PATIENT INFORMATION LEAFLET

DYNACEF TABLETS RANGE

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
2. What you need to know before you take DYNACEF
3. How to take DYNACEF
4. Possible side effects
5. How to store DYNACEF
6. Contents of the pack and other information

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.

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 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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