

Package Leaflet: Information for the User

Calvepen™ 333 mg Tablets

Calvepen™ 666 mg Tablets

Phenoxymethylpenicillin Calcium

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™ tablets are and what they are used for
2. What you need to know before you take Calvepen™ tablets
3. How to take Calvepen™ tablets
4. Possible side effects
5. How to store Calvepen™ tablets
6. Contents of the pack and other information

1. What Calvepen™ tablets are and what they are used for

Calvepen™ tablets belong 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™ 333mg tablets contain 333 mg of Phenoxymethylpenicillin Calcium equivalent to 300 mg of Phenoxymethylpenicillin.

Calvepen™ 666 mg tablets contains 666 mg of Phenoxymethylpenicillin Calcium equivalent to 600 mg of Phenoxymethylpenicillin

Calvepen™ tablets are 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™ tablets

DO NOT take Calvepen™ tablets

- 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™ tablets

- if you suffer from severe gastrointestinal impairments accompanied by vomiting and diarrhoea. You should not be treated with Calvepen™ tablets, because sufficient absorption is not ensured.
- if you are taking the contraceptive pill. You may need to take extra contraceptive precautions such

as using a condom.

- If you are being treated with methotrexate at the same time, your doctor will monitor your methotrexate serum levels.

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

Other medicines and Calvepen™ tablets

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).
- Methotrexate (a medicinal product to treat e.g. cancers and psoriasis).

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

Calvepen™ tablets 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™ tablets.

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™ tablets if you are breast-feeding.

Driving and using machines

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

3. How to take Calvepen™ tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets with a drink of water half an hour before food.

Calvepen™ tablets

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 **333mg** (equivalent to 300mg of Phenoxymethylpenicillin) to **666mg** (equivalent to 600mg of Phenoxymethylpenicillin) given four times daily.

Children: 6-12 years:

Typical dose is **333mg** (equivalent to 300mg of Phenoxymethylpenicillin) given four times daily.

Under 6 years:

Calvepen 250mg/5ml oral suspension is recommended.

Prevention of Rheumatic Fever:

Typical dose is 333mg (equivalent to 300mg of Phenoxymethylpenicillin) given twice a day.

If you take more Calvepen™ tablets than you should

If you take too much Calvepen™ tablets, contact your doctor or local hospital casualty department at once. Take the container with you.

If you forget to take Calvepen™ tablets

If you forget to take a dose of Calvepen™ tablets, 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™ tablets

Keep taking your tablets until you finish your course of treatment. Don't stop taking it because you feel better. If you stop taking the tablets 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 get

- a rash, you have itchy skin or other skin problems
- have difficulty breathing
- have 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) and 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 and 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 HPRA 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™ tablets

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 label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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™ tablets contain

The active substance is phenoxymethylpenicillin calcium. Each tablet contains 333 mg or 666 mg phenoxymethylpenicillin calcium.

The other ingredients are

Crospovidone, gelatin, magnesium stearate, maize starch, hypromellose, colloidal anhydrous silica and talc.

What Calvepen™ tablets look like and contents of the pack

Calvepen™ 333 mg film-coated tablets are white and oval having “105” engraved on one side and Clonmel logo on the other.

Calvepen™ 666 mg film-coated tablets are white and oval having “104” engraved on one side and Clonmel logo on the other.

Calvepen™ 333 mg tablets are available in high density polypropylene tubes with low density polyethylene caps (securitainers) containing 4, 10, 100 and 500 tablets.

Calvepen™ 666 mg tablets are available in high density polypropylene tubes with low density polyethylene caps (securitainers) containing 4, 100 and 500 tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder/Manufacturer

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