Patient Information Leaflet

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

ZEFKOL 0,5 g INJECTION (powder for injection)

ZEFKOL 1,0 g INJECTION (powder for injection)

Read this leaflet carefully before ZEFKOL is administered

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- ZEFKOL has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

WHAT ZEFKOL CONTAINS

Each vial contains cefazolin sodium corresponding to 0,5 g or 1,0 g cefazolin base.

WHAT ZEFKOL IS USED FOR

ZEFKOL is in a group of medicines called cephalosporin antibiotics. It is used to treat bacterial infections of the respiratory tract, urinary tract, skin and skin structure, bones and joints, heart membrane and valves, and septicaemia, caused by various sensitive bacteria.

ZEFKOL should only be administered by or under the supervision of your doctor.

BEFORE YOU ARE ADMINISTERED ZEFKOL

You should not be administered ZEFKOL

- if you are hypersensitive (allergic) to ZEFKOL, the cephalosporin class of antibiotics, penicillins or other beta-lactam antibiotics;
- if you are pregnant, planning to be pregnant, or breastfeeding;
- for premature babies and infants under 1 month of age.

Special care should be taken with ZEFKOL

The presence of other medical problems may affect the use of ZEFKOL. Talk to your doctor, pharmacist or healthcare professional before receiving ZEFKOL

- if you have kidney disease;
- if you have stomach or bowel problems such as colitis.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving ZEFKOL.

You should not receive ZEFKOL

- if you are pregnant, planning to become pregnant or if you suspect you are pregnant;
- if you are breastfeeding.

Using other medicines with ZEFKOL

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

In particular, you should check with your doctor, pharmacist or other healthcare professional if you are taking any of the following to be sure that it is safe to receive ZEFKOL at the same time:

- aminoglycoside antibiotics or water tablets (diuretics), because the risk of toxic effects on the kidneys may be increased;
- probenecid.

Before you begin using any new medicine (prescription or non prescription) or if you develop any new medical problem while you are using ZEFKOL, check with your doctor, pharmacist or other healthcare professional.

HOW ZEFKOL IS GIVEN

You will not be expected to give yourself ZEFKOL. It will be given to you by a person who is qualified to do so.

Do not share medicines prescribed for you with any other person.

ZEFKOL is administered by injection into a vein (intravenously), by a drip (infusion) or into a muscle (intramuscular), by your doctor, or under his or her supervision. Your doctor will determine the correct dosage and route of administration based on the sensitivity of the causative bacteria, the severity of the infection, your age and your overall condition and kidney function.

Important safety information

- ZEFKOL should not be used if it contains particles, is cloudy or discoloured, or if the vial is cracked or damaged.
- To clear up your infection completely, ZEFKOL should be used for the full course of treatment as prescribed by your doctor. Your symptoms may improve before the infection is completely treated.
- ZEFKOL can cause unusual results with certain lab tests to check for glucose (sugar) in your urine. Tell your doctor, pharmacist or healthcare professional that you are using ZEFKOL if your urine is tested for glucose (sugar).

- Long-term or repeated use of ZEFKOL may cause a second infection. Tell your doctor, pharmacist or healthcare professional if signs of a second infection occur. Your medicine may need to be changed to treat this.
- Contact your doctor immediately if stomach pain or cramps, severe diarrhoea, or bloody stools occur. Do not treat diarrhoea without first checking with your doctor.

If you receive more ZEFKOL than you should

Since your doctor or nurse will administer ZEFKOL to you, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you miss a dose of ZEFKOL

Your doctor will take corrective measures.

POSSIBLE SIDE EFFECTS

ZEFKOL may cause side effects.

Not all side effects reported for ZEFKOL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving ZEFKOL, please consult your doctor, pharmacist or other healthcare professional for advice.

- Get emergency medical help if you have any of these signs of an allergic reaction: rash, hives, difficulty in breathing, itching, tightness of the chest, swelling of your face, lips, tongue or throat.

The following side effects may occur:

Allergic reactions, fever, headache, diarrhoea, nausea, vomiting, abdominal pain, skin rash, hives, oral thrush, bleeding gums, coughing up blood, difficulty in swallowing, dizziness, increased menstrual flow or vaginal bleeding, nosebleeds, paralysis,

prolonged bleeding from cuts, red or dark brown urine, red or black tarry stools, shortness of breath, itchiness of the genitals and anus, changes in the blood, confusion, seizures, chills, difficulty in breathing, inflammation of the large intestine that has clinical signs including diarrhoea and abdominal pain, inflammation of the liver, yellowing of the skin or eyes, kidney problems, pain, redness or swelling at the injection site.

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

STORING AND DISPOSING OF ZEFKOL

Dry Powder: Store at 15 to 25 °C and protect from light.

Constituted solution: Reconstituted ZEFKOL diluted in sterile water for Injection, 5 % dextrose injection, 0,9 % sodium chloride injection or bacteriostatic water for injection is stable for 24 hours when stored below 25 ºC and for 10 days when stored in a refrigerator (2 to 8 ºC).

Solutions of ZEFKOL for infusion in 10 % dextrose injection, 5 % dextrose in lactated Ringer's injection, 5 % dextrose and 0,9 % sodium chloride injection (may also be used with 5 % dextrose and 0,45 % or 0,2 % sodium chloride injection), lactated Ringer's injection, Ringer's injection or Plasma-Lyte with 5 % dextrose should be used within 24 hours after dilution if stored at 15 to 25 ºC, or within 96 hours if stored in a refrigerator (2 to 8 ºC). (DO NOT FREEZE ZEFKOL DILUTED WITH THE ABOVE DILUENTS).

Do not store your medicine in the bathroom.

Do not use this medicine after the expiry date which is clearly marked on the label and outside of the box.

Return any expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF ZEFKOL

A clear glass vial sealed with a rubber stopper and an aluminium-plastic combined cap, containing dry powder equivalent to 0,5 g or 1,0 g cefazolin, in packs of 1 or 10 vials.

IDENTIFICATION OF ZEFKOL

Dry powder: Sterile, white or almost white powder in a clear glass vial.

REGISTRATION NUMBERS

ZEFKOL 0,5 g INJECTION : 37/20.1.1/0136

ZEFKOL 1,0 g INJECTION : 37/20.1.1/0137

Botswana S3:

ZEFKOL 0,5 g Injection: BOT0801438

ZEFKOL 1,0 g Injection: BOT0801437

Namibia NS2

ZEFKOL 0,5 g Injection:06/20.1.1/0269

ZEFKOL 1,0 g Injection:06/20.1.1/0270

NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

Acino Pharma (Pty) Ltd

106, 16th Road

Midrand

1686

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