Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking Dalacin C?

Dalacin C contains the active ingredient Clindamycin hydrochloride. Dalacin C is used to treat infections in different parts of the body caused by bacteria.

For more information, see Section <u>1. Why am I taking</u> <u>Dalacin C?</u> in the full CMI.

2. What should I know before I take Dalacin C?

Do not use if you have ever had an allergic reaction to Dalacin C, clindamycin, lincomycin, lactose, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have liver, kidney or bowel problems, or have had severe diarrhoea associated with the use of antibiotics, or any other medical conditions, take any other medicines, or

are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section <u>2. What should I know</u> before I take Dalacin C? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dalacin C and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I take Dalacin C?

- Your doctor will tell you how many capsules you need to take each day.
- Swallow the capsules whole with a full glass of water. Dalacin C can be taken with or without food.
- Do not take Dalacin C immediately before lying down.

More instructions can be found in Section <u>4. How do I</u> <u>take Dalacin C?</u> in the full CMI.

5. What should I know while taking Dalacin C?

Things you	 Remind
should do	any doctor,
	dentist, or pharmacist

	you visit that you are taking Dalacin C. • If you get a severe diarrhoea, or a severe skin rash, tell your doctor, pharmacist, or nurse immediately. Do this even if it occurs several weeks after you have stopped taking Dalacin C.
Things you should not do	 Do not stop using this medicine without talking to your doctor. Do not take Dalacin C immediately

	before lying down.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how Dalacin C affects you.
Drinking alcohol	 No information available.
Looking after your medicine	 Store it in a cool dry place below 25°C, away from moisture, heat, or sunlight.

For more information, see Section <u>5. What should I know</u> while taking Dalacin C? in the full CMI.

6. Are there any side effects?

Side effects include pain/stiffness/swelling in joints; skin rash; vomiting; nausea; change/loss of taste; vaginal infection. Serious side effects include severe diarrhoea which may have blood and mucus; weight loss and fevers, night sweats, fatigue, cough, pain, weakness, confusion; severe chills and sore throat or mouth ulcers; bleeding/bruising more easily than normal; signs of allergy on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing; burning sensation in the chest/throat; little or no urine.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

DALACIN® C Capsules

Active ingredient(s): [Clindamycin hydrochloride]

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dalacin C. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dalacin C.

Where to find information in this leaflet:

- 1. Why am I taking Dalacin C?
- 2. What should I know before I take Dalacin C?
- 3. What if I am taking other medicines?
- 4. How do I take Dalacin C?
- 5. What should I know while taking Dalacin C?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking Dalacin C?

Dalacin C contains the active ingredient Clindamycin hydrochloride. Dalacin C is an antibiotic. It is used to treat infection in different parts of the body caused by bacteria.

This medicine works by killing or stopping the growth of the bacteria causing your infection.

It will not work against viral infections such as colds or flu.

Dalacin C is recommended for patients who are allergic to penicillin or patients for whom penicillin is not suitable.

Ask your doctor if you have any questions about why Dalacin C has been prescribed for you.

Your doctor may have prescribed Dalacin C for another reason.

Dalacin C is not addictive.

2. What should I know before I take Dalacin C?

Warnings

Do not take Dalacin C if:

- you are allergic to clindamycin, lincomycin or any of the ingredients listed at the end of this leaflet
- you are allergic to lactose
- the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- have had severe diarrhoea associated with the use of antibiotics
- have severe liver disease
- have kidney disease

- have bowel disease or any gastrointestinal (stomach or gut) problems
- take any medicines for any other conditions.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Clindamycin crosses the placenta. Dalacin C should only be used in pregnancy if clearly needed.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Dalacin C is not recommended during breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Dalacin C and affect how it works.

 erythromycin, rifampicin, rifaximin - medicines used to treat bacterial infections

- carbamazepine, phenobarbital, phenytoin, primidone medicines used to manage seizures
- enzalutamide, apalutamide, midostaurin medicines used to treat certain cancers
- lumacaftor a medicine used for the treatment of cystic fibrosis
- St. John's wort used to assist emotional health
- dexamethasone used to treat various inflammatory, endocrine or rheumatic conditions
- some medicines that may be used during surgery.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dalacin C.

