEF
It is important that you continue the course of treatment even if you begin to feel better after a few days. This is because the infection may come back or get worse.

4. Possible side effects
DYNACEF can have side effects.
Not all side effects reported for DYNACEF are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DYNACEF, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using DYNACEF 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
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to DYNACEF. You 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:
- a severe infection of the lining of the bowel, characterised by diarrhoea, fever and abdominal pain
- flu-like symptoms with a painful red or purplish rash that spreads and blisters (Stevens-Johnson syndrome)
- severe blistering rash where layers of the skin may peel off to leave large areas of raw exposed skin over the body, together with a feeling of being generally unwell, fever, chills, and aching muscles (toxic epidermal necrolysis)
- you have a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly, or filled with fluid – especially on the palms or soles of your feet (a serious skin allergy called erythema multiforme)
- seizures (fits), fainting, convulsions, anxiety, light-headedness
- liver problems (signs include yellow discolouration of the skin and eyes (jaundice) and pain in the upper right abdomen), pale stools, dark-coloured urine
- kidney problems (passing more urine than is normal for you or more frequently)
- pancreatitis (upper abdominal pain that radiates into the back, swollen and tender abdomen, nausea, vomiting, fever and increased heart rate)
- an allergic reaction called Kounis syndrome (your child may experience symptoms such as chest discomfort, acute chest pain, faintness, headache, nausea and dyspnoea).

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

Tell your doctor if you notice any of the following:
Frequent side effects:
- fungal infections such as oral or vaginal thrush
- superinfection (a second infection which occurs during the course of the existing infection, by other bacteria or organisms resistant to DYNACEF)
- you get infections more easily than usual. This could be because of a blood disorder. This is more likely if you are taking this medicine for a long time
- diarrhoea, nausea, vomiting, stomach pain
- appetite loss.

Less frequent side effects:
- abnormal blood test results including anaemia
- headache, dizziness, pins and needles, numbness, or tingling feelings
- hepatitis (inflammation of the liver with symptoms such as nausea, mild fever, abdominal pain), abnormal liver test results
- indigestion, bloating, flatulence (gas), blood in your stools
- ringing in the ears, hearing loss
- fatigue, general feeling of discomfort, illness, or unease
- skin rash, dry scaly skin, redness with bumps, hives
- skin blisters in a clustered arrangement on the face and possibly perineum, that may spread to the limbs, trunk, hands, feet, and scalp (linear IgA bullous disease).

The following side effects have been reported but the frequency for them to occur is not known:
- unusual tiredness, lack of energy or physical weakness.

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.
By reporting side effects, you can help provide more information on the safety of DYNACEF. 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
Store all medicines out of reach of children.
DYNACEF 100 mg and DYNACEF 200 mg:
Store at or below 25 °C, protected from light and humidity.
Store in the original package.
Do not use after the expiry date stated on the carton.
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 contains:
The active substance is cefpodoxime.
DYNACEF 100 mg: Each film coated tablet contains cefpodoxime proxetil equivalent to cefpodoxime 100 mg. Each 100 mg tablet contains sugar (9 mg lactose monohydrate per tablet).
DYNACEF 200 mg: Each film coated tablet contains cefpodoxime proxetil equivalent to cefpodoxime 200 mg. Each 200 mg tablet contains sugar (18 mg lactose monohydrate per tablet).

The other ingredients are
DYNACEF 100 mg and DYNACEF 200 mg:
Cores:
Carmellose calcium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, sodium lauryl sulphate.

Coating:
Opadry White (as the colourant) 03A28718 which includes: Hypromellose, titanium dioxide and talc.

What DYNACEF looks like and contents of the pack
DYNACEF 100 mg: White to off-white, round, biconvex, film coated tablets with "100" debossed on one side and plain on the other side.
DYNACEF 200 mg: White to off-white, round, biconvex, film coated tablets with "200" debossed on one side and plain on the other side.

DYNACEF is packed as follows:
DYNACEF 100 mg: One silver aluminium/aluminium lidding foil blister strip containing 10 tablets in a printed outer carton.
DYNACEF 200 mg: One or two silver aluminium/aluminium lidding foil blister strip containing 10 or 20 tablets in a printed outer carton.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
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14 August 2025

Registration numbers
DYNACEF 100 mg: A44/20.1.1/0012
DYNACEF 200 mg: A48/20.1.1/0583

NAMIBIA:
DYNACEF 100 mg: NS2 12/20.1.1/0058

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S4

DYNACEF 100 mg filmbedekte tablette
DYNACEF 200 mg filmbedekte tablette
Sefpodoksiem
Bevat suiker, laktosemonohidraat (9 mg vir DYNACEF 100 mg en 18 mg vir DYNACEF 200 mg).
Wesenlik 'natriumvry'.

