

Package leaflet: Information for the user

Clindamycin 75 mg/5 ml Granules for oral solution

Clindamycin

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.
- 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.

The name of your product is Clindamycin 75 mg/5 ml Granules for oral solution, but it will be referred to as Clindamycin oral solution throughout this leaflet.

What is in this leaflet

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

1. What Clindamycin oral solution is and what it is used for

Clindamycin oral solution contains clindamycin palmitate hydrochloride which is an antibiotic used in the treatment of serious bacterial infections.

2. What you need to know before you take Clindamycin oral solution

Do not take Clindamycin oral solution:

If you are allergic (hypersensitive) to clindamycin, lincomycin or to any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Clindamycin oral solution if:

- you have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhoea during or after using Clindamycin oral solution **tell your doctor immediately** since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics.
- you suffer from problems with your kidneys or liver.
- you suffer from asthma, eczema or hay fever.
- you develop any severe skin reactions or hypersensitivity to Clindamycin oral solution.

Acute kidney disorders may occur. Please inform your doctor about any medication you currently take and if you have any existing problems with your kidneys. If you experience decreased urine output, fluid retention causing swelling in your legs, ankles or feet, shortness of breath, or nausea you should contact your doctor immediately.

Due to the risk of inflammation of the oesophagus (oesophagitis) and oesophageal ulcer, it is important to always take Clindamycin oral solution exactly as described in section 3. Clindamycin oral solution does not get into the brain and is therefore not suitable for treating serious infections in and around the brain. Your doctor may need to give you another antibiotic if you have these infections.

Other medicines and Clindamycin oral solution

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

- muscle relaxants used for operations (neuromuscular blockers).
- oral contraceptive pills. You should use extra contraception such as condoms whilst taking Clindamycin oral solution and for seven days after taking Clindamycin oral solution.
- warfarin or similar medicines – used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.
- CYP3A4 or CYP3A5 inducers like rifampicin may impact effectiveness of the medicine.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or think you might be pregnant you should contact your doctor **before** taking Clindamycin oral solution.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Tell your doctor if you will be breast-feeding while taking Clindamycin oral solution as clindamycin may be passed into breast milk. Your doctor will decide if Clindamycin oral solution is appropriate for you. Although it is not likely that a nursing infant will take in very much of the active substance from the milk it drinks, if your baby gets bloodstained diarrhoea or shows any signs of illness, tell your doctor at once. You should stop breast-feeding if this happens.

Driving and using machines

No effects on the ability to drive or use machines have been seen with Clindamycin oral solution.

Clindamycin oral solution contains sucrose and ethyl parahydroxybenzoate.

Sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains 1.8 g of sucrose in each 5 ml of oral solution. This should be taken into account in patients with diabetes mellitus.

May be harmful to the teeth.

Ethyl parahydroxybenzoate

This medicine contains 0.6 mg ethyl parahydroxybenzoate in each 5 ml of oral solution.

May cause allergic reactions (possibly delayed).

Benzoate salts may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take Clindamycin oral solution

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

Clindamycin oral solution should be taken no less than 30 minutes before lying down to avoid a possible irritation of the oesophagus.

Adults and Elderly Patients

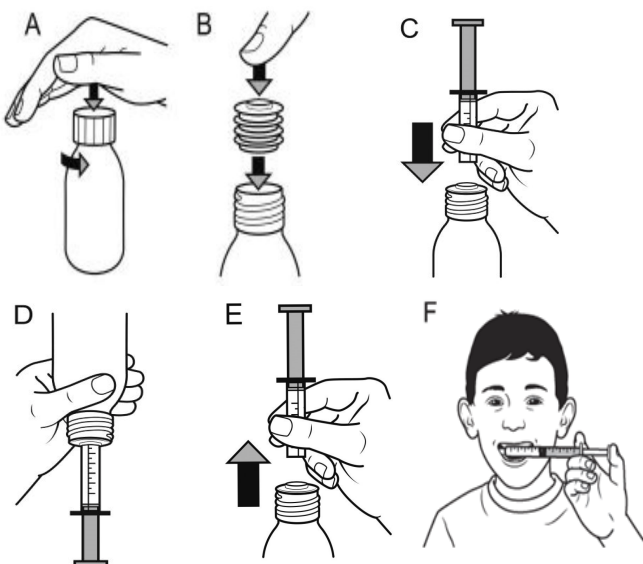
The recommended dose is between 150 and 450 mg of clindamycin (10 to 30 ml of Clindamycin oral solution) every 6 hours, depending on the severity of your infection.

Use in children and adolescents

Your doctor will carefully calculate the amount of Clindamycin oral solution that your child should take based on the total body weight of the child.

