

Package leaflet: Information for the user

Calvepen™ 250mg/5ml Powder for Oral Suspension

Phenoxyethylpenicillin Calcium

This medicine will be referred to as **Calvepen™ 250 mg Suspension** throughout this leaflet.

Read all of this 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 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Calvepen™ 250 mg Suspension is and what it is used for
2. What you need to know before you take Calvepen™ 250 mg Suspension
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1. What Calvepen™ 250 mg Suspension is and what it is used for

Calvepen™ 250 mg Suspension belongs to a group of medicines called antibiotics. Calvepen™ is a member of the penicillin family and is used to kill bacteria which cause a number of different infections.

Calvepen™ 250 mg Suspension is used to treat certain kinds of infection. Your doctor will decide if this treatment is suitable for your infection. Calvepen™ is also used in patients with rheumatic fever to prevent the infection returning.

2. What you need to know before you take Calvepen™ 250 mg Suspension

DO NOT take Calvepen™ 250 mg Suspension

- if you are allergic to penicillin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Potentially life-threatening skin rashes (Stevens Johnson syndrome, toxic epidermal necrolysis) have been reported with the use of some penicillin's appearing initially as reddish target-like spots or circular patches often with central blisters on the trunk. Additional signs to look for include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). If you develop a rash or these skin symptoms, stop taking Calvepen, seek urgent advice from a doctor and tell him that you are taking this medicine.

Talk to your doctor or pharmacist before taking Calvepen™ 250 mg Suspension

- if you suffer from severe gastrointestinal impairment accompanied by vomiting and diarrhoea. You should not be treated with Calvepen™ 250 mg Suspension, because sufficient absorption is not ensured.
- if you are taking the contraceptive pill. You may need to take extra contraceptive precaution such as using a condom.

Prolonged use of an antibiotic may result in infections due to bacteria resistant to the antibiotic.

Other medicines and Calvepen™ 250 mg Suspension

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

Please consult your doctor if you are taking:

- Other antibacterial medicines (e.g. tetracyclines, sulphonamides, chloramphenicol or neomycin)
- Probenecid (used in the treatment of gout)
- The contraceptive pill (you will need to take extra contraceptive precautions such as using a condom).

The presence of Calvepen™ 250 mg Suspension may alter the results of urobilinogen tests. If you are having blood tests done, make sure that the doctor knows that you are taking Calvepen™ 250 mg Suspension.

Calvepen™ 250 mg Suspension can alter the results of some urine tests for sugar. If you are a diabetic and you routinely test your urine, you should tell your doctor because other tests may have to be used instead, in order to monitor your diabetes while you are taking Calvepen™ 250 mg Suspension.

Pregnancy and breast-feeding

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.

You should not take Calvepen™ 250 mg Suspension if you are breast-feeding.

Driving and using machines

Calvepen™ 250 mg Suspension is unlikely to affect your ability to drive or use machines. However, make sure you know how you react to Calvepen™ 250 mg Suspension before driving a vehicle or operating machinery. If in doubt, talk to your doctor.

Calvepen™ 250 mg Suspension contains sucrose, methyl parahydroxybenzoate (E218) and sodium

Calvepen™ 250 mg Suspension contains 2.5 g of sucrose per 5 ml dose. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Calvepen™ 250 mg Suspension contains methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

This medicine contains 15 mg sodium (main component of cooking/table salt) in each 5ml.

This is equivalent to 0.75 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Calvepen™ 250 mg Suspension

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Shake the bottle well before use.

Oral penicillin should be given before meals, and in divided doses, preferably four times per day.

Your doctor may decide to change the dose depending on the type and severity of the infection.

The usual doses for each age group are:

Adults and over 12 years:

Typical dose is 250mg (5ml) to 500mg (10ml) given four times daily.

Children: 6-12 years:

Typical dose is 250mg (5ml) given four times daily

Children: 1-6 years:

Typical dose is 125mg (2.5ml) given four times daily

Infants under 1 year:

Typical dose is 62.5mg (1.25ml) given four times daily

Prevention of Rheumatic Fever:

Typical dose is 250mg (5ml) twice a day.

If you take more Calvepen™ 250 mg Suspension than you should

If you take too much Calvepen™ 250 mg Suspension, contact your doctor or local hospital casualty department at once. Take the bottle with you.

If you forget to take Calvepen™ 250 mg Suspension

If you forget to take a dose of Calvepen™ 250 mg Suspension, take it as soon as you remember. Then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Calvepen™ 250 mg Suspension

Keep taking your suspension until you finish your course of treatment. Don't stop taking it because you feel better. If you stop taking the suspension too soon the infection may start again because all of the bacteria may not have been killed.

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

4. Possible side effects

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

Tell your doctor/dentist immediately if you have:

- a rash, you have itchy skin or other skin problems
- difficulty breathing
- muscle weakness
- pseudomembranous enterocolitis (bacterial infection of the large intestine. Symptoms include abdominal pain or diarrhoea)

Common: may affect up to 1 in 10 people

Gastrointestinal:

- nausea
- vomiting
- loss of appetite
- stomach pain
- flatulence (wind)
- diarrhoea

Skin:

- rash
- itching
- hives (immediate presence of hives indicates penicillin allergy, use of Calvepen should be discontinued)
- eruption of the skin (exanthema)
- inflammation of mucous membranes especially in the mouth

Rare: may affect up to 1 in 1,000 people

Skin:

- growth of bacteria or yeast on the tongue
- dry mouth
- changes in taste

Liver: temporary change in liver blood tests, which is reversible

Very rare: may affect up to 1 in 10,000 people

Immune system:

- severe allergic reactions causing fever, joint pain, changes in blood counts, angioneurotic oedema (sudden swelling of the lips, cheeks, eyelids, tongue and throat), laryngeal oedema (accumulation of fluid in the larynx), bronchospasm (wheezing, shortness of breath), increase in the heartbeat, vasculitis (inflammation of blood vessels), serious skin reactions (Steven-Johnson syndrome) and a sudden drop in blood pressure up to life threatening shock

Kidney: impaired kidney function due to inflammation

Gastrointestinal: inflammation which causes abdominal pain or diarrhoea, tooth discolouration

Blood and cells: severe reduction in blood cells which can cause weakness, bleeding, bruising or make infections more likely

Hepato-biliary: raised liver enzymes.

Not known: frequency cannot be estimated from the available data

Skin: Toxic epidermal necrolysis (which causes severe illness and flaking of the skin).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calvepen™ 250 mg Suspension

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

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

If you store the suspension in the fridge use it within two weeks. If you do not store your suspension in the fridge, use it within one week.

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.

6. Contents of the pack and other information

What Calvepen™ 250 mg Suspension contains

The active substance is phenoxymethylpenicillin calcium. Each 5 ml spoonful contains 250 mg phenoxymethylpenicillin calcium.

The other ingredients are

Caramel custard dry aroma, hypromellose, golden syrup flavour, methyl parahydroxybenzoate (E218), sodium carragenate, sodium chloride, sodium citrate and sucrose.

What Calvepen™ 250 mg Suspension looks like and contents of the pack

The oral suspension is available as a white to off-white powder and your pharmacist will add water and make 100 ml of suspension. The suspension is white to off-white in colour.

A spoon with graduations of 2.5 ml and 5 ml may be supplied with the pack of this product.

Pack sizes: 100 ml bottles

Marketing authorisation holder/Manufacturer

Clonmel Healthcare Ltd

Waterford Road

Clonmel

Co. Tipperary

Ireland

This leaflet was last revised in November 2020.