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om DYNACEF te gebruik
- 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 gesondheidsorgverskaffer.
- DYNACEF 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.

Inhoud van hierdie inligtingsblad

1. Wat DYNACEF is en waarvoor dit gebruik word
DYNACEF bevat sefpodoksiemproksetiel en behoort aan 'n groep antibiotika wat bekend staan as kefalosporiene.
DYNACEF tablette word deur volwassenes gebruik vir 'n verskeidenheid bakteriële infeksies van die mangels, keel (faringitis), longe (brongitis, pneumonie) en sinusholtes.

2. Wat u nodig het om te weet, voordat u DYNACEF neem
Moet nie DYNACEF neem:
- indien u hipersensitief (allergies) is vir sefpodoksiem, kefalosporien antibiotika, penisillien, of enige van die ander bestanddele van DYNACEF nie (sien afdeling 6)
- indien u swanger is of borsvoed nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met DYNACEF:
- indien u allergies is vir sekere antibiotika. Vertel asseblief u dokter indien u allergies is vir sekere antibiotika. Vertel asseblief u dokter aangaande alle vorige allergiese reaksies, veral met medisyne, wat u ondervind het
- indien u allergies is vir penisillien antibiotika, aangesien daar 'n toenemende moontlikheid is dat u ook allergies vir kefalosporiene mag wees (insluitend DYNACEF)
- indien u diarree ontwikkel, veral indien dit erg en/of aanhoudend voorkom, gedurende behandeling, of tydens die eerste paar weke na die behandeling met DYNACEF. Dit mag tekens van 'n ernstige siekte wees, wat pseudomembraneuse kolitis genoem word ('n inflammatoriese siekte wat die kolon aantas en veroorsaak word deur die bakterie, *Clostridium difficile*)
- indien u nierprobleme het (dit mag nodig wees om u dosis aan te pas)
- indien u DYNACEF vir langer as 10 dae gebruik, aangesien u dokter gereelde bloedtoetse mag aanvra
- indien u sekere bloed, of urientoetse ondergaan, aangesien DYNACEF met die toetsresultate mag inmeng
- indien u newe-effekte, insluitend konvulsies (stuipe), verwarring, bewussynsbelemmering, of bewegingsversteurings ervaar, veral indien u nierprobleme het.

Kinders
Veiligheid en doeltreffendheid van DYNACEF is nie vasgestel vir kinders jonger as een jaar oud nie.

Ander medisyne en DYNACEF
Vertel altyd u gesondheidsorgverskaffer, indien u enige ander medisyne neem (Dit sluit aanvullende, of tradisionele medisyne in).
Sekere medisyne mag wisselwerkings met DYNACEF toon. In hierdie gevalle, mag dit nodig wees om die dosis te verander of die behandeling van een van die medisyne te onderbreek.

Medisyne wat 'n interaksie met DYNACEF mag toon is:
- medisyne wat gebruik word om ulkusse te behandel, soos ranitidien en teensuurmiddels (gebruik om slegte spysvertering te behandel), mag die werking van DYNACEF vertraag
- probenesied (gebruik vir die behandeling van jig), mag die bloedvlakke van DYNACEF verhoog en die moontlikheid vir newe-effekte laat toeneem
- aminoglikosied antibiotika (bv. gentamisien) (gebruik om infeksies te behandel), mag die werking van u niere aantas
- sekere diuretika (watertablette bv. furosemied), wat gebruik word om urinering te laat toeneem, mag u niere aantas
- teenstolmiddels soos warfarien (gebruik om bloed te verdun), mag die risiko vir bloeding, verhoog
- geboortebeperkingstablette (mondelikse voorbehoedmiddels), mag ondoeltreffend wees.

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

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is, of u baba borsvoed, vermoed dat u swanger is, of n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat u DYNACEF gebruik.

