

TRIDENT LIFELINE PVT LTD

2004, 3rd Floor, North Extension, Begumpura, Falsawadi, Ring
Road, Surat-395003, Gujarat, India.

**Patient Information Leaflet****Cefuroxime Axetil for oral suspension USP 125 mg/5 ml (HOSPIN)****Package Leaflet: Information for the user****HOSPIN 125 mg/5 ml granules for oral suspension Cefuroxime**

Read all of this leaflet carefully before you start taking 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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What HOSPIN is and what it is used for
2. What you need to know before you take HOSPIN
3. How to take HOSPIN
4. Possible side effects
5. How to store HOSPIN
6. Contents of the pack and other information

1. What HOSPIN is and what it is used for

HOSPIN is an antibiotic used in adults and children. It works by killing bacteria that cause infections. It belongs to a group of medicines called *cephalosporins*.

HOSPIN is used to treat infections of:

- the throat
- sinus
- middle ear
- the lungs or chest
- the urinary tract
- the skin and soft tissues.

HOSPIN can also be used:

- to treat Lyme disease (an infection spread by parasites called ticks).

Your doctor may test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to HOSPIN during your treatment.

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**Patient Information Leaflet****Cefuroxime Axetil for oral suspension USP 125 mg/5 ml (HOSPIN)****2. What you need to know before you take HOSPIN****Do not take HOSPIN:**

- **if you are allergic** to cefuroxime axetil or **any cephalosporin antibiotics** or any of the other ingredients of HOSPIN (listed in section 6).
 - if you have ever had a severe allergic (hypersensitive) reaction to any other type of betalactam antibiotic (penicillins, monobactams and carbapenems).
- If you think this applies to you, **don't take HOSPIN** until you have checked with your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking HOSPIN.

Children

HOSPIN is not recommended for children aged under 3 months, as the safety and effectiveness are not known in this age group.

You must look out for certain symptoms, such as allergic reactions, fungal infections (such as *candida*) and severe diarrhoea (*pseudomembranous colitis*) while you are taking HOSPIN. This will reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

If you need a blood test

HOSPIN can affect the results of a test for blood sugar levels, or a blood screen called the *Coombs test*. If you need a blood test:

- **Tell the person taking the sample** that you are taking HOSPIN.

Other medicines and HOSPIN

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines used to **reduce the amount of acid in your stomach** (e.g. *antacids* used to treat **heartburn**) can affect how HOSPIN works.

Probenecid
Oral anticoagulants

- **Tell your doctor or pharmacist** if you are taking any medicine like this.

Contraceptive pills

HOSPIN may reduce the effectiveness of the contraceptive pill. If you are taking the contraceptive pill while you are being treated with HOSPIN you also need to use a **barrier**

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method of contraception (such as condoms). Ask your doctor for advice.

Pregnancy and breast-feeding and fertility

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

HOSPIN can make you **dizzy** and have other side effects that make you less alert.

→ **Don't drive or use machines** if you do not feel well.

Important information about some of the ingredients of HOSPIN

HOSPIN suspension contains sugar (sucrose). If you are diabetic you need to take this into account for your diet.

HOSPIN suspension also contains **aspartame**, which is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly. HOSPIN suspension also contains benzyl alcohol (E1519) which may cause allergic reactions.

→ **Check with your doctor** that HOSPIN is suitable for you.

3. How to take HOSPIN

Always take this medicine exactly as your doctor or pharmacist has told you to.

Check with your doctor or pharmacist if you are not sure.

Take HOSPIN after food. This will help to make the treatment more effective.

Shake the bottle before use.

HOSPIN suspension can be diluted in cold fruit juices, or milk drinks but should be taken immediately.

Don't mix HOSPIN with hot liquids.

For step-by-step instructions on how to make up HOSPIN suspension see **Instructions for reconstitution** at the end of this leaflet.

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**Patient Information Leaflet****Cefuroxime Axetil for oral suspension USP 125 mg/5 ml (HOSPIN)****The recommended dose****Adults**

The recommended dose of HOSPIN is 250 mg to 500 mg twice daily depending on the severity and type of infection.

Children

The recommended dose of HOSPIN is 10 mg/kg (to a maximum of 125 mg) to 15 mg/kg (to a maximum of 250 mg) twice daily depending on:

- the severity and type of infection
- the weight and age of the child, up to a maximum of 500 mg per day.

