



PACKAGE LEAFLET

ENCEF 300 mg Capsules Taken by mouth

Active substance: Each capsule contains 300 mg cefdinir.

Excipients: Carboxymethylcellulose calcium, polyoxyl 40 stearate, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate. Titanium dioxide, Indigotine FD&C Blue #2, iron oxide yellow, gelatin (from bovine bone).

Read all of this PACKAGE LEAFLET carefully before you start using this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the period when you take this medicine, tell your doctor that you take this medicine when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you for this medicine.*

In This Leaflet:

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1. WHAT ENCEF IS AND WHAT IT IS USED FOR

The active substance of ENCEF 300 mg Capsules is cefdinir. Cefdinir belongs to a group of antibacterial medicines called third-generation cephalosporins.

ENCEF is presented in opaque PVC-Aclar/Aluminum blister packs containing 10 or 20 capsules.

ENCEF is used to treat infections caused by bacteria in which the medicine is active.

Some infections for which the medicine can be used in adults and adolescents are inflammation of the lungs (pneumonia), chest infections in patients with prolonged breathing difficulties, sinus infections, throat/tonsil infections, and skin infections.

Some infections for which the medicine can be used in children: Middle ear infection, throat/tonsil infections, and skin infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ENCEF

DO NOT use ENCEF

- Do not use ENCEF if you are allergic to antibiotics from the class of cephalosporins.

TAKE SPECIAL CARE with ENCEF

- If you are allergic to cefdinir, cephalosporin antibiotics, penicillins or other medicines,
- If you develop an infection caused by resistant microorganisms, which will require treatment,

during the time you are using the medicine,

- If you have ever had colitis (intestinal inflammation),
- If you have severe kidney disease, consult your doctor.
- Tell your doctor if you have diarrhea during or after the treatment. This may be a sign of serious intestinal inflammation (pseudomembranous colitis), which may occur following antibiotic treatment and may require stopping treatment and starting specific treatment.

Please consult your doctor if these warnings apply to you even at any time in the past.

Using ENCEF with food and drink

You may take ENCEF with or without food.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Tell your doctor if you are pregnant or planning to become pregnant.

If you notice that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Tell your doctor if you are breastfeeding.

Driving and using machines

No effect on the ability to drive and use machines has been reported.

Important information about some of the ingredients of ENCEF

There are no excipients, which require warning.

Taking other medicines

You should consult your doctor or pharmacist before taking any medicines at the same time as ENCEF, especially those listed below:

- Do not take antacids containing aluminum or magnesium (medicines used for heartburn and stomach pain) at the same time as ENCEF. If you need to use these medicines, take ENCEF at least 2 hours before or 2 hours after taking them.
- Probenecid may decrease the ability of your kidneys to excrete the medicine.
- Do not take iron supplements and iron-fortified foods at the same time as ENCEF. If you need to use these medicines, take ENCEF at least 2 hours before or 2 hours after taking them.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. HOW TO TAKE ENCEF

Instructions for proper use and dose/administration frequency:

Take your medicine as instructed by your doctor or pharmacist.

The use of ENCEF in adolescents 13 years and older and in adults should be as follows:

The total daily dose for all infections is 600 mg.



Lung inflammation (pneumonia): 300 mg twice daily (for 10 days)

Chest infections in patients with prolonged breathing difficulties: 300 mg twice daily (for 5-10 days) or 600 mg once daily (for 10 days)

Sinus infections: 300 mg twice daily (for 10 days) or 600 mg once daily (for 10 days)

Throat/tonsil infections: 300 mg twice daily (for 5-10 days) or 600 mg once daily (for 10 days)

Skin infections: 300 mg twice daily (for 10 days)

Route and method of administration:

Take your capsule by your mouth with a glass of water.

Different age groups:

Use in the elderly:

No dose adjustment is required in elderly patients who do not experience kidney diseases.

Use in special conditions:

Kidney insufficiency:

If you are an adult patient with kidney problems, the dose of ENCEF you should take is 300 mg once daily.

If you are a patient undergoing hemodialysis, the initial dose you should take is 300 mg or 7 mg/kg every other day. After the hemodialysis therapy is finished, 300 mg or 7 mg/kg should be administered. Subsequent doses should be either 300 mg or 7 mg/kg every other day.

Please talk your doctor or pharmacist if you think that the effect of ENCEF is either too strong or too weak.

If you take more ENCEF than you should:

If you have taken more ENCEF than you should, consult your doctor or pharmacist.

If you forget to take ENCEF:

Do not take a double dose to make up for a forgotten dose.

If you stop taking ENCEF:

No information is available on the effects that may occur when treatment with ENCEF is stopped.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ENCEF can cause side effects in patients with sensitivity to its ingredients.

Side effects that may occur in 1% or more of patients

Diarrhea

Vaginal moniliasis (a fungal disease of the vagina caused by fungi of the genus *Monilia*)

Nausea

Headache

Abdominal pain



Vaginal inflammation

Side effects that may occur in less than 1% of patients

Rash
Indigestion
Flatulence
Vomiting
Abnormal stools
Loss of appetite
Constipation
Dizziness
Dry mouth
Weakness
Sleeplessness
Increased vaginal discharge
Moniliasis (a fungal disease caused by fungi of the genus Monilia)
Itching
Drowsiness

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

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

5. HOW TO STORE ENCEF

Keep ENCEF out of the reach and sight of children and in its original package.

Store at room temperature below 25°C.

Use it in accordance with the expiry date.

Do not use ENCEF after the expiry date, which is stated on the package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder:

DEVA Holding A.Ş.
Küçükçekmece - İSTANBUL/TÜRKİYE

Manufacturing Site:

DEVA Holding A.Ş.
Kapaklı - TEKİRDAĞ/TÜRKİYE

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