

PACKAGE LEAFLET: INFORMATION FOR THE USER

Clindamycin 150 mg/ml Solution for Injection or Infusion
Clindamycin phosphate

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Clindamycin 150 mg/ml Solution for Injection or Infusion is and what it is used for
2. Before you take Clindamycin 150 mg/ml Solution for Injection or Infusion
3. How to take Clindamycin 150 mg/ml Solution for Injection or Infusion
4. Possible side effects
5. How to store Clindamycin 150 mg/ml Solution for Injection or Infusion
6. Further information

1. What Clindamycin 150 mg/ml Solution for Injection or Infusion is and what it is used for

This medicine contains clindamycin phosphate, which is an antibiotic. It is used to cause infections. Clindamycin is usually reserved for the treatment of serious infections, especially when other antibiotics have been unable to clear the infection and when the infection is caused by bacteria that are sensitive to clindamycin.

Therapeutic indications

Clindamycin is indicated for the treatment of:

- Intra-abdominal infections
- Skin and soft tissue infections
- Respiratory tract infections
- Pelvic inflammatory disease

2. Before you take Clindamycin 150 mg/ml Solution for Injection or Infusion

Do not take Clindamycin 150 mg/ml Solution for Injection or Infusion

- if you are allergic (hypersensitive) to the active substance (clindamycin) or to one of the ingredients of Clindamycin 150 mg/ml Solution for Injection or Infusion.

Take special care with Clindamycin 150 mg/ml Solution for Injection or Infusion

- if you have impaired hepatic (liver) and renal (kidney) function
- if you have disturbances in neuromuscular transmission (myasthenia gravis (muscle weakness), Parkinson's disease, etc)
- if you have a history of gastrointestinal disorders (e.g. earlier inflammations of the colon)
- if you have atopic (allergic) disease
- if diarrhoea is developed; it can be a symptom of colitis

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines,

In particular tell your doctor or pharmacist if you are taking:

- **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).

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.

Driving and using machines

Side effects like dizziness, sleepiness and headaches can constrict the ability to drive and use machines.

Important information about some of the ingredients of Clindamycin 150mg/ml Solution for Injection or Infusion

This medicinal product contains less than 1mmol sodium (23mg) per dose, i.e essentially “sodium free”..

3. How to take Clindamycin 150 mg/ml Solution for Injection or Infusion

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

- 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

Children (over 1 month of age up to 12 years):

- 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.

Your doctor will 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 150mg/mg Solution for Injection or Infusion can cause side effects, although not everybody gets them.

Very common: affecting more than 1 user in 10

- gastrointestinal disturbances occur in the form of nausea, vomiting, stomach pains or diarrhoea.

Common: affecting 1 to 10 users in 100

- mild, transient increase of the serum transaminases (in liver enzymes).
- intramuscular injection may be followed by local irritations, pain, indurations and sterile abscess at the injection site.

Uncommon: affecting 1 to 10 users in 1.000

-Symptoms of colitis such as severe diarrhoea, severe stomach and abdominal cramps, blood in the faeces.

Rare: affecting 1 to 10 users in 10.000

- instances of cardiopulmonary arrest and low blood pressure (hypotension) have been reported following too rapid intravenous administration.
- cutaneous inflammations.
- swellings, drug fever as well as skin redness (erythema exudativum multiforme) and toxic epidermal necrolysis.

Very rare: affecting less than 1 user in 10.000

- transient hepatitis with cholestatic jaundice
- polyarthritis

- severe acute allergic reactions such as anaphylactic shock.

Unknown: the frequency cannot be estimated from the available data
Taste and smell perversion, headaches, sleepiness, dizziness.

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet tell your doctor or pharmacist.

5. How to store Clindamycin 150 mg/ml Solution for Injection or Infusion

Keep out of the reach and sight of children

Store below 25°C
Store in the original package in order to protect from light.
Do not refrigerate or freeze

Do not use Clindamycin 150mg/ml Solution for Injection or Infusion after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not use Clindamycin 150mg/ml Solution for injection or Infusion if the solution is not clear.

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 150 mg/ml Solution for Injection or Infusion contains

The active substance of Clindamycin 150 mg/ml Solution for Injection or Infusion is clindamycin phosphate.

Each ml of solution contains clindamycin phosphate equivalent to 150mg of clindamycin.