HOSPIN is not recommended for children aged under 3 months, as the safety and effectiveness are not known in this age group.

Depending on the illness or how you or your child responds to treatment, the initial dose may be changed or more than one course of treatment may be needed.

Patients with kidney problems

If you have a kidney problem, your doctor may change your dose.

→ **Talk to your doctor** if this applies to you.

If you take more HOSPIN than you should

If you take too much HOSPIN you may have neurological disorders, in particular you may be **more likely to have fits (seizures)**.

→ **Don't delay. Contact your doctor or your nearest hospital emergency department immediately.** If possible, show them the HOSPIN pack.

If you forget to take HOSPIN

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop taking HOSPIN

Don't stop HOSPIN without advice

It is important that you take the full course of HOSPIN. Don't stop unless your doctor advises you to – even if you are feeling better. If you don't complete the full course of treatment, the infection may come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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**Patient Information Leaflet****Cefuroxime Axetil for oral suspension USP 125 mg/5 ml (HOSPIN)****4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Conditions you need to look out for

A small number of people taking HOSPIN get an allergic reaction or potentially serious skin reaction. Symptoms of these reactions include:

- **severe allergic reaction.** Signs include **raised and itchy rash, swelling**, sometimes of the face or mouth causing **difficulty in breathing**.
- **skin rash**, which may **blister**, and looks like **small targets** (central dark spot surrounded by a paler area, with a dark ring around the edge).
- **a widespread rash with blisters and peeling skin.** (These may be signs of *Stevens-Johnson syndrome* or *toxic epidermal necrolysis*).

Other conditions you need to look out for while taking HOSPIN include:

- **fungal infections.** Medicines like HOSPIN can cause an overgrowth of yeast (*Candida*) in the body which can lead to fungal infections (such as thrush). This side effect is more likely if you take HOSPIN for a long time.
- **severe diarrhoea (*Pseudomembranous colitis*).** Medicines like HOSPIN can cause inflammation of the colon (large intestine), causing severe diarrhoea, usually with blood and mucus, stomach pain, fever
- **Jarisch-Herxheimer reaction.** Some patients may get a high temperature (fever), chills, headache, muscle pain and skin rash while being treated with HOSPIN for Lyme disease. This is known as the *Jarisch-Herxheimer reaction*. Symptoms usually last a few hours or up to one day.

→ **Contact a doctor or nurse immediately if you get any of these symptoms.**

Common side effects

These may affect **up to 1 in 10** people:

- fungal infections (such as *Candida*)
- headache
- dizziness
- diarrhoea
- feeling sick
- stomach pain.

Common side effects that may show up in blood tests:

- an increase in a type of white blood cell (*eosinophilia*)
- an increase in liver enzymes.

Uncommon side effects

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These may affect **up to 1 in 100** people:

- being sick
- skin rashes.

Uncommon side effects that may show up in blood tests:

- a decrease in the number of blood platelets (cells that help blood to clot)
- a decrease in the number of white blood cells
- positive Coomb's test.

Other side effects

Other side effects have occurred in a very small number of people, but their exact frequency is unknown:

- severe diarrhoea (*pseudomembranous colitis*)
- allergic reactions
- skin reactions (including severe)
- high temperature (*fever*)
- yellowing of the whites of the eyes or skin
- inflammation of the liver (*hepatitis*).

Side effects that may show up in blood tests:

- red blood cells destroyed too quickly (*haemolytic anaemia*).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store HOSPIN

Keep this medicine out of the sight and reach of children.

The suspension should be stored in a fridge at all times when not taking the medicine.

Do not allow it to freeze. It can be kept in the fridge for up to 10 days.

Do not use HOSPIN if it shows any sign of deterioration.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Don't 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 to protect the environment.

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**Patient Information Leaflet****Cefuroxime Axetil for oral suspension USP 125 mg/5 ml (HOSPIN)****6. Contents of the pack and other information****What HOSPIN contains**

The active substance is 125 mg per 5 ml of cefuroxime (present as cefuroxime axetil).

What HOSPIN looks like and contents of the pack

HOSPIN Suspension 125 mg/5 ml is supplied in an amber, glass, multidose bottle. The bottle contains 40 ml, 50 ml, 60 ml, 70 ml 80 ml or 100 ml of the 125 mg/5 ml suspension. This medicine must be made up with water using the original granules that were supplied in the bottle. The bottle is contained within a carton. Not all pack sizes may be marketed.