4. How do I take Dalacin C?

How much to take

- Your doctor will tell you how many capsules you need to take each day. This may depend on your condition and whether you are taking any other medicines. The usual adult dose of Dalacin C is one capsule of 150 mg taken four times a day. The number of capsules may increase with more serious infections. Your doctor will tell you how long to take your capsules.
- Dalacin C capsules are not recommended in young children who cannot swallow capsules.

When to take Dalacin C

 Space the doses of Dalacin C capsules evenly apart and take them at about the same time each day.

This will allow the medicine to have its best effect. It will also help you remember when to take it.

How to take Dalacin C

- Swallow the capsules whole with a full glass of water. Dalacin C can be taken with or without food.
- Do not take Dalacin C immediately before lying down. You must wait at least half an hour. This will reduce the chance of any discomfort or pain in your throat or stomach after you take your medicine.

If you forget to take Dalacin C

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you have missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much Dalacin C

If you think that you have used too much Dalacin C, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking Dalacin C?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Dalacin C capsules.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

- If you get severe diarrhoea, tell your doctor, pharmacist, or nurse immediately. Do this even if it occurs several weeks after you have stopped taking Dalacin C. Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care.
- Do not take any medicines for diarrhoea without first checking with your doctor.
- If you get a severe skin rash tell your doctor immediately. Do this even if the rash occurs after Dalacin C has been stopped. A severe skin rash may mean you are having an allergic reaction to Dalacin C. You may need urgent medical care.
- If you get a sore, white mouth or tongue while taking or soon after stopping Dalacin C, tell your doctor. Also tell your doctor if you get vaginal itching or discharge. This may mean you have a fungal/yeast infection called thrush. Sometimes the use of Dalacin C allows fungi/yeast to grow and the above symptoms to occur. Dalacin C does not work against fungi/yeast.
- If you become pregnant while taking Dalacin C, tell your doctor immediately.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- Do not take Dalacin C immediately before lying down.
- Do not take Dalacin C to treat any other illnesses unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.
- If you stop taking Dalacin C suddenly, the infection may not clear completely or your symptoms may return.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dalacin C affects you.

Drinking alcohol

No information available.

Looking after your medicine

• Keep your Dalacin C capsules in the pack until it is time to take them.

If you take the capsules out of the pack, they may not keep well.

Store it in a cool dry place where the temperature stays below 25°C, away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

When to discard your medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
 pain, stiffness or swelling in your joints skin rash which maybe red or itchy vomiting, nausea change or loss of taste 	Speak to your doctor if you have any of these side effects and they worry you.

Serious side effects

Serious side effects	What to do
 vaginal infection (itching, burning and a thick, white discharge) diarrhoea which may have blood and mucus, stomach pain, fever weight loss and fevers, night sweats, fatigue, cough, chest pain, swelling, stomach pain, rash, pain, weakness, confusion frequent infections such as fever, severe chills, 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
 sore throat or mouth ulcers. bleeding or bruising more easily than normal sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing a burning sensation in the chest rising up to the throat/heartburn painful red area of skin with blistering or peeling, or bleeding in the lips, eyes, moth, nose and genitals high fever quickly followed by a skin rash little or no urine with drowsiness, nausea, vomiting, breathlessness. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/safety/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Dalacin C contains

Active ingredient (main ingredient)	clindamycin hydrochloride
Other ingredients	gelatin
(inactive ingredients)	lactose monohydrate
	magnesium stearate
	maize starch

	purified talc titanium dioxide edible ink (Opacode monogramming ink S-1-27794 BLACK, TekPrint SW-9008 Black Ink, Opacode S-1-8152HV)
Potential allergens	Lactose

Do not take this medicine if you are allergic to any of these ingredients.

What Dalacin C looks like

Dalacin C capsules with a strength of 150 mg are available in blister packs of 100 capsules or 24 capsules. The opaque, white capsules are marked with "Clin 150" and "Pfizer" in black.

AUST R 12275

Who distributes Dalacin C

Pfizer Australia Pty Ltd

Level 17, 151 Clarence Street SYDNEY NSW 2000

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

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