

PART III: PATIENT MEDICATION INFORMATION

**PrClindamycin IV Infusion
(clindamycin phosphate)
Sterile solution**

Read this carefully before you start taking Clindamycin IV Infusion and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Contact your doctor or pharmacist if you have any questions about the drug.

Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Clindamycin IV Infusion.

Antibacterial drugs like Clindamycin IV Infusion treat only bacterial infections. They do not treat viral infections such as the common cold. Although you may feel better early in treatment, Clindamycin IV Infusion should be taken exactly as directed. Misuse or overuse of Clindamycin IV Infusion could lead to the growth of bacteria that will not be killed by Clindamycin IV Infusion. This means that Clindamycin IV Infusion may not work for you in the future.

What Clindamycin IV Infusion is used for?

Clindamycin IV Infusion is used for the treatment of serious bacterial infections

How does Clindamycin IV Infusion work?

Clindamycin IV Infusion reduces the production of key proteins in germs. This prevents growth in germs and reduces the infection.

What are the ingredients in Clindamycin IV Infusion?

Medicinal ingredients: Clindamycin phosphate

Nonmedicinal ingredients: Dextrose monohydrate, disodium edetate dehydrated and water for injection. It may also contain hydrochloric acid and/or sodium hydroxide for pH adjustment.

Clindamycin IV Infusion comes in the following dosage forms:

Clindamycin IV Infusion is available in ready-to-use 50 mL minibags containing clindamycin premixed with 5% dextrose w/v as a sterile solution.

Each 100 mL minibag (filled with 50 mL) contains clindamycin phosphate equivalent to 300 mg, 600 mg or 900 mg clindamycin. The single dose minibags are available as follows:

- 300 mg/50 mL, Box of 10 minibags
- 600 mg/50 mL, Box of 10 minibags
- 900 mg/50 mL, Box of 10 minibags

Clindamycin IV Infusion is for intravenous infusion only.

Do not use Clindamycin IV Infusion if:

You are allergic (hypersensitive) to:

- Clindamycin

- Lincomycin
- Other ingredients in the product (see list of nonmedicinal ingredients).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Clindamycin IV Infusion. Talk about any health conditions or problems you may have, including if you:

- have had intestinal disorders such as:
 - colitis (inflammation of the colon)
 - inflammatory bowel disease
- have diarrhea or get diarrhea when you take antibiotics
- suffer from problems with your stomach or intestines (e.g. bowel disease, colitis).
- suffer from problems with your kidneys or liver.
- are pregnant or planning to become pregnant. Clindamycin passes to the human fetus
- are breastfeeding or planning to breastfeed. Clindamycin is passed to the infant through human breast milk. Because of the potential for serious adverse reactions in nursing infants, clindamycin should not be administered to nursing mothers.
- you have glucose-6-phosphate dehydrogenase (G-6-PD) deficiency and are taking primaquine. You may need to have routine blood tests while taking Clindamycin IV Infusion with primaquine, to monitor for potential blood cell changes.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Clindamycin IV Infusion:

- erythromycin (an antibiotic)
- muscle relaxants used during operations
- primaquine (antimalarial)
- Aminoglycosides (a class of antibiotics)
- St-John's Wort (*Hypericum perforatum*)

How to take Clindamycin IV Infusion:

The health care professional will administer Clindamycin IV Infusion and will:

- Decide:
 - the dose and rate of administration of the medicine
- Ensure that:
 - the medicine will be given as an injection (infusion) through the vein
 - the medicine will be given for the full treatment period
 - the medicine will be inspected to determine there is:
 - no discolouration
 - no leaks
 - no solid particles floating in solution
 - no haziness in the solution

Usual dose:

Your doctor will determine the dose and for how long you should receive it.

Long term use of Clindamycin IV Infusion:

- If you have to use clindamycin for a long time, your doctor may arrange regular liver, kidney and blood tests.
- Do not miss these check-ups with your doctor.
- Long term use can also make you more likely to get other infections that do not respond to clindamycin treatment.

This particular product format in minibags is not suitable for use in children 12 years of age and under.

Overdose:

If you think you have taken too much Clindamycin IV Infusion, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Your healthcare professional will ensure that this product is administered each day and doses are not missed, as it works best when there is a constant amount in the body. If the medicine is stopped too soon, your symptoms may return. If you feel a dose has been missed contact your healthcare professional.

Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by clindamycin phosphate or other antibacterial drugs in the future.

What are possible side effects from using Clindamycin IV Infusion?

These are not all the possible side effects you may feel when taking Clindamycin IV Infusion. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

Clindamycin IV Infusion can cause side effects such as:

- skin reddening, rash, itching, hives
- throat ulcers, sore throat
- feeling sick, being sick
- stomach pain and diarrhea
- injection site irritation
- thrombophlebitis (inflammation of the vein due to blood clot)
- low red blood cells (anemia) with symptoms such as bruising or bleeding
- low white blood cells (neutropenia) which can lead to an increased chance of infections
- vaginal infection or vaginitis (inflamed vagina)

Contact your doctor immediately if the following happens:

- you have symptoms 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)
- blistering and peeling of large areas of skin
- fever
- cough
- feeling unwell
- swelling of the gums, tongue or lips
- you have symptoms of liver problems such as:
 - yellowing of the skin and whites of the eyes (jaundice).
- you have symptoms of *Clostridium difficile* colitis (bowel inflammation) such as:
 - severe, persistent, watery or bloody diarrhea with or without
 - fever
 - abdominal pain or tenderness

This may happen months after the last dose of medication. If this occurs, stop taking and contact your doctor right away.

Serious side effects and what to do about them			
Symptom/effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Liver problems with symptoms such a yellowing skin or eyes, abdominal pain, nausea, vomiting		√	√
COMMON Diarrhea Rash		√ √	
RARE Skin reactions: itching	√		
NOT KNOWN <i>Clostridium difficile</i> associated disease (bowel inflammation), with symptoms such as persistent or severe diarrhea, abdominal pain, nausea and vomiting			√
Injection site reactions with symptoms as pain, redness and skin irritation	√		
Serious allergic (hypersensitivity) reaction with symptoms such as swelling of eyes, mouth, throat, difficulty breathing, blistering or peeling skin, rash, itching			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your health care professional.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 1908C
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

The healthcare professional will store Clindamycin IV Infusion minibags under appropriate conditions (15°C to 25°C).

If you want more information about Clindamycin IV

Infusion:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); or by calling Sandoz Canada Inc. at: 1-800-361-3062

or by written request at:
145 Jules-Léger
Boucherville QC
J4B 7K8

or by e-mail at:
medinfo@sandoz.com

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