PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

CLINDAHEXAL 150 (capsules)

Clindamycin

Each CLINDAHEXAL 150 mg capsule contains sugar (78,80 mg lactose monohydrate).

Read all of this leaflet carefully before you start taking CLINDAHEXAL:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- CLINDAHEXAL capsules have 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 CLINDAHEXAL is and what it is used for
2. What you need to know before you take CLINDAHEXAL
3. How to take CLINDAHEXAL
4. Possible side effects
5. How to store CLINDAHEXAL
6. Contents of the pack and other information

1. What CLINDAHEXAL is and what it is used for

CLINDAHEXAL capsules belong to a group of medicines called antibiotics and are used in the treatment of serious bacterial infections.

- Infections of the upper and lower respiratory tract (sore throat and discomfort when swallowing, feeling of tension or fullness in the nose, infection of the middle ear, which may cause temporary hearing loss and pain, serious lung infection with fever, chills, shortness of breath and cough, phlegm and occasionally blood, inflammation of the tonsils and inflammation of the mucous membrane in the bronchial tubes).
- Infections of the skin and soft tissue (abscesses, feeling hot, tender, and red skin sometimes with fever and chills, infected wounds) and dental infections (infection of the root canal of the tooth, and inflammation of the gums).

2. What you need to know before you take CLINDAHEXAL

Do not take CLINDAHEXAL:

- If you are hypersensitive (allergic) to clindamycin, lincomycin or any of the other ingredients of CLINDAHEXAL capsules (listed in section 6).
- If you are pregnant, plan to become pregnant or breastfeeding your baby.
- Do not give CLINDAHEXAL to infants below 30 days of age.

Warnings and precautions

Take special care with CLINDAHEXAL:

- If you have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhoea during or after using CLINDAHEXAL capsules 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.
- If you suffer from problems with your kidneys or liver.
- If you are allergic to penicillin, because anaphylaxis has been observed after clindamycin treatment of patients with existing penicillin allergy.

- CLINDAHEXAL 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.
- If you develop any severe skin reactions or hypersensitivity to CLINDAHEXAL.
- If you have a history of gastro-intestinal disease (conditions affecting the digestive system).
- If you suffer from porphyria.
- Acute kidney disorders may occur. Please inform your doctor about any medication you currently take and if you have any existing problems with your kidneys. If you experience decreased urine output, fluid retention causing swelling in your legs, ankles or feet, shortness of breath, or nausea you should contact your doctor immediately.

Children and adolescents

CLINDAHEXAL is not indicated for use in infants below 30 days of age.

Other medicines and CLINDAHEXAL

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

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

- Muscle relaxants used during operations or hospital procedures (neuromuscular blockers).
- Erythromycin (an antibiotic).
- Medicines that prevent blood-clotting (warfarin or similar medicines).
- CYP3A4 or CYP3A5 inducers like rifampicin (used for the treatment of TB) may impact the effectiveness of CLINDAHEXAL.

CLINDAHEXAL with food, drink and alcohol

CLINDAHEXAL capsules should be taken with meals. If CLINDAHEXAL is taken between meals, it should be taken with a full glass of water.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking this medicine.

CLINDAHEXAL should be used in pregnancy only if clearly needed.

CLINDAHEXAL should not be taken if you are breastfeeding as the active substance in this medicine may be passed into breast milk.

Driving and using machines

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

CLINDAHEXAL contains lactose

CLINDAHEXAL capsules contains an ingredient called lactose (milk sugar). Patients with rare hereditary conditions of lactose/fructose or galactose intolerance should not take CLINDAHEXAL capsules.

CLINDAHEXAL capsules contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to take CLINDAHEXAL

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

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

The usual dose for adults is:

- for mild to moderately severe infection: 150 mg every six hours.
- for severe infections: 300 mg to 450 mg every six hours.

If you have the impression that the effect of CLINDAHEXAL capsules are too strong or too weak, tell your doctor or pharmacist.

If you take more CLINDAHEXAL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take CLINDAHEXAL

Do not take a double dose to make up for the forgotten individual doses. Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next capsule at the usual time. Then keep taking the medicine as your doctor has told you.

If you stop taking CLINDAHEXAL

Your doctor will tell you how long your treatment with CLINDAHEXAL capsules will last. Do not stop treatment early, because the infection you are being treated for may come back again or get worse.

4. Possible side effects

CLINDAHEXAL capsules can have side effects.

Not all side effects reported for CLINDAHEXAL capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CLINDAHEXAL capsules, please consult your doctor, pharmacist or other health care provider for advice.

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

- Signs of severe allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eye lids, face or lips, rash or itching (especially affecting the whole body).

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

Tell your doctor immediately if you notice any of the following:

- Severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This may occur with some antibiotics and can be a sign of a serious bowel inflammation.
- Serious skin reactions:
    - 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 rash with small puss-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 CLINDAHEXAL.

- A rare skin eruption that is characterised by the rapid appearance of areas of red skin studded with small blisters filled with white/yellow fluid (Acute Generalised Exanthematous Pustulosis (AGEP)).
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.
- Acute Kidney Injury.

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

Frequent side effects:

- Stomach pain.
- Diarrhoea.
- Inflammation of the lining of the intestine (pseudomembranous colitis).
- Liver function shown by blood tests test may be affected.

Less frequent side effects:

- Nausea and/or vomiting.
- Rash characterised by a flat, red area on the skin that is covered with small bumps (rash maculopapular).

The frequency of the following side effects are unknown:

- Infection inside and around the vagina.
- Decrease in the number of blood cells which may cause bruising or bleeding or weaken the immune system (agranulocytosis).
- Decrease in the number of white blood cells (leukopenia, neutropenia) (seen in a blood test).
- Decrease in the number of blood platelets (thrombocytopenia) (seen in a blood test).
- Increase in the number of white blood cells (eosinophilia) (seen in a blood test).
- Severe allergic reactions which can be life-threatening.

- Impaired sense of taste.
- Inflammation or ulcers in the oesophagus (tube leading from the mouth to the stomach).
- Widespread rash with red flat spots that look like measles (rash morbilliform).
- 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).
- Itching.

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 "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of CLINDAHEXAL.

Suspected side effects can also be reported directly to the HCR via Patientsafety.sacg@novartis.com.

5. How to store CLINDAHEXAL

- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- Store at or below 25 °C.
- Do not use the capsules after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CLINDAHEXAL contains

The active substance is clindamycin hydrochloride equivalent to clindamycin base.

Each CLINDAHEXAL 150 capsule contains 150 mg of clindamycin base.

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

The hard gelatine capsules are composed of: Black iron oxide (E172), gelatine, red iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172).

What CLINDAHEXAL looks like and contents of the pack

Opaque brown/red-brown hard gelatine capsules, size 1, filled with homogenous powder.

CLINDAHEXAL is packed in white opaque PVC/Aluminium blisters containing 10 capsules each. 2 (10) blister strips to be packed into a carton i.e. 20 capsules per carton or 10 (10) blister strips to be packed into a carton i.e. 100 capsules per carton, or in white polypropylene securitainers containing 20 or 100 capsules.

Not all packs may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

Not applicable.

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