Veiligheid by swanger vroue, is nie vasgestel nie.
U moet of nie borsvoed nie, of nie DYNACEF gebruik, indien u 'n moeder is wie u baba borsvoed nie. Dit is weens die moontlikheid dat klein hoeveelhede DYNACEF in moedersmelk, uitgeskei mag word. Dit mag skadelik wees vir u baba.

Bestuur en hantering van masjiene
DYNACEF tablette kan lei tot duiseligheid.
Dit is nie altyd moontlik om te voorspel tot watter mate DYNACEF 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 hoe DYNACEF hulle aantas nie.

DYNACEF 100 mg en 200 mg bevat laktose
Indien u dokter aangedui het dat u 'n onverdraagsaamheid teenoor sommige suikers toon, kontak u dokter, voordat u hierdie medikasie neem.

DYNACEF 100 mg en 200 mg bevat natrium
DYNACEF bevat minder as 1 mmol (0,023 g) natrium per tablet, dit wil sê wesenlik 'natriumvry'.

3. Hoe om DYNACEF te neem
Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
Neem DYNACEF altyd presies soos deur u dokter aanbeveel word. U moet u dokter of apteker raadpleeg indien u onseker is.

Die DYNACEF dosis sal verskil vir elke pasiënt, selfs al is hulle simptome dieselfde as u eie.
Die dosis mag afhang van die volgende faktore:
- waarvoor die medisyne gebruik word
- ander mediese toestande, wat u mag hê
- indien ander medisyne ook geneem word, of nie.

Indien u 'n nierversteuring het, sal u 'n laer dosis as die gewone volwasse dosis ontvang. U dokter sal die gepaste dosis, in ooreenstemming met u toestand, bepaal.

U dokter sal aandui hoe lank u behandeling met DYNACEF sal duur. Moet nie behandeling vroegtydig staak nie, aangesien u toestand mag hervat, of versleg.
Indien u onder die indruk is dat die werking van DYNACEF té sterk, of té swak is, vertel u dokter of apteker.

Indien u meer DYNACEF neem as wat u behoort
In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal, of gifbeheersentrum so gou as moontlik.

Simptome van oordosering, mag die volgende insluit:
Aanvalle/stuipe en abnormale breinfunksie (veral by pasiënte met niersiekte). Hierdie simptome sal verdwyn, namate die medisynevlakke in u stelsel afneem.

Indien u vergeet om DYNACEF te neem
Indien u vergeet om DYNACEF te neem, neem die dosis so gou as wat u onthou en gaan dan voort om DYNACEF op die gewone tye te neem. Moet nie 'n dubbeldosis neem om op te maak vir die vergete individuele doserings nie.

Indien u die gebruik van DYNACEF staak
Dit is belangrik dat u die behandelingskursus voortsit, selfs al begin u beter voel na 'n paar dae. Die rede hiervoor, is dat die infeksie mag hervat, of vererger.

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

Indien enige van die volgende gebeur, staak die gebruik van DYNACEF en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond, of keel, wat sluk en asemhaling mag bemoeilik
- uitslag of gejeuk.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ondervind, kon u 'n ernstige allergiese reaksie teenoor DYNACEF ervaar het. U mag dringende mediese aandag, of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- 'n erge infeksie, van die dermwand, gekenmerk deur diarree, koors en buikpyn
- griep-soortige simptome, met 'n pynlike rooi, of perserige uitslag, wat versprei en blase vorm (Stevens-Johnson-sindroom)
- erge blaasvormende uitslag, waar vellae mag afskilfer en groot rou blootgestelde veloppervlaktes oor die liggaam tot gevolg het, saam met 'n gevoel van algemene ongesteldheid, koors, koue rillings en seer spiere (toksiese epidermale nekrolise)
- u het 'n veluitslag, of velletsels, met 'n pienk/rooi ring en bleek kern, wat mag jeuk, skubberig is, of met vloeistof gevul mag wees – veral op die handpalms, of voetsole ('n ernstige velallergie, wat erythema multiforme, genoem word)
- aanvalle (stuipe), floute, konvulsies, angstigheid, lighoofdigheid
- lewerprobleme (tekens sluit geel verkleuring van die vel en oë (geelsug) en pyn in die boonste regterkantste buik, in), bleek stoelgang, donkerkleurige urine
- nierprobleme (urineer meer, of meer gereeld as wat normaal is vir u)
- pankreatitis (boonste buikpyn wat uitstraal in die rug, geswelde en gevoelige buik, naarheid, braking, koors en verhoogde harttempo)
- 'n allergiese reaksie genaamd Kounis-sindroom (u kind kan simptome soos borspyn, akute borspyn, flouheid, hoofpyn, naarheid en dispnee ervaar).

