PATIENT INFORMATION LEAFLET

FOR CLINDAMYCIN CIPLA

SCHEDULING STATUS: **S4**

Clindamycin Cipla 150 mg capsules

Clindamycin Hydrochloride

Contains sugar (lactose monohydrate): 214,08 mg per capsule.

Read all of this leaflet carefully before you start taking CLINDAMYCIN CIPLA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- CLINDAMYCIN CIPLA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What CLINDAMYCIN CIPLA is and what it is used for

2. What you need to know before you take CLINDAMYCIN CIPLA

3. How to take CLINDAMYCIN CIPLA

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1. What CLINDAMYCIN CIPLA is and what it is used for

CLINDAMYCIN CIPLA contains the active ingredient clindamycin hydrochloride which belongs to a class of medicines called antibiotics. CLINDAMYCIN CIPLA is used to treat serious infections caused by certain organisms sensitive to it.

2. What you need to know before you take CLINDAMYCIN CIPLA

Do not take CLINDAMYCIN CIPLA:

- If you are hypersensitive (allergic) to clindamycin, lincomycin, doxorubicin or any of the other ingredients of CLINDAMYCIN CIPLA (listed in **section 6**);
- if you have a gastro-intestinal disease (disease of the digestive tract) or you are suffering with diarrhoea;
- if you are pregnant or planning on becoming pregnant; or
- if you are breastfeeding your baby.

Warnings and precautions

Take special care with CLINDAMYCIN CIPLA:

- Treatment with CLINDAMYCIN CIPLA has been associated with colitis. Colitis is inflammation of the inner lining of the colon and is associated with diarrhoea, severe stomach cramps, fever and blood or mucus in the stool. If you experience any of these symptoms please contact your doctor immediately and stop taking CLINDAMYCIN CIPLA.
- CLINDAMYCIN CIPLA cannot penetrate the brain and is therefore not suitable for treating serious infections in and around the brain such as meningitis (inflammation of the membranes that cover the brain and spinal cord).
- If you have a history of gastrointestinal disease (disease of the digestive tract), particularly colitis. You should not take CLINDAMYCIN CIPLA (see "**Do not take CLINDAMYCIN CIPLA**").
- If you are taking or need to take CLINDAMYCIN CIPLA for a long period of time, you must go for regular liver and kidney function tests.
- If you develop an additional infection while taking CLINDAMYCIN CIPLA please contact your doctor immediately.
- If you suffer from allergies, you should take CLINDAMYCIN CIPLA with caution and report skin reactions and other allergic reactions to your doctor.

Other medicines and CLINDAMYCIN CIPLA

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines can affect the way CLINDAMYCIN CIPLA works, or the medicine itself can reduce the effectiveness of other medicines taken at the same time. This includes:

• The contraceptive pill. CLINDAMYCIN CIPLA may reduce the contraceptive effect of oestrogen in the contraceptive pill. If you are using the contraceptive pill, use extra contraception such as condoms or a diaphragm while you are taking CLINDAMYCIN CIPLA and for at least 7 days afterwards.

• If you have used antibiotics such as lincomycin and clindamycin previously, and they did not work, then CLINDAMYCIN CIPLA may not work either.

• Erythromycin, streptogramins, linezolid, chloramphenicol and streptomycin (antibiotics used to treat infections). CLINDAMYCIN CIPLA may reduce the effects of these medicines.

• Muscle relaxant medicines. CLINDAMYCIN CIPLA may enhance the effect of these medicines, with a potential danger for respiratory depression.

• Neostigmine and pyridostigmine (used to treat myasthenia gravis – a condition marked by muscular weakness). CLINDAMYCIN CIPLA may reduce the effect of these medicines.

• If you are about to receive or have received oral typhoid vaccine recently, you should not take CLINDAMYCIN CIPLA for 3 days before and after receiving oral typhoid vaccine. CLINDAMYCIN CIPLA will inactivate the vaccine.

• Medicines used to prevent blood clotting such as warfarin (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.

• Rifampicin (used to treat tuberculosis) or other medicines that affect some liver enzymes, called CYP3A4 or CYP3A5 inducers, may reduce the effectiveness of CLINDAMYCIN CIPLA.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Do not use CLINDAMYCIN CIPLA if you are pregnant or planning on becoming pregnant without first discussing with your doctor. You should not breastfeed your baby while taking CLINDAMYCIN CIPLA.

Driving and using machines

You should take care when driving or using machinery until it is known how CLINDAMYCIN CIPLA affects you.

CLINDAMYCIN CIPLA contains lactose monohydrate (milk sugar)

If you know or you have been told by your doctor that you cannot tolerate lactose, you should not take CLINDAMYCIN CIPLA.

