

PART III: CONSUMER INFORMATION

PrCLINDAMYCINE – 150

PrCLINDAMYCINE – 300

(Clindamycin Hydrochloride Capsules USP)**Clindamycin 150 mg and 300 mg****Antibiotic**

This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CLINDAMYCINE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

CLINDAMYCINE is used for:

- the treatment of serious bacterial infections; and
- the prevention of serious bacterial infections in patients undergoing surgery .

What it does:

Clindamycin interferes with protein synthesis in bacteria, thereby preventing growth and killing the bacteria causing your infection.

When it should not be used:

Do not use CLINDAMYCINE if:

- You have a history of hypersensitivity (allergies) to preparations including clindamycin or lincomycin or to any ingredient in the formulation or component of the container (see what the non-medicinal ingredients are).

What the medicinal ingredient is:

Clindamycin hydrochloride USP

What the non-medicinal ingredients are:

Stearic acid, talc; capsule shell: gelatin, titanium dioxide and FD&C Blue #1(150 mg and 300 mg) FD&C Red #40, D&C Red #33, D&C Red #28, and FD&C Yellow #5 (150 mg).

The edible ink on the capsule shell contains the non-medicinal ingredients: shellac glaze-45% (20% esterified), titanium dioxide, ammonium hydroxide 28%, propylene glycol and simethicone.

What dosage forms it comes in:

150 mg and 300 mg capsules

WARNING AND PRECAUTIONS

BEFORE you use CLINDAMYCINE talk to your doctor or pharmacist if:

- You have a history of intestinal disorders such as colitis (inflammation of the colon), or inflammatory bowel disease.
- You have diarrhea or usually get diarrhea when you take antibiotics or have ever suffered from problems with your stomach or intestines (e.g. bowel disease, colitis).
- You suffer from problems with your kidneys or liver.
- You have glucose-6-phosphate dehydrogenase (G-6-PD) deficiency and taking primaquine. You need to have routine blood tests while taking CLINDAMYCINE with primaquine to monitor for potential blood cell changes.
- You are pregnant or planning to become pregnant. Clindamycin passes to the human fetus.
- You 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 taken by nursing mothers

INTERACTIONS WITH THIS MEDICATION**Drugs that may interact with CLINDAMYCINE include:**

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

- Erythromycin (an antibiotic).
- Muscle relaxants used for operations.
- Aminoglycosides (a class of antibiotics)
- Primaquine (antimalarial)
- St. John's wort

Tell your doctor if you are taking or being administered any other topical or oral medication, including erythromycin or neuromuscular blocking agents.

PROPER USE OF THIS MEDICATION

Your doctor will assess for your child's ability to swallow CLINDAMYCINE capsules. If the child is unable to reliably swallow a capsule, CLINDAMYCINE capsule should not be used. Your doctor will recommend a suitable dosage form for your child.

Take your medicine (or give the medicine to your child) as your doctor has told you. If you are not sure, ask your doctor or pharmacist.

Treatment of infection:**Adults Dose:**

150 mg to 450 mg by mouth every 6 hours depending on the severity of infection.

Child dose (for children weighing ≥ 40 pounds (18.2 Kg) and able to swallow):

IMPORTANT: PLEASE READ

One of the following dosage ranges should be selected depending on the severity of the infection:

- 8-12 mg/kg/day (4-6 mg/lb/day)
- 13-16 mg/kg/day (6.5-8.0 mg/lb/day)
- 17-25 mg/kg/day (8.5-12.5 mg/lb/day)

Severity of the infection	Mild	Moderate	Severe
Weight in pounds (weight in Kg)	4-6 mg/lb/day (8-12 mg/kg/day)	6.5-8.0 mg/lb/day (13-16 mg/kg/day)	8.5-12.5 mg/lb/day (17-25 mg/kg/day)
22-40 (10-18.2 Kg)	*	*	*
>40-55 (>18.2-25 Kg)	*	*	150 mg q. 8h.
>55-75 (>25-34 Kg)	*	150 mg q. 8h.	150 mg q. 6h.
>75-100 (>34-45.5 Kg)	150 mg q. 8h.	150 mg q. 6h	300 mg q. 8h
>100 (>45.5 Kg) use adult dosage	150 mg q. 6h.	300 mg q. 6h	450 mg q. 6h

* Other appropriate dosage forms may be used.

Keep taking this medicine for the full time of treatment, even if you (or your child) begin to feel better after a few days.

Prevention of infection (patients undergoing surgery):

Adult dose:

300 mg by mouth at 1 hour before procedure; then 150 mg at 6 hours after the first dose.

Child dose (for children weighing \geq 40 pounds (18.2 Kg) and able to swallow):

Refer to other dosage form, because the capsules may not be suitable. Use of the appropriate dosage form may be necessary.

The capsules should be taken with a full glass of water to avoid throat irritation. The capsules can be taken with or without food.

Long term use of CLINDAMYCINE

If you have to take CLINDAMYCINE 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 CLINDAMYCINE treatment.

Taking CLINDAMYCINE with primaquine

Patients with G-6-PD deficiency taking the combination of clindamycin and primaquine should have routine blood examinations during therapy with primaquine to monitor for potential blood cell changes.

Taking CLINDAMYCINE with food and drink

The capsules may be taken either before or after a meal.

REMEMBER: This medication is for YOU. Never give it to others. It may harm them even if their symptoms are the same as yours.

Overdose:

In case of drug overdose, contact your doctor, hospital emergency department or regional Poison Centre immediately, even if there are no symptoms.

Missed Dose:

If you missed a dose of this medication, take it as soon as you remember. This will help to keep a constant amount of medication in your blood. But, if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time.

If you stop taking CLINDAMYCINE

If you stop taking the medicine too soon your infection may come back again or get worse.

Do not stop taking CLINDAMYCINE unless your doctor tells you to. If you have any further questions on how to take this product, ask your doctor or pharmacist.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, CLINDAMYCINE can cause side effects, these include:

- Reddening of the skin, skin rash, itching, hives
- Throat ulcers, sore throat, feeling sick, being sick, stomach pain and diarrhea

IMPORTANT: PLEASE READ

- Reduced numbers of blood cells which may cause bruising or bleeding or weaken the immune system
- Vaginal infection of vaginitis (inflammation of the vagina)

Tell your doctor immediately if you develop:

- 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).
- Blistering and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips.
- Liver problem, yellowing of the skin and whites of the eyes (jaundice).
- Severe or persistent diarrhea (watery or bloody) with or without abdominal pain, nausea, fever or vomiting.

These may be symptoms of Clostridium difficile associated disease (bowel inflammation). This may happen months after the last dose of medication. If this occurs, stop taking **CLINDAMYCINE** and contact your doctor immediately.

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 pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking CLINDAMYCINE, contact your doctor or pharmacist.

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 Problem		√	√
COMMON Diarrhea Rash		√ √	

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	
RARE Nausea, abdominal pain Vomiting Skin reactions : itching	√	√ √	
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)			√

HOW TO STORE IT

Keep in a safe place out of the reach and sight of children. Store at room temperature (15°C to 30°C), away from heat and direct light.

Do not store in the fridge or freezer.

Do not store in the bathroom as moisture and heat can cause damage.

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 0701E
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.

MORE INFORMATION

For more information, please contact your doctor, pharmacist or other healthcare professional.

This leaflet plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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