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter, indien u enige van die volgende opmerk:
Algemene newe-effekte:
- swaminfeksies soos orale, of vaginale sproei
- superinfeksie ('n tweede infeksie, wat voorkom tydens die duur van die bestaande infeksie, deur ander bakterieë of organismes wat weerstandig is teenoor DYNACEF)
- u kry infeksies makliker as gewoonlik. Dit mag wees, weens 'n bloedversteuring. Dit is meer waarskynlik, indien u hierdie medisyne langdurig gebruik
- diarree, naarheid, braking, maagpyn
- aptytverlies.

Minder algemene newe-effekte:
- abnormale bloedtoetsresultate, insluitend anemie
- hoofpyn, duiseligheid, spelde en naalde, gevoelloosheid, of 'n tintelende gevoel
- hepatitis (lewerinflammasie, met simptome soos naarheid, ligte koors, buikpyn), abnormale lewertoetsresultate
- indigestie, voel opgeblaas, winderigheid (winde), bloed in u stoelgang
- gelui in die ore, gehoorverlies
- uitputting, algemene gevoel van ongesteldheid, siekte, of ongemak
- veluitslag, droë skubberige vel, rooiheid, met knoppe, urtikarie
- velblase in 'n gegroepeerde rangskikking op die gesig en moontlik perineum, wat na die ledemate, romp, hande, voete en kopvel kan versprei (lineêre IgA bulleuse siekte).

Die volgende newe-effekte is aangemeld, maar die frekwensie van voorkoms, is onbekend:
- ongewone moegheid, energietekort, of fisieke swakheid.

Indien u enige newe-effekte opmerk, wat nie in hierdie inligtingsblad genoem word nie, raadpleeg asseblief u dokter, of apteker.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word.
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van DYNACEF in te win. U kan ook 'n epos direk aan die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za, om die veiligheid van die produk te verseker.

5. Hoe om DYNACEF te bewaar
Bewaar alle medisyne buite die bereik van kinders
DYNACEF 100 mg en DYNACEF 200 mg:
Bewaar teen of benede 25 °C, beskerm teen lig en vogtigheid.
Bewaar in die oorspronklike verpakking.
Moet nie gebruik na die vervaldatum wat op die kartonhouer aangedui word nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette), weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat DYNACEF bevat:
Die aktiewe bestanddeel is sefpodoksiem.
DYNACEF 100 mg: Elke filmbedekte tablet bevat sefpodoksiemproksetiel, gelykstaande aan sefpodoksiem 100 mg. Elke 100 mg tablet bevat suiker (9 mg laktosemonohidraat per tablet).
DYNACEF 200 mg: Elke filmbedekte tablet bevat sefpodoksiemproksetiel, gelykstaande aan sefpodoksiem 200 mg. Elke 200 mg tablet bevat suiker (18 mg laktosemonohidraat per tablet).

Die ander bestanddele is
DYNACEF 100 mg en DYNACEF 200 mg:
Kerne:
Hidroksiepropielsellulose, kalsiumkarmellose, laktosemonohidraat, magnesiumstearaat, natriumlourielsulfaat.

Bedekking:
Opadry Wit (as die kleurmiddel) 03A28718, wat die volgende bevat: Hipromellose, titaandioksied en talkum.

Hoe DYNACEF lyk en die verpakkingsinhoud
DYNACEF 100 mg: Wit, tot naaswit, ronde bikonvekse, filmbedektetablette, met "100" gedebosseleer aan een kant en glad aan die teenoorgestelde kant.
DYNACEF 200 mg: Wit tot naaswit, ronde, bikonvekse filmbedekte tablette met "200" gedebosseleer aan een kant en glad aan die teenoorgestelde kant.

DYNACEF word soos volg verpak:
DYNACEF 100 mg: Een silwer aluminium/aluminium dekkingsfoelie stulpstrook, wat 10 tablette in 'n buitenste gedrukte kartonhouer, bevat.
DYNACEF 200 mg: Een of twee silwer aluminium/aluminium dekkingsfoelie stulpstrook wat 10 of 20 tablette in 'n gedrukte buitenste kartonhouer, bevat.
Nie alle verpakkingshoeveelhede word noodwendig bemark nie.

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