3. How to take CLINDAMYCIN CIPLA

Do not share medicines prescribed for you with any other person.

Always take CLINDAMYCIN CIPLA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose for adults is 150 mg (1 capsule) approximately every six hours.

CLINDAMYCIN CIPLA should be taken with a full glass of water to avoid the possibility of oesophageal irritation.

Your doctor will tell you how long your treatment with CLINDAMYCIN CIPLA will last.

Do not stop treatment early even if you feel better as completing the course of treatment will more likely ensure that the infection is completely treated.

Remember to take CLINDAMYCIN CIPLA at the same time each day.

Unnecessary or overuse of CLINDAMYCIN CIPLA can lead to decreased effectiveness

If you have the impression that the effect of CLINDAMYCIN CIPLA is too strong or too weak, tell your doctor or pharmacist.

If you take more CLINDAMYCIN CIPLA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the rest of the remaining CLINDAMYCIN CIPLA with you so the doctor will know what you have taken.

If you take too much CLINDAMYCIN CIPLA you may experience gastro-intestinal side effects such as severe abdominal cramps or diarrhoea.

If you forget to take CLINDAMYCIN CIPLA

It is important to take each dose at a scheduled time.

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Then continue with your normal schedule.

Do not take a double dose to make up for forgotten dose individual doses

If you have missed several doses, consult your doctor.

If you stop taking CLINDAMYCIN CIPLA

Do not stop treatment early even if you feel better as completing the course of treatment will more likely ensure that the infection is completely treated.

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

Do not stop taking CLINDAMYCIN CIPLA unless your doctor tells you to.

4. Possible side effects

CLINDAMYCIN CIPLA can have side effects.

Not all side effects reported for CLINDAMYCIN CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLINDAMYCIN CIPLA, please consult your healthcare provider for advice.

If any of the following happens, stop taking CLINDAMYCIN CIPLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- skin rash, lesions, itchiness of the skin, blistering or peeling of the skin or any other type of skin irritation; or
- chest tightness, difficulty breathing, feeling dizzy or fainting due to low blood pressure.

These are all very serious side effects. If you have them, you may have had an allergic reaction to CLINDAMYCIN CIPLA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Severe, persistent or bloody diarrhoea that may be accompanied by stomach pain/cramps, nausea, vomiting and inflammation in your throat;
- jaundice (yellowing of the skin or the white part of your eye);
- signs of recurrent infections such as fever;
- prolonged bleeding after injury, bruising easily.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Abnormalities in the results of liver tests;
- diarrhoea, abdominal discomfort/pain, nausea, vomiting;
- inflammation of the gullet (oesophagus);

- pseudomembranous colitis (swelling or inflammation of the large intestine (colon) due to an overgrowth of Clostridium difficile (C difficile) bacteria. This infection is a common cause of diarrhoea after antibiotic use;
- red measles-like rash (rash morbilliform).

Less frequent side effects

- Ulcer of the gullet (oesophagus);
- maculopapular rash (flat, red area on the skin that is covered with small bumps);
- urticaria (hives).

Frequency unknown side effects

- Vaginitis (inflammation of the vagina);
- *Clostridium difficile* infection;
- abnormal blood results such as decreased number of white blood cells; increased number of eosinophils; low levels of platelets;
- taste disturbance;
- itchiness, fever and small pimples, scaling of the skin, blistering, redness of your skin, flu-like symptoms;
- joint pain in five or more joints (polyarthritis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of CLINDAMYCIN CIPLA.

5. How to store CLINDAMYCIN CIPLA

Store all medicines out of reach of children.

Store at or below 25 °C in a cool, dry place.

Store in the original packaging in order to protect from light and moisture.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the carton and blister strip.

Do not use CLINDAMYCIN CIPLA if you notice visible signs of deterioration.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLINDAMYCIN CIPLA contains

The active substance is clindamycin hydrochloride.

Each capsule contains clindamycin hydrochloride equivalent to 150 mg clindamycin.

The other ingredients are lactose monohydrate, maize starch, talc, vegetable magnesium stearate.

The capsule shell is made up of titanium dioxide (E171) and gelatine.

The printing ink is made of shellac, iron oxide black (E172), propylene glycol (E1520), ammonium hydroxide (E527).

What CLINDAMYCIN CIPLA looks like and contents of the pack

Capsules.

Size 1 hard gelatine white-white capsules, with marking “CLIN 150”, filled with white crystalline powder.

Aluminium-PVC blister strips containing 20, 24 or 100 capsules.

Not all pack sizes may be marketed.

The Aluminium-PVC blisters are contained in an outer cardboard carton.

Not all pack sizes may be available.

Holder of certificate of registration

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