

## PATIENT INFORMATION LEAFLET

### CEFALEXIN 250 mg AND 500 mg CAPSULES

#### CEFALEXIN

**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 signs of illness 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.

**In this leaflet:**

1. What these capsules are and what they are used for
2. Before you take these capsules
3. How to take these capsules
4. Possible side effects
5. How to store these capsules
6. Further information

#### **1. WHAT THESE CAPSULES ARE AND WHAT THEY ARE USED FOR**

Cefalexin capsules contain the active ingredient cefalexin, which is an antibiotic.

Antibiotics work by killing the bacteria (germs) that can cause an infection.

Cefalexin Capsules are used to treat the following infections:

- the lungs and breathing airways (bronchitis and mild to moderate pneumonia)
- the skin and soft tissue (such as wound infection)

#### **2. BEFORE YOU TAKE THESE CAPSULES**

**Do not take these capsules if:**

- you are allergic (hypersensitive) to cefalexin other cephalosporins (similar antibiotics) or any of the other ingredients of these capsules (see list of ingredients in section 6)

An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.

**Take special care with these capsules if you:**

- have had an allergic reaction to cefalexin, cephalosporins, penicillins or other drugs
- develop diarrhoea
- have a severe kidney disorder (you may need a reduced dose)

If any of the above applies to you, speak to your doctor.

**Taking other medicines:**

Please tell your doctor or pharmacist if you are taking or have recently taken any of the following medicines, including medicines obtained without a prescription, as they may interact with your Cefalexin capsules.

This is especially true of:

- probenecid (a treatment for gout)
- metformin (a treatment for diabetes)
- aminoglycosides and other cephalosporins (a treatment for infections)
- furosemide (drug to increase urine output)

It may still be all right for you to be given Cefalexin capsules and your doctor will be able to decide what is suitable for you

**Effects on laboratory tests**

Tell your doctor if you are taking Cefalexin capsules and you are having **blood** or **urine tests** as Cefalexin capsules may interfere with the results of these tests.

**Pregnancy and breast feeding:**

You should tell your doctor if you are pregnant or breastfeeding and he/she will decide if it is OK for you to take Cefalexin Capsules. Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines:**

Cefalexin capsules should not affect your ability to drive or use machines. Use with caution when driving or operating heavy machinery until you're aware of how this drug affects you.

**Important information about some of the ingredients of this medicine:**

This medicine contains Sunset yellow (E110), Quinoline yellow (E104) and Patent Blue V (E131) which may cause allergic reactions.

### 3. HOW TO TAKE THESE CAPSULES

Always take these capsules exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.

**Dosage in adults:**

The recommended adult dose in adults is: 1-4g to be taken orally, daily in divided doses. Most infections can be treated by 500mg every 8 hours (1.5g/day).

- For skin and soft tissue infections, sore throat, 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
- A reduced dose is needed for patients with severe kidney disorders

**Dosage in children:**

- The usual dose in children is 25-50mg/kg (body weight) in 3 divided doses. In severe infections the dosage may be doubled

In the treatment of beta-haemolytic streptococcal infections (a type of bacteria) treatment should be given for at least 10 days.

**If you take more capsules than you should:**

Do not take more capsules than your doctor tells you to.

If you ever take too many capsules, go to your nearest hospital casualty department or call your doctor immediately.

**If you forget to take these capsules:**

If you forget to take a dose, take it as soon as you remember. If you have missed several doses, tell your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

**4. Possible side effects**

Like all medicines, Cefalexin Capsules can cause side effects, although not everybody gets them.

***If any of the following serious side effects occur, stop taking this medicine and tell your doctor or pharmacist immediately, or go to your nearest hospital accident and emergency department taking your medicine with you.***

- swelling of your face, lips, tongue or throat (angioedema)
- a sudden allergic reaction with shortness of breath, rash, wheezing and drop of blood pressure
- itchy spots or rash on the arms and legs or severe, extensive, blistering skin rash (erythema multiforme, Steven-Johnson syndrome)

Tell your doctor if you experience the following -

- Diarrhoea (which may be bloody or have mucus in it)

**The following side effects have also been reported:**

***Common: (affecting at least 1 in 100 patients but less than 1 in 10 patients)***

- Diarrhoea, nausea

***Uncommon: (affecting at least 1 in 1,000 patients but less than 1 in 100 patients)***

- Changes in blood tests that check how well your liver is working
- Increase in some types of white blood cells (eosinophilia)
- Skin rash, hives or itching

***Rare: (affecting at least 1 in 10,000 patients but less than 1 in 1,000 patients)***

- Blood problems: change in the number of cells in the body responsible for combating infections (symptoms may include infections and abnormal bruising or bleeding), increase in the number of cells responsible for blood clotting; haemolytic anaemia, a type of anaemia caused by the breakdown of red blood cells.
- Dizziness and headache
- Abdominal pain, vomiting, indigestion, inflammation of the intestinal tract (pseudomembranous colitis)
- Reversible kidney inflammation (interstitial nephritis)
- Genital and anal itching, and inflammation of the vagina
- Tiredness
- Inflammation of the liver (hepatitis), yellowing of the skin and eyes (cholestatic icterus)

***Other side effects: (Frequency not known)***

- Pain or inflammation in the joints (arthralgia, arthritis)
- Vaginal thrush (candidiasis)
- Fever
- Hallucinations, confusion and agitation

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.

## 5. HOW TO STORE THESE CAPSULES

- Keep out of the reach and sight of children.
- Do not use these capsules after the expiry date which is stated on the carton.
- The expiry date refers to the last day of the month.
- Store below 30°C. Store in the original package.

### Disposal

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

**Cefalexin 250mg Capsules:** Each capsule contains 250mg Cefalexin (as monohydrate).

**Cefalexin 500mg Capsules:** Each capsule contains 500mg Cefalexin (as monohydrate).

### What these capsules contain

The **active** substance is Cefalexin (as monohydrate).

The **other ingredients** are:

Capsule content: Microcrystalline cellulose, Magnesium, Stearate and water. Capsule Shell: Gelatin, sodium lauryl sulphate, sunset yellow (E110), quinoline yellow (E104), titanium dioxide (E171), patent blue (E131) and black imprinting ink (containing shellac, propylene glycol, water, potassium hydroxide and black iron oxide)

### What Cefalexin Capsules look like and contents of the pack

Cefalexin Capsules are available in **two** strengths.

**Cefalexin 250 mg Capsules** are size '2' capsules with dark green cap and white body imprinted with '250' in black ink on cap containing white to yellowish-white granular powder.

**Cefalexin 500 mg Capsules** are size '0' capsules with dark green cap and light green body imprinted with '500' in black ink on cap containing white to yellowish-white granular powder.

Cefalexin 250 mg Capsules are packed in blisters of 4, 7, 10, 12, 16, 20, 21, 24, 28, 30, 100 and 112 capsules.

Cefalexin 500 mg Capsules are packed in blisters of 7, 8, 10, 12, 14, 15, 16, 20, 21, 28, 30, 40 and 100 capsules.

**Not all pack sizes may be marketed.**

### Marketing Authorisation Holder and Manufacturer

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