

Package leaflet: Information for the user

Clindamycin 150mg/ml solution for injection or infusion clindamycin phosphate

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Clindamycin Injection is and what it is used for

Clindamycin 150mg/ml solution for injection or infusion (called Clindamycin Injection in the rest of this leaflet). belongs to a group of medicines called antibiotics. Antibiotics are used to treat infections. Clindamycin injection is used to kill certain serious bacterial infections. You will usually be in hospital when you receive this medicine.

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse 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 using 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 have any allergies such as hayfever, asthma or eczema;
- if you have problems with your kidneys. 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 have problems with your liver.

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:

- **erythromycin** an antibiotic used to treat infection: Clindamycin Injection and erythromycin may not work as well when they are used together.
- **oral contraceptive pill**: the pill may not work and may not prevent pregnancy. Use additional contraception, such as a condom, while receiving Clindamycin Injection and for 7 days after your last dose of Clindamycin Injection.
- **warfarin** or other similar medicines used to thin the blood: you may bleed more than usual when taking these medicines together with Clindamycin Injection. Your doctor may need to perform regular blood tests to check how well your blood clots.
- CYP3A4 or CYP3A5 inducers like Rifampicin may impact effectiveness of the medicine.

If you are in hospital to have an operation or a hospital procedure **tell your doctor you are taking Clindamycin Injection**. Clindamycin Injection may increase the effect of certain medicines (such as those given to help your muscles relax).

Tell your doctor or nurse if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Pregnancy

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 they give you 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.

Important information about the ingredients of Clindamycin injection.

This medicine contains less than 1 mmol sodium (23 mg) per 2 ml ampoule, (prior to dilution) that is to say essentially 'sodium-free'.

This medicine contains 26 mg sodium (main component of cooking/table salt) in each 4 ml ampoule (prior to dilution). This is equivalent to 1.3% of the recommended maximum daily dietary intake of sodium for an adult.

3. How Clindamycin Injection is given to you

You will usually be in hospital when you are given Clindamycin Injection.

You will be given Clindamycin Injection by a doctor or nurse as an injection into your muscle, or infusion into a vein (using a drip). The injection or infusion will take 10-60 minutes.

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.

The recommended dose is

In adults and elderly

- The usual dose is 600-1200mg clindamycin per day. This will be given in 2, 3 or 4 equal doses over a 24-hour period.
- If you have a very severe infection your doctor may increase your dose to a maximum of 2700mg per day. This will be given in 2, 3 or 4 equal doses over a 24-hour period.

Doses up to 4800mg per day have been given in life-threatening cases.

Use in Children

The dose for children is based on your child's body weight.

- The doctor will decide how much to give your child.
- The usual dose is 15 to 25mg per kg of body weight. This will be given in 3 or 4 equal doses over a 24-hour period.
- If your child has a very severe infection your doctor may increase the dose to at least 300mg. The dose is not related to the weight of your child. This will be given in 3 or 4 equal doses over a 24-hour period.

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 the clindamycin 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 Injection treatment

If you are given more Clindamycin Injection than you should

If you think you have been given too much Clindamycin Injection tell a doctor or a nurse.

If you think you have missed a dose of Clindamycin Injection

Clindamycin Injection will be given to you by a doctor or nurse. If you think you have missed a dose tell your doctor or nurse.

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

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 the eyelids or face or lips or throat or tongue, rash or itching (especially if 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)
- heart and lungs stop functioning (when the heart suddenly stops pumping blood around the body)
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea

Other side effects

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 lightheaded, dizzy or faint)
- 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 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 Injection

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

Keep ampoules in outer carton.

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

Do not store above 25°C.

Do not refrigerate or freeze.

Once your doctor or nurse has opened the ampoule it should be used immediately. Any remaining Clindamycin Injection must be thrown away by the doctor or nurse.

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 Injection contains

- The active substance is clindamycin phosphate. Each ml contains 150mg 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 solution in a glass ampoule containing 2ml or 4ml of the solution for injection. This product is available in cartons containing 1 x 2ml, 1 x 4ml, 5 x 2ml or 5 x 4 ml ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Focus Pharmaceuticals Limited,
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS,
United Kingdom
Tel: 0208 588 9131
Email: medicalinformation@advanzpharma.com

Manufacturer

Vianex SA, 12th Km Athens Lamia National Road, Metamorfofi, Athens, Greece

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

For information in large print, audio CD or Braille please telephone + 44 (0)208 588 9131 or email medicalinformation@advanzpharma.com.

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Technical Leaflet for healthcare professionals

CLINDAMYCIN 150MG/ML SOLUTION FOR INJECTION OR INFUSION

GENERAL INFORMATION

Injection:

Clindamycin 150mg/ml Solution for Injection or Infusion is for single use only. Any unused content should be discarded.

Solution for infusion:

Clindamycin 150mg/ml Solution for Injection or Infusion can be diluted with solutions for infusion containing: 0.9% sodium chloride and 5% dextrose.

THERAPEUTIC INDICATIONS

Clindamycin is indicated for the treatment of severe infections. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

Clindamycin does not penetrate the blood/brain barrier in therapeutically effective quantities.

POSOLOGY AND METHOD OF ADMINISTRATION

For intravenous or intramuscular infusion only.

Parenteral (I.M. or I.V. administration). Clindamycin 150mg/ml Solution for Injection and Infusion must be diluted prior to I.V. administration and should be infused over at least 10-60 minutes.

Adults: Serious infections: 600mg-1.2g/day in two, three or four equal doses.

More severe infections: 1.2-2.7g/day in two, three or four equal doses.

Single I.M. injections of greater than 600mg are not recommended nor is administration of more than 1.2g 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 4.8g 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 I.V. infusion.

Children (over 1 month of age): Serious infections: 15-25mg/kg/day in three or four equal doses.

More severe infections: 25-40mg/kg/day in three or four equal doses. In severe infections it is recommended that children be given no less than 300mg/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. *See Precautions* for other factors which should be taken into consideration.

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

The concentration of clindamycin in diluent for infusion should not exceed 18mg per ml and **INFUSION RATES SHOULD NOT EXCEED 30MG PER MINUTE**. The usual infusion rates are as follows:

<u>Dose</u>	<u>Diluent</u>	<u>Time</u>
300mg	50ml	10 min
600mg	50ml	20 min
900mg	50-100ml	30 min
1200mg	100ml	40 min

STORAGE AND DISPOSAL OF CLINDAMYCIN 150MG/ML SOLUTION FOR INJECTION OR INFUSION

Unopened product: Do not store above 25°C. Keep ampoules in outer carton.

Injection:

The product should be used immediately after opening. Dispose of any remaining solution after a single use.

Infusion:

Shelf life

Unopened: 2 years

After dilution: 24 hours

Specific text for preparations for Infusion or Injection

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally be no longer than 24 hours at 2 to 8°C, unless reconstitution/dilution (etc) has taken place in controlled and validated aseptic conditions. The reconstitution/dilution should be made under aseptic conditions. The solution should be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

Solution for injection is for single use only. Any unused product should be discarded.

Each ml of solution contains 6.57mg (0.286mMol) of sodium, prior to dilution.

Clindamycin 150mg/ml Solution for Injection or Infusion has been shown to be physically and chemically compatible for at least 24 hours in dextrose 5% water and sodium chloride injection

solutions containing the following antibiotics in usually administered concentrations: Amikacin sulphate, aztreonam, ceftazidime sodium, ceftizoxime sodium, gentamicin sulphate, piperacillin and tobramycin. The compatibility and duration of stability of drug admixtures will vary depending upon concentration and other conditions.