PACKAGE LEAFLET: INFORMATION FOR THE USER

Clindamycin 150mg/ml, Solution for Injection

Clindamycin phosphate

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 your pharmacist.
- • 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

The name of your medicine is "**Clindamycin 150mg/ml, solution for injection**" (referred to as Clindamycin Injection throughout this leaflet).

1. WHAT CLINDAMYCIN INJECTION IS AND WHAT IT IS USED FOR

Clindamycin Injection contains clindamycin phosphate, which is an antibiotic used in the treatment of serious bacterial infections.
Clindamycin Injection is a sterile solution for injection into a vein (intravenously) or into a muscle (intramuscularly).

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN CLINDAMYCIN INJECTION

You should not be given Clindamycin Injection:
- If you are allergic to clindamycin, lincomycin or any of the other ingredients in this medicine (listed in section 6)

If you are unsure, talk to your doctor.

Clindamycin should not be used in new born babies.

Warnings and precautions
You should tell your doctor before you are given Clindamycin Injection:
- If you have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered from problems with your stomach or intestines (bowel disease). If you develop severe or prolonged or bloody diarrhoea during or after being given Clindamycin Injection, **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 even after 2 to 3 weeks following treatment with antibiotics.
- If you suffer from liver or kidney problems. Your doctor may give you a lower dose.
- If you suffer from asthma, eczema or hay fever.

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.

If you are taking this medicine for a long time, you will have regular tests to check that your liver and kidneys are working properly. Your doctor will also perform these tests if this medicine is given to an infant less than 2 years old.
Clindamycin Injection 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 Injection
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
Some medicines can affect the way Clindamycin Injection works, or Clindamycin Injection itself can reduce the effectiveness of other medicines taken at the same time. These include:
- muscle relaxants used during operations.
- oral contraceptives pills. You should use extra contraception such as condoms whilst receiving this medicine and for seven days after receiving Clindamycin Injection.
- 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, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you are given this medicine.

Breast-feeding
Tell your doctor if you will be breast-feeding while taking Clindamycin Injection as clindamycin may be passed into breast milk.

Your doctor will decide if Clindamycin Injection 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 Injection.

Information about sodium content
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, that is to say essentially "sodium-free".

3. HOW CLINDAMYCIN INJECTION IS GIVEN

Your doctor will give you your medicine as an injection into your vein (intravenous) or your muscle (intramuscular).
If it is given into a vein, it is always mixed with a sugar or saline (salt) solution before use and given using a drip.
When giving you Clindamycin Injection, your doctor will ensure that the concentration of clindamycin does not exceed 18 mg per ml and the rate it is given to you does not exceed 30 mg per minute. If Clindamycin Injection is given too fast it could rarely cause a heart attack.

Adults:
The recommended dose of Clindamycin Injection is 600mg to 2700mg per day in twoto four equal doses, depending on the severity of your infection. Higher doses than this (up to 4800 mg daily) may be given by your doctor for very severe infections.

Children:
The recommended dosage for children (over 1 month of age) is 15mg to 40mg of clindamycin per kg bodyweight each day in three or four equal doses. Higher doses of up to 300 mg per day (regardless of body weight) may be given by your doctor for very severe infections until a full response to treatment is observed.

Normally Clindamycin Injection is only given to patients in hospital. The medical staff will be keeping a close eye on you during your treatment. If you need to have more than one course of treatment with clindamycin, your doctor may want to check that it is not having any effect on the way your kidneys and liver are working.

Long term use can also make you more likely to get other infections that do not respond to Clindamycin treatment.
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 immediately if you develop:
- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is a common side effect which may occur during or after completing treatment with antibiotics and can be a sign of serious bowel inflammation
- signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, dizziness, swelling of eyelids, face or lips or throat or tongue, rash or itching (especially affecting the whole body)
- potentially life threatening skin rashes:
  - blistering and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips
  - a widespread rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes and genitals (**Stevens-Johnson syndrome),** and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface - **toxic epidermal necrolysis**) widespread red skin rash with small pus-containing blisters (**exfoliative dermatitis bullous**)
  - 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) known as erythema multiforme
  - fever, swollen lymph nodes or skin rash, these may be symptoms of a condition known as DRESS (Drug reaction with eosinophilia and systemic symptoms) can be severe and life-threatening. The symptoms of DRESS usually begins several weeks after exposure to Clindamycin
  - 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))
- yellowing of the skin and whites of the eyes (jaundice).
- a marked decrease in the number of blood cells which may cause bruising or bleeding or weaken the immune system (agranulocytosis), a slight decrease in the number of white blood cells (leukopenia), reduced blood platelet (thrombocytopenia)
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea

Common: may affect up to 1 in 10 people
- blood clot (vein inflammation)
- abnormalities in liver function tests
- rash characterised by a flat, red area on the skin that is covered with small bumps

Uncommon: may affect up to 1 in 100 people
- change of sense of taste
- low blood pressure (feeling light headed, dizzy or faint), heart and lungs stop functioning (when the heart suddenly stops pumping blood around the body)
- feeling sick, diarrhoea
- itchy skin
- hives

- pain, abscess (boil)

Not known: frequency cannot be estimated from available data
- reduced numbers of blood cells which may cause bruising or bleeding or weaken the immune system
- an increase in the number of white blood cells (eosinophilia)
- stomach pain, being sick (throwing up) inflammation of the lining of the oesophagus (gullet) open sores or lesions in the lining of the oesophagus (gullet)
- infection inside and around the vagina
- irritation at the site of the injection

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 the Yellow Card Scheme at: 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 INJECTION

Keep this medicine out of the sight and reach of children. You should not be given Clindamycin Injection after the expiry date which is stated on the label and carton after EXP.
Do not store above 25°C. Do not refrigerate or freeze. Your doctor, pharmacist or nurse will know how to store Clindamycin Injection properly.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Clindamycin Injection contains
• The active substance is clindamycin phosphate. Each ml of solution contains clindamycin phosphate equivalent to 150mg of clindamycin.
• The other ingredients are disodium edetate, sodium hydroxide and water for injections.

What Clindamycin Injection looks like and contents of the pack
Clindamycin Injection is a clear, colourless solution in an ampoule.
Each 2ml ampoule contains 300mg Clindamycin as Clindamycin phosphate. Each 4ml ampoule contains 600mg Clindamycin as Clindamycin phosphate.
Each carton contains ten ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Istituto Biochimico Italiano G. Lorenzini SpA, Via Fossignano 2, 04011 Aprilia (LT), Italy.

Manufacturer:
Lisapharma S.p.A, Via Licinio 11, 22036 Erba – Como, Italy

This leaflet was last revised in 11/2021 .

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for medical or healthcare professionals only.

Instructions for use and handling:
Do not use Clindamycin injection if you notice any particulate matter in the solution or if there is strong colouration of the solution.

Clindamycin Injection has been shown to be physically and chemically compatible for at least 24 hours in 5% dextrose and sodium chloride injection solutions.
From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally be no longer than 24 hours at 2-8°C unless dilution has taken place in controlled and validated aseptic conditions

Clindamycin injection should be used undiluted for intramuscular administration.
Clindamycin injection must be diluted prior to intravenous administration and should be infused over at least 10 – 60 minutes.

The concentration of clindamycin in diluent for infusion should not exceed 18 mg per mL and **infusion rates should not exceed 30mg per minute**. The usual infusion rates are as follows:

Dose	Diluent	Time
300 mg	50 mL	10 min
600 mg	50 mL	20 min
900 mg	50-100 mL	30 min
1200 mg	100 mL	40 min

The product should not be admixed with other drug products which are chemically or physically unstable at low pH (see section 6.2 of the Summary of Product Characteristics). The compatibility and duration of stability of drug admixtures will vary depending upon concentration and other conditions.

Storing Clindamycin Injection:
Do not store above 25°C. Do not refrigerate or freeze.

Dosage instructions

Adults:
Serious infections: 600 mg - 1.2 g/day in two, three or four equal doses.
More severe infections: 1.2 - 2.7 g/day in two, three or four equal doses.
Single IM injections of greater than 600 mg are not recommended nor is administration of more than 1.2 g in a single one hour infusion.
For more serious infections, these doses may have to be increased. In life-threatening situations, doses as high as 4.8 g daily have been given intravenously to adults.
Alternatively, the drug may be administered in the form of a single rapid infusion of the first dose followed by continuous IV. infusion.

Paediatric population (over 1 month of age):
Serious infections: 15 - 25 mg/kg/day in three or four equal doses.
More severe infections: 25 - 40 mg/kg/day in three or four equal doses. In severe infections it is recommended that children be given no less than 300 mg/day regardless of body weight.

Elderly patients: The half-life, volume of distribution and clearance, and extent of absorption after administration of clindamycin phosphate are not altered by increased age. Analysis of data from clinical studies has not revealed any age-related increase in toxicity. Dosage requirements in elderly patients should not be influenced, therefore, by age alone.

Treatment for infections caused by beta-haemolytic streptococci should be continued for at least 10 days to guard against subsequent rheumatic fever or glomerulonephritis.