How to take Clindamycin oral solution

1. Open the bottle and at first use insert the “Press-In” Bottle Adapter (PIBA) (see pictures A-B).
2. Insert the syringe into the PIBA and draw out the required volume from the inverted bottle (see pictures C-D).
3. Remove the filled syringe from the bottle in the upright position (see picture E).
4. Discharge the syringe contents into the mouth. Repeat steps 2 to 4 as needed to achieve the required dose.
5. Replace the cap on the bottle (PIBA remains in place).
6. Rinse the syringe with water and allow to air dry.



If you are giving Clindamycin oral solution to a child:

- Make sure that the child is sitting up or standing.
- Put the syringe into the child's mouth, placing the barrel-opening in the area between the gums and the inside of the cheek (see picture F).

- Push the plunger slowly, giving the child time to swallow the medicine as it squirts out. Do not push the plunger too quickly as the medicine may come out too quickly and the child may choke.
- Give the child some water to drink in order to ensure that all the medicine is washed down.

Long-term use of Clindamycin oral solution

If you have to take Clindamycin oral solution for a long time, your doctor may arrange regular liver, kidney and blood tests. Do not miss these check-ups with your doctor. Long-term use can also make you more likely to get other infections that do not respond to Clindamycin oral solution treatment.

If you take more Clindamycin oral solution than you should

If you accidentally take too much Clindamycin oral solution contact your doctor at once or go to the nearest hospital emergency department. Always take the labelled medicine package with you, whether there is any Clindamycin oral solution left or not. Do not take any more solution until your doctor tells you to.

If you forget to take Clindamycin oral solution

If the forgotten dose is just a few hours late, use it straight away. If it is nearly time for your next dose miss out the forgotten one. **Do not take a double dose to make up for a missed dose.**

If you stop taking Clindamycin oral solution

If you stop taking the medicine too soon your infection may come back again or get worse. Do not stop taking Clindamycin oral solution unless your doctor tells you to. If you have any further questions on how to take this product, 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 immediately if you develop:

- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is an uncommon side effect which may occur during or after completing treatment with antibiotics and can be a sign of serious bowel inflammation or pseudomembranous colitis.
- signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, dizziness, swelling of the eyelids or face or lips or throat or tongue, rash or itching (especially affecting the whole body).
- blistering and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips.
- yellowing of the skin and whites of the eyes (jaundice).
- potentially life-threatening skin rashes:
 - a widespread rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes or genitals, known as Stevens-Johnson syndrome, or a more severe form with extensive peeling of the skin (more than 30% of the body surface) known as *toxic epidermal necrolysis*
 - a rare skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP))
 - skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge - *erythema multiforme*)
 - widespread red skin rash with small pus-containing blisters (*bullous exfoliative dermatitis*)

- fever, swollen lymph nodes or skin rash, these may be symptoms of a condition known as DRESS (Drug reaction with eosinophilia and systemic symptoms) and can be severe and life-threatening
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea.

Other possible side effects may include:

Common: may affect up to 1 in 10 people

- abnormal liver function tests (poor liver function)
- pain in the stomach/abdomen, diarrhoea

Uncommon: may affect up to 1 in 100 people

- feeling sick or being sick
- rash characterized by a flat red area on the skin that is covered with small bumps, hives

Not known: frequency cannot be estimated from the available data

- infection inside and around the vagina
- inflammation of the large intestine which causes abdominal pain, fever or diarrhoea due to infection by *Clostridioides difficile*
- effects on your blood system: reduced numbers of blood cells which may cause bruising or bleeding or weaken the immune system
- changes in the way things taste
- inflammation of the lining of the oesophagus (gullet)*, open sores or lesions in the lining of the oesophagus (gullet)*
- yellowing of the skin and whites of the eyes (jaundice)
- red or scaly skin (exfoliative dermatitis), red measles-like rash (rash morbilliform), itching

*Side effects that are more likely to occur if Clindamycin oral solution is taken in a lying position.

Reporting of side effects

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. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clindamycin oral solution

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 carton and bottle labels. The expiry date refers to the last day of that month.

After first opening use the reconstituted oral solution within 2 weeks.

Store below 30 °C. Store in the original package in order to protect from light.

Do not refrigerate reconstituted solution.

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 Clindamycin oral solution contains

- The active substance is clindamycin. Each 5 ml of Clindamycin oral solution contains 123.5 mg clindamycin palmitate hydrochloride equivalent to 75 mg clindamycin.
- The other ingredients are sucrose, ethyl parahydroxybenzoate (E214), poloxamer 188, cherry flavour (including flavouring substances), simethicone 30% emulsion.

What Clindamycin oral solution looks like and contents of the pack

Amber, type III glass bottle safely closed with a child resistant screw cap with tamper evident closure, containing 32 g of granules (for pack size of 80 ml).

Clindamycin oral solution (after reconstitution) is a colourless to slightly yellowish, clear to slightly cloudy solution with characteristic cherry odour.

Prior to reconstitution with water the product is presented as white to off white granules.

A 10 ml oral syringe of 0.5 ml graduations along with a press-in bottle adapter are also provided.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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