

**Clindamycin Injection USP 300mg/2ml,
600mg/4ml, 900mg/6ml**

PATIENT INFORMATION LEAFLET

Clindamycin injection USP Sterile Solution 150 mg/ml

Clindamycin Phosphate

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 your pharmacist.

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 your pharmacist.

In this leaflet:

1. What Clindamycin Solution is and what it is used for
2. Before you are given Clindamycin Solution
3. How Clindamycin Solution is given to you
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1. What Clindamycin Solution is and what it is used for

Clindamycin Solution is a sterile solution for injection into a vein (intravenously) or into a muscle (intramuscularly). The

solution contains clindamycin phosphate which is an antibiotic used in the treatment of serious bacterial infections.

2. Before you are given Clindamycin Solution

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

In premature babies or neonates.

Take special care with Clindamycin Solution

Before you are given this medicine make sure that your doctor knows 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 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 hayfever.

Clindamycin 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.

Taking other medicines

Some medicines can affect the way Clindamycin Solution works, or Clindamycin itself can reduce the effectiveness of other medicines taken at the same time. These include:

muscle relaxants used during operations.

oral contraceptive pills. You should use extra contraception such as condoms whilst receiving Clindamycin and for seven days after receiving Clindamycin .

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.

Please tell your doctor if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

Pregnancy

If you are pregnant or think you might be pregnant you should contact your doctor before being given Clindamycin Solution.

Breast-feeding

Do not breastfeed while taking Clindamycin .

Driving and using machines

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

Important information about some of the ingredients of Clindamycin Solution

Clindamycin Solution contains benzyl alcohol (9.45 mg/ml as preservative) and must not be given to premature babies or babies less than one month old. It may cause allergy and toxic reactions and has caused serious side effects in the brain, heart, blood, and breathing rate in children, which have been fatal in some cases.

3. How Clindamycin Solution is given to you

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 , 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 Dalacin is given too fast it could rarely cause a heart attack.

Adults/Elderly

The recommended dose of Clindamycin Solution is 600 to 2700 mg clindamycin per day in two to 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 15 to 40 mg 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 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 treatment.

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

Possible side effects

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

signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, 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 blisters and peeling 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**)

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)

Common side effects, (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

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*)

itchy skin

hives

pain, abscess (boil)

Frequency not known (cannot be estimated from available data):

an increase in the number of white blood cells (eosinophilia)

stomach pain, being sick (throwing up)

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.

5. How to store Clindamycin Solution

Keep out of the reach and sight of children.

Clindamycin Solution will not be used after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

This medicine will not be stored above 25°C.

This medicine will not be refrigerated or frozen.

Further information

What Clindamycin Solution contains

The active substance is clindamycin phosphate. Each ml of solution contains clindamycin phosphate equivalent to 150 mg of clindamycin.

The other ingredients are benzyl alcohol, disodium edetate and sterilised water for injections

6. What Clindamycin Solution looks like and contents of the pack

Clindamycin Solution is a clear, colourless solution. It is supplied in glass ampoules containing either 2 ml or 4 ml of

solution. Each ampoule is packed in a cardboard carton with a leaflet.

7.Manufactured in India by: TAJ PHARMACEUTICALS LTD.

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