Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Spectracef 200 mg

Spectracef 400 mg

Film-coated tablets

Active ingredient and quantity:
Spectracef 200 mg: Each tablet contains 200 mg cefditoren as cefditoren pivoxil
Spectracef 400 mg: Each tablet contains 400 mg cefditoren as cefditoren pivoxil

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Spectracef is used in adult and adolescent patients (12 years of age or older) for the treatment of the following infections caused by microorganisms susceptible to cefditoren:

- Acute pharyngo-tonsillitis
- Acute maxillary sinusitis
- Acute exacerbations of chronic bronchitis
- Community-acquired pneumonia, mild to moderate
- Uncomplicated skin and skin structure infections, such as cellulitis, infected wounds, abscesses, folliculitis, impetigo and boils.

Therapeutic group: Antibiotic in the third-generation cephalosporin group.

Spectracef belongs to a group of antibiotics called cephalosporins, that act by inhibiting the synthesis of the cell wall of bacteria.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to cefditoren, antibiotics, particularly penicillin or to any other β-lactam antibiotic, or to any of the other ingredients in this medicine (as listed in section 6).
- You are sensitive (allergic) to casein, you should note that this medicine contains sodium caseinate.
- You have a condition called primary carnitine deficiency.

Special warnings about using this medicine

Before treatment with Spectracef, tell your doctor if:

- You have any liver and/or kidney disease.
- You are on anticoagulant therapy.
- You have previous history of gastrointestinal disease, particularly colitis.
- You receive concurrent treatment with nephrotoxic active substances such as aminoglycoside antibiotics or potent diuretics (such as furosemide) as these combinations may have undesirable effects on renal function and have been associated with ototoxicity.

Consult your doctor if you experience any of the following effects during the treatment:

- If you experience any allergic reaction such as itching, redness, rash, swelling or breathing difficulties while taking treatment.
- If you get diarrhea while taking this medicine or once you finish treatment.

As with other antibiotics, prolonged treatment with Spectracef may result in an overgrowth of non-sensitive microorganisms that would require discontinuation of treatment and the administration of the appropriate therapy.

Treatment with Spectracef may interfere with the results of certain analytical tests and can induce a false positive in the following tests:

- Direct Coombs' test.
- Determination of glucose level in urine.

A false negative result may occur for:

- Glucose level determination in plasma or blood.

Children and adolescents

This medicine is not intended for children and adolescents under the age of 12 years.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

It is recommended to wait for at least 2 hours between taking antacids and Spectracef.

Taking Spectracef together with probenecid increases the levels of cefditoren in the blood.

Spectracef is not recommended to be taken together with intravenous famotidine, since it can make it difficult to reach the proper blood levels of cefditoren.

Using this medicine and food

Take the tablets with food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Spectracef is not recommended to be taken during pregnancy or while breastfeeding.

Driving and using machines
Spectracef can cause dizziness and somnolence, which may interfere with the ability to drive or use any tools or machines.

Important information about some of this medicine's ingredients
Spectracef contains sodium
Spectracef 200 mg contains less than 23 mg sodium per dose, that is to say, essentially "sodium-free".
Spectracef 400 mg contains approximately 26.2 mg sodium per dose, equivalent to 1.3% of the maximum recommended daily intake of sodium for an adult.

3. How to use this medicine

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

Adults and adolescents (over 12 years)
- Acute pharyngo-tonsillitis: 1 tablet of 200 mg cefditoren every 12 hours for 10 days.
- Acute maxillary sinusitis: 1 tablet of 200 mg cefditoren every 12 hours for 10 days.
- Acute exacerbations of chronic bronchitis: 1 tablet of 200 mg cefditoren every 12 hours for 5 days.
- Community-acquired pneumonia:
  - In mild cases: 1 tablet of 200 mg cefditoren every 12 hours for 14 days.
  - In moderate cases: 1 tablet of 400 mg cefditoren every 12 hours for 14 days.
- Uncomplicated skin and skin structure infections: 1 tablet of 200 mg cefditoren every 12 hours for 10 days.

Elderly
No dose adjustment is necessary for elderly patients, except in case of severe renal and/or hepatic function impairment.

Patients with renal impairment
No dose adjustment is necessary for patients with mild renal impairment. In patients with moderate renal insufficiency, the total daily dose should not exceed a dose of 200 mg cefditoren every 12 hours. In patients with severe renal insufficiency, a single dose of 200 mg cefditoren daily is recommended. An appropriate dose for patients on dialysis has not yet been established.

Patients with hepatic impairment
No dose adjustment is necessary for patients with mild to moderate hepatic impairment. In the case of severe insufficiency, there are no data available that would allow a recommended dose to be established.

Do not exceed the recommended dose. Swallow the tablet whole with a sufficient amount of water (one glass of water). Take the medicine with meals.

Do not split, crush or chew the tablet as it is film coated.

If you took too much of Spectracef
If you took too much Spectracef than has been recommended, you should immediately consult your doctor or pharmacist.

