PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

DALACIN® C 150 mg capsules

Clindamycin hydrochloride

Contains sugar

Each capsule contains approximately 209,5 mg lactose monohydrate

Read all of this leaflet carefully before you start taking DALACIN C

- 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.
- DALACIN C 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 DALACIN C is and what it is used for
2. What you need to know before you take DALACIN C
3. How to take DALACIN C
4. Possible side effects
5. How to store DALACIN C
6. Contents of the pack and other information

1. What DALACIN C is and what it is used for

DALACIN C contains clindamycin hydrochloride which is an antibiotic used in the treatment of serious bacterial infections.

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2. What you need to know before you take DALACIN C

Do not take DALACIN C:

- if you are hypersensitive (allergic) to clindamycin, lincomycin, doxorubicin or any of the other ingredients of DALACIN C (listed in section 6).
- if you have diarrhoea or a history of problems with your stomach or intestines.
- if you are pregnant or are planning to have a baby.
- if you are breastfeeding your baby.

Talk to your doctor or health care provider immediately if any of the above applies to you.

Warnings and precautions

Talk to your doctor or health care provider if:

- you are pregnant or are planning to have a baby.
- you develop any severe skin reactions or hypersensitivity while taking DALACIN C.
- 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 DALACIN C **tell your doctor immediately** since it may be necessary to interrupt or change your treatment. This may be a sign of bowel inflammation or infection (*pseudomembranous colitis* or *clostridium difficile* colitis) which can occur during or after treatment with antibiotics.
- you suffer from asthma, eczema or hayfever.
- you suffer from problems with your kidneys or liver.

DALACIN C 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.

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Acute kidney disorders may occur. Please inform your health care provider about any medicine 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 health care provider immediately.

Long term use of DALACIN C

Long term use can make you more likely to get other infections that do not respond to DALACIN C treatment.

Children

DALACIN C should only be used for children who are able to swallow capsules. Do not give DALACIN C capsules to children weighing less than 10 kg. The use of whole capsules may not be suitable to provide the exact mg/kg doses required for the treatment of children.

Other medicines and DALACIN C

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

If you are having a surgical procedure, tell your doctor and/or anaesthetist that you are using DALACIN C before receiving any medicines that cause paralysis of muscle (neuromuscular blocking medicines).

If you are taking strong CYP3A4 or CYP3A5 inducers like rifampicin (used to treat tuberculosis (TB)), the effectiveness of DALACIN C may be reduced.

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 health care provider for advice before taking this medicine.

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Do not take DALACIN C during pregnancy.

Do not breastfeed your baby while using DALACIN C. The active substance in this medicine may be passed into breast milk.

Driving and using machines

The effect of DALACIN C on the ability to drive or use machines has not been evaluated.

It is not always possible to predict to what extent DALACIN C may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DALACIN C affects them.

DALACIN C contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take DALACIN C

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

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

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

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Your doctor will tell you how long your or your child's treatment with DALACIN C will last. Do not stop treatment early, even if you start to feel better. If you have the impression that the effect of DALACIN C is too strong or too weak, tell your doctor or pharmacist.

DALACIN C capsules should always be swallowed whole and washed down with a full glass of water. Do not chew, crush or open the capsules.

Adults and elderly patients

The recommended dose of DALACIN C is between 150 and 450 mg (1 to 3 capsules) every 6 hours, depending on the severity of your infection.

Children

The recommended dose in children is between 8 - 25 mg/kg/day divided into 3 or 4 equal doses, depending on the severity of the infection. Your doctor will work out the number of capsules that your child should have.

Patients with liver and kidney problems

If you have to take DALACIN C for a long time, your doctor may arrange regular liver, kidney and blood tests.

If you take more DALACIN C than you should

If you take more DALACIN C than you should, you might experience the following: severe diarrhoea, bloody diarrhoea, stomach cramping and pain.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you, whether there are any DALACIN C capsules left or not. Do not take any more capsules until your doctor tells you to.

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If you forget to take a dose of DALACIN C

If the forgotten dose is just a few hours late, take it straight away. If it is nearly time for your next dose, miss out the forgotten one. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DALACIN C

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

4. Possible side effects

DALACIN C can have side effects.

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

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

- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is a side effect which may occur during or after completing treatment with antibiotics and can be a sign of serious bowel inflammation or infection.
- signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, dizziness, swelling of the eyelids, face, lips, throat or tongue, rash or itching (especially affecting the whole body).
- widespread rash, redness, blistering, pustules or peeling of large areas of skin that may be combined with fever, feeling unwell, or swelling of the mouth, nose, eyes, genitals or lymph nodes.
- yellowing of the skin and whites of the eyes (jaundice).

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

Tell your doctor if you notice any of the following:

Frequent side effects

- increased number of certain white blood cells that fight disease
- diarrhoea
- stomach pain
- rash
- abnormal liver function tests

Less frequent side effects

- impaired sense of taste
- vomiting
- nausea
- hives
- itching

Other side effects

- vaginal infection
- reduced number of certain blood cells which may cause bruising or bleeding or weaken the immune system
- allergic reactions
- inflammation of the lining of the oesophagus (gullet), open sores or ulcers in the lining of the oesophagus
- swelling under the skin, especially around face, throat, limbs or genitals
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea

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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 or 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 DALACIN C.

5. How to store DALACIN C

- Store all medicines out of reach of children.
- This medicine must be stored at or below 30 °C.
- Do not use this medicine after the expiry date stated on the label and carton.
- 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 DALACIN C contains

- The active substance is clindamycin hydrochloride. Each capsule contains clindamycin hydrochloride equivalent to 150 mg clindamycin base.
- The other ingredients are lactose monohydrate, magnesium stearate, starch maize and talc.

The capsule shell contains gelatin and titanium dioxide. The printing ink contains black iron oxide.

What DALACIN C looks like and contents of the pack

Hard gelatin capsule (number 1 size) with white cap and white body marked with "Clin 150" and "Pfizer" in black ink.

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DALACIN C 150 mg capsules are packed in glass bottles and blisters containing 20 and 100 capsules.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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