The other ingredients are edetate disodium, sodium hydroxide (for pH adjustment) and sterilised water for injections.

What Clindamycin 150 mg/ml Solution for Injection or Infusion looks like and contents of the pack

Clindamycin 150 mg/ml Solution for injection or Infusion is a clear colourless solution in a clear ampoule.

Type I, clear glass ampoules

Pack sizes

2ml: carton box with 5 ampoules

4ml: carton box with 5 ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Fannin (UK) Ltd.

DCC Vital, Westminster Industrial Estate
Repton Road
Measham
DE12 7DT

England

Hikma Farmacêutica (Portugal), S.A.

Estrada do Rio da Mó, nº 8, 8A – 8B

Fervença

2705 – 906 Terrugem SNT

Portugal

Tel: +351 21 980 84 10

Fax: +351 21 961 51 02

e-mail: geral@hikma.pt

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland, UK: Clindamycin 150mg/ml Solution for injection or Infusion

This leaflet was last approved in March 2017

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

Under certain circumstances, clindamycin therapy may be an alternative form of treatment in patients with penicillin allergy (penicillin hypersensitivity). There have been no reports of a cross-allergy between clindamycin and penicillin and, based on the structural differences between the substances, this is not to be expected. However, in individual cases, information does not exist on anaphylaxis (hypersensitivity) towards clindamycin in persons with an already existing penicillin allergy. This should be taken into consideration in a course of clindamycin treatment in patients with a penicillin allergy.

Clindamycin should not be used in case of acute infections of the respiratory tract, if these are caused by viruses.

Clindamycin is not suitable for the treatment of meningitis, for the concentration of antibiotic obtained in the liquor cerebrospinalis is too little.

Instructions for use and handling

Dilution and infusion:

Clindamycin **must** be diluted prior to IV administration (not exceeding 12 mg clindamycin per ml) and should be infused over at least 10 – 40 minutes (nor exceeding 30mg/min). It can never be injected as an IV bolus.

<u>Dose</u>	<u>Diluent</u>	<u>Minimum infusion-time</u>
300 mg	50 ml	10 minutes
600 mg	50 ml	20 minutes
900 mg	100 ml	30 minutes
1200 mg	100 ml	40 minutes

Clindamycin may be diluted with 0.9% sodium chloride solution, 5% glucose solution or Ringer's lactate. Intramuscular administration is indicated when intravenous infusion is not possible for any reasons.

Dosage in presence of liver diseases

In patients with liver disease of moderate to severe degree, elimination half-life of clindamycin is prolonged. A reduction in dosage is generally not necessary if clindamycin is administered every 8

hours. However, the plasma concentration of clindamycin should be monitored in patients with severe hepatic insufficiency. Depending on the results, this measure can make a reduction in dosage or an increase in the dose intervals necessary.

Dosage in presence of kidney diseases

In the presence of kidney diseases, elimination half-life is prolonged; however, a dosage reduction is not necessary in the event of mild to moderate impairment of renal function. Nevertheless, the plasma concentration should be monitored in patients with severe renal insufficiency or anuria. Depending on the results, this measure can make a reduction in dosage or an increase in the dose interval of 8 or even 12 hours necessary.

Compatibility and stability:

Clindamycin should not be combined with erythromycin as, with regard to the antibacterial action, an antagonist effect has been observed *in vitro*.

There is cross-resistance between clindamycin and lincomycin.

Due to its neuromuscular-blocking properties, clindamycin can potentiate the effect of muscle relaxants.

The reliability of the contraceptive effect of oral contraceptives applied concomitantly with clindamycin is subject to question. Hence, during clindamycin therapy, other, non hormonal contraceptive measures should be taken in addition.

The following drugs are physically incompatible with clindamycin: ampicillin, phenytoin sodium, barbiturates, aminophylline, calcium gluconate, ciprofloxacin, magnesium sulphate, ceftriaxone sodium, diphenylhydantoin, idarubicin hydrochloride. Solutions of clindamycin salts have a low pH and incompatibility may reasonably be expected with alkaline preparations or with drugs unstable at low pH.

After dilution:

Chemical and physical in-use stability has been demonstrated for 48 hours at 25°C with 0.9% sodium chloride solution, 5% glucose solution or Ringer's lactate solutions.