If you forget to take Spectracef
If you forget to take a dose, take the next dose as soon as possible, and then continue with the usual dosing schedule. Do not take a double dose to make up for a forgotten dose.

Even if your health improves, do not stop treatment with this medicine without consulting your doctor.

If you stop taking Spectracef
Complete the full course of treatment as there is a risk of the disease reoccurring.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

Like with all medicines, using Spectracef may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

<u>Very common side effects (affect more than one in 10 users):</u>
- diarrhea.

<u>Common side effects (affect 1-10 in 100 users):</u>
- headache, nausea, abdominal pain, feeling of indigestion and vaginal infection.

<u>Uncommon side effects (affect 1-10 in 1,000 users):</u>
- fungal infections
- loss of appetite
- nervousness, dizziness and sleep disturbances
- pharyngitis, rhinitis and sinusitis
- constipation, flatulence, vomiting, oral candidiasis, eructation, dry mouth and loss of sense of taste
- changes in hepatic function
- rash, itching and hives
- vaginal inflammation and discharge
- fever, weakness and sweating
- changes have been observed in the number of blood cells (leukopenia, thrombocytosis), changes in liver function test (elevated ALT).

<u>Rare side effects (affect 1-10 in 10,000 users):</u>
- hemolytic anemia and alteration of lymphatic ganglia

- dehydration
- dementia, depersonalisation, emotional weakness, euphoria, hallucinations and increased libido
- loss of memory, discoordination, hypertonia, meningitis and tremor
- photosensitivity, loss of visual acuity, eye pain and inflammation of eyelid
- buzzing in the ear
- alterations of heart rhythm, heart failure and fainting
- low blood pressure
- asthma
- mouth ulcers, stomatitis, hemorrhagic colitis, ulcerative colitis, gastrointestinal bleeding, hiccups, inflammation and discoloration of the tongue, Clostridium difficile-associated diarrhea.
- acne, alopecia, eczema, exfoliative dermatitis (cracking and flaking of the skin) and herpes simplex
- muscular pain
- painful urination, kidney inflammation, alterations in the frequency of urination, incontinence and urinary infection
- painful breasts, menstrual disorders and erectile dysfunction
- body odor and chills
- alterations have been observed in the number of blood cells (eosinophilia, neutropenia, thrombocytopenia), coagulation disorders (prolongation of coagulation time, reduction in thromboplastin time, platelet disorders), changes in liver function test (elevated AST, alkaline phosphatase), alterations in the values of certain blood components (hyperglycemia, hypokalemia, bilirubinemia, elevated LDH, hypoproteinemia, increased creatinine) or in the urine (albuminuria).

<u>Side effects of unknown frequency (the frequency of these effects has not been established yet):</u>

- pneumonia
- Stevens-Johnson Syndrome (blistering and erosion of the skin and mucous membranes)
- skin blushing
- toxic epidermal necrolysis (a severe form of Stevens-Johnson Syndrome followed by painful skin and detachment of the top layer of the skin)
- acute renal failure
- anaphylactic shock
- serum sickness disease (a delayed allergic skin reaction)
- decrease in the number of blood cells (agranulocytosis)
- decrease in the values of carnitine in the blood
- cholestasis (blocked bile flow from the liver)
- aplastic anemia (decrease in the number of blood cells)
- liver injury
- hepatitis.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Report side effects

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page

(www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the package/tray. The expiry date refers to the last day of that month.
Do not store different medicines in the same package.
Storage conditions
Store in the original package.
Do not store above 25°C.

Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to throw away this medicine. This will help protect the environment.

6. Additional information

In addition to the active ingredient, Spectracef 200 mg and Spectracef 400 mg also contain:

Tablet core:
Sodium caseinate, croscarmellose sodium, mannitol, magnesium stearate and sodium tripolyphosphate;
Tablet coating:
Opadry Y-1-7000 (hypromellose, titanium dioxide, macrogol 400) and carnauba wax;
Printing ink *Opacode S-1-20986 blue*:
Shellac glaze, n-butyl alcohol, brilliant blue FCF lacquer, isopropyl alcohol, titanium dioxide, propylene glycol and ammonia solution concentrated.

What Spectracef 200 mg and Spectracef 400 mg film-coated tablets look like and contents of the pack

Spectracef 200 mg are white, film-coated elliptical tablets, on one side, the TMF logo is printed in blue ink. Each pack contains 20 tablets.
Spectracef 400 mg are white, film-coated elliptical tablets, on one side, the TMF logo is printed in blue ink. Each pack contains 10 tablets.

Manufacturer's name and address:
Meiji Pharma Spain, S.A., Av. de Madrid, 94, 28802, Alcalá de Henares, Madrid, Spain

Registration holder's name and address: Taro International Ltd., 14 Hakitor St., Haifa Bay, 2624761

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Spectracef 200 mg: 166-36-36015
Spectracef 400 mg: 166-37-36016

This leaflet was approved in December 2020.