

Read all of this leaflet carefully before you start taking this medicine.

- 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. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Cephadar® capsules are and what they are used for

Cephadar® Capsules contain cephalexin as the active ingredient, which belongs to a class of antibiotics called 'cephalosporins'.

Cephadar® Capsules are used to treat following infections caused by bacteria that can be killed by cephalexin: Respiratory tract infections (RTI's), urinary tract infections (UTI's), skin and soft tissue infections, otitis media and other infections due to sensitive organisms.

2. Before you take Cephadar® capsules

Do not take Cephadar® capsules if you:

- Are allergic (hypersensitive) to cephalexin, other cephalosporins (similar antibiotics) or penicillin group of antibiotics, or to any of the ingredients in the product. An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- Have porphyria; a hereditary metabolic disorder.

Take special care with Cephadar® capsules if you:

- Have had allergic reaction to cephalexin, cephalosporins, penicillins or other drugs in the past
- Have a severe kidney disorder (you may need reduced dose)
- Develop diarrhoea. This could be symptom of the inflammation of the large intestine. Other symptoms include pain and fever.

Tell your doctor if you are having blood and urine tests. **Cephadar®** Capsules may interfere with these tests.

Taking other medicines, herbal or dietary supplements

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription. In particular, tell your doctor if you are taking any of the following:

- other antibiotics, especially amphotericin, capreomycin, vancomycin, gentamicin or neomycin
- diuretics (water tablets) such as furosemide, bumetanide
- probenecid for a treatment of gout
- metformin for treatment of diabetes
- drugs used to treat leukemia

Cefalexin may reduce the effects of oral contraceptives.

Combined use of cephalosporins and oral anticoagulants (warfarin) may prolong prothrombin time.

It may be still be all right for you to be given **Cephadar®** Capsules and your doctor will be able to decide what is suitable for you.

Taking Cephadar® capsules with food and drink

These capsules may be taken before, during or after your meals.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Cephadar® Capsules are not expected to affect your ability to drive or operate machinery.

3. How to take Cephadar® capsules

The doctor will decide on the most appropriate dose for you, based on the nature and severity of your infection. Always take **Cephadar®** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the Capsules whole with water.

Dosage

Adults: The usual total daily dose is 1g to 4g a day, in divided doses.

Most infections can be treated by 500mg every 8 hours. For skin and soft tissue infections, sore throat (Streptococcal pharyngitis), and mild, uncomplicated urinary tract infections, the usual dose is 250mg every 6 hours or 500mg every 12 hours. For more severe infections, larger doses may be needed.

Elderly: You should take the normal adult dose, unless you have severe kidney problems, when the maximum daily dose will be 500mg.

Children over 5 years: Your doctor will calculate the correct dose, depending on the child's weight. The usual daily dose is 25mg to 50mg for each kilogram of their weight, and is usually split up into smaller amounts taken every 8 or 12 hours. For most infections the schedule of 250mg every 8 hours is suggested. In severe infections the dose may be doubled. If your child is taking **Cephadar®** Capsules for ear infections, he or she may have to take 75mg to 100mg for each kilogram of their weight, split up into smaller doses throughout the day.

This medicine is not recommended for use in children under 5 years of age.

Use all the capsules your doctor has given you. **Do not stop taking them**, even if you feel better.

If you take more Cephadar® capsules than you should

Contact your doctor or nearest hospital casualty department immediately for advice if you or a child have swallowed too many capsules. Take this leaflet, the pack or any capsules with you, if you can. Symptoms of overdose include nausea, vomiting, stomach upset, appearance of blood in the urine.

If you forget to take Cephadar® capsules

If you miss a dose, take it as soon as you remember. If it is almost time to take the next dose, skip the missed dose and carry on as before. Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, cephalexin Capsules can cause side effects, although not everyone gets them. Tell your doctor immediately if you get any of these side effects:

- rash
 - fever
 - itchy skin
 - swelling of the lips, eye lids, tongue
 - difficulty in breathing, sudden wheeziness.
- These are the signs of an allergic reaction. Stop taking the capsules immediately.

Serious side effects

The following side effects are serious. You should stop taking this medicine and contact your doctor immediately if you experience them:

- severe peeling or blistering of the skin
- severe diarrhoea

The following side effects have been reported

- Flaky skin, red or purple inflamed skin patches; pus in your eyes; blisters in your nose or mouth.
- Diarrhoea, stomach pain, heartburn, indigestion
- Lower gut pain, inflammation of colon (colitis), severe diarrhoea containing mucus or blood
- Feeling sick (nausea) or being sick (vomiting)
- Measle like rash
- Itching
- Red wheals on the skin (urticaria)
- Pus in the eyes
- Blisters in the nose or mouth
- Rash with wide spread joint pain and/ or stiffness, swollen lymph glands, fever and, possibly, cloudy urine
- Changes in blood counts, which may show up as bruising in a very tired feeling. You will need a blood test to confirm this
- Damage to your liver or kidneys which can be detected by a blood and/ or urine test
- Yellow skin and eye whites (jaundice)
- Weakness, fainting
- Feeling confused or agitated, seeing or hearing things that are not there (hallucinations), extreme restlessness
- Dizziness, tiredness, headache, sleep disorders, nervousness
- itching around the anus or genitals, inflamed vagina, discharge from the vagina caused by thrush (candidiasis)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Cephadar® capsules

- Keep out of the reach and sight of children.
- Do not use **Cephadar®** capsules after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in a dry place. Do not store above 30°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Cephadar® capsules contains

Each capsule of **Cephadar®** contains 250 mg or 500 mg Cephalexin (as cephalexin monohydrate).

Inactive ingredients: Magnesium stearate, sodium starch glycolate.

What Cephadar® capsules looks like and contents of the pack

Cephadar® 250 are capsules with green opaque body coded (Cephadar 250) and blue opaque cap coded (DAD).

Cephadar® Forte 500 are capsules with lavender opaque body coded (Cephadar 500) and blue opaque cap coded (DAD).

Cephadar® 250 mg and **500** mg capsules are available in packs of 16 (two blisters of 8), 20 (two blisters of 10) and 50 (50 blisters of 10).

Not all pack sizes may be marketed

Marketing authorization Holder and Manufacturer

Dar Al Dawa Development & Investment Co. Ltd. (Na'ur, Jordan)

Tel. (+962 6) 57 27 132

Fax. (+962 6) 57 27 776

To report any side effects:

o Jordan

– Contact marketing authorization holder

o Saudi Arabia

– National Pharmacovigilance and Drug Safety Centre (NPC)

– Fax: + 966 112057662

– Call NPC at + 966 112038222, Exts: 2317-2356-2353-2354-2334-2340

– Toll free phone: 8002490000

– E-mail: npc.drug@sfga.gov.sa

– Website: www.sfga.gov.sa/npc

• United Arab Emirates

o Pharmacovigilance and Medical Device Section

o Drug Department

o UAE Ministry of Health & Prevention

– Hotline: 80011111

– Email: pv@moh.gov.ae

– P.O. Box: 1853 Dubai UAE

o Sudan

o National Medicines and Poisons Board (NMPB)

– Fax: + 249 183522263

– E-mail: info@nmpb.gov.sd

– Website : www.nmpb.gov.sd

o Other countries

– Please contact the relevant competent authority.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.