P16898

PACKAGE LEAFLET: INFORMATION FOR THE USER

CLINDAMYCIN 150MG/ML SOLUTION FOR INJECTION OR INFUSION

(clindamycin)

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

In this leaflet:

1. What Clindamycin Injection is and what it is used for
2. Before you use Clindamycin Injection
3. How to use Clindamycin Injection
4. Possible side effects
5. How to store Clindamycin Injection
6. Further 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. Before you use Clindamycin Injection

Do not use Clindamycin Injection
- if you are allergic (hypersensitive) to clindamycin or lincomycin (another antibiotic) or any of the other ingredients of Clindamycin Injection (see section 6);
- if you have meningitis.

Tell your doctor or nurse if any of the following apply to you:
- if you have colitis (severe stomach cramps, diarrhoea). Clindamycin Injection may not be suitable for you;
- if you have ever had problems with your stomach or bowels;
- if you have any allergies such as hayfever, asthma or eczema;
- if you have problems with your kidneys;
- if you have problems with your liver.

Using other medicines
Make sure your doctor knows if you are taking any medicine listed here:
- **erythromycin** an antibiotic used to treat infection: Clindamycin Injection and erythromycin may not work as well when they are used together.
- **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.

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
- If you are pregnant, thinking of getting pregnant, or are breast-feeding, ask your doctor or nurse for advice before they give you Clindamycin Injection.

Important information about some of the other ingredients in Clindamycin Injection
- Your medicine contains **sodium (salt).** This medicinal product contains 0.286mMol (or 6.57mg) sodium per ml of solution (prior to dilution). To be taken into consideration by patients on a controlled sodium diet.

3. How to use Clindamycin Injection

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.

Adults and the 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.

Children (over 1 month old)
- The dose for children is based on your child's body weight.
- 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.

Your doctor will test **your blood** and check that your **liver and kidneys are working properly** if:
- you are given Clindamycin Injection for a long time;
- your baby is given Clindamycin Injection.

If you have problems with your liver and kidneys **your dose may be reduced.**

If you forget to use 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 too much Clindamycin Injection
If you think you have been given too much Clindamycin Injection tell a doctor or a nurse.
If you have any further questions on the use of this product, ask your doctor or nurse.

4. Possible side effects

Like all medicines, Clindamycin Injection can cause side effects, although not everybody gets them.

If you have any of the following side effects while taking your medicine **tell your doctor immediately. If you are not in hospital YOU MUST go straight away.**
These side effects are rare but very serious.

- **Severe allergic reaction** which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away.**
- **Symptoms of colitis** such as severe diarrhoea, severe stomach and abdominal cramps, blood in the faeces. This may occur many months after your treatment has been finished.
- **Severe skin reaction** for example, pinky-red spots or blotches with clear or violet coloured centres.
- **Heart attack** if your injection is given too quickly.

Other side effects which may occur
- nausea (feeling sick)
- vomiting
- stomach pain
- itchy or sore vagina; discharge from the vagina
- skin rash or itching or blistering of the skin
- jaundice (where your skin and whites of the eyes appear yellow)
- low blood pressure (you may feel faint or dizzy on standing)
- changes in your blood which may make you bruise or bleed more easily and make you more likely to get an infection

Effects which may occur at the site of injection
- itching
- pain
- abscesses
- swollen and painful veins.

If you need a **blood test** tell your doctor you are taking Clindamycin Injection because it may affect the results.

See section 2 of this leaflet for side effects that may be caused by **sodium**, one of the ingredients in your medicine ('Important information about some of the ingredients in Clindamycin Injection')

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or nurse.

5. How to store Clindamycin Injection

Keep out of the sight and reach of children.
Do not store above 25°C.
Keep ampoules in outer carton.

Do not use after the expiry date stated on the carton and ampoule. The expiry date refers to the last day of the month.
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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Clindamycin Injection contains
- The active substance is clindamycin Each ml contains 150mg clindamycin.
- The other ingredients are disodium edetate, sodium hydroxide and water for injections.

What Clindamycin solution for 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.
Your medicine is available in cartons containing 5 x 2ml ampoules or 5 x 4ml ampoules.

Manufacturer
Your ampoules are manufactured by: Vianex SA,
12th Km Athens Lamia National Road, Metamorfosi, Athens, Greece.

Procured from within the EU by the PPA holder: Imbat Ltd,
Unit L2, North Ring Business Park, Santry, Dublin 9.

Repackaged by: Doncaster Pharmaceuticals Group Ltd,
Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

PPA No: 1151/156/1

Leaflet revision & issue date (ref): 02.01.14

P16898

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.

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:

Dose	Diluent	Time
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 25ºC. 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 8ºC, 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.
Infusion: 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, cefoxitin sodium, 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.

P16898