# **DALACIN® C Injection**

# **Consumer Medicine Information (CMI) summary**

The full CMI on the next page has more details. If you are worried about receiving this medicine, speak to your doctor or nurse.

# 1. Why am I being treated with Dalacin C injection?

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

For more information, see Section 1, Why am I being treated with Dalacin C injection? in the full CMI.

# 2. What should I know before treatment with Dalacin C injection?

You should not be treated with Dalacin C Injection if you have ever had an allergic reaction to Dalacin C injection, clindamycin, lincomycin, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have liver, kidney, bowel, stomach or gut problems, or have had severe diarrhoea associated with the use of antibiotics, allergy to latex or history of allergy to different things, 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 2. What should I know before treatment with Dalacin C injection? in the full CMI.

# 3. What if I am taking other medicines?

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

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

# 4. How is Dalacin C injection given?

Your doctor will decide what dose you will receive. Dalacin C Injection is given as an injection into a muscle or as a slow drip into a vein.

More instructions can be found in Section 4. How is Dalacin C injection given? in the full CMI.

# 5. What should I know during or after treatment with Dalacin C injection?

Things you should do	<ul> <li>Remind any doctor, dentist, or pharmacist you visit that you have been given Dalacin C injection.</li> <li>If you get severe diarrhoea, severe stomach pain; a severe skin rash; chest pain, shortness of breath, nausea, vomiting, sweating, fast/irregular heartbeats; or feel lightheaded or dizzy tell your doctor, pharmacist, or nurse immediately. Do this even if it occurs several weeks after you have been given Dalacin C injection.</li> </ul>	
Things you should not do	Do not stop receiving Dalacin C injection because you are feeling better, unless advised by your doctor.	
Driving or using machines		
Drinking alcohol	No information available.	

For more information, see Section <u>5. What should I know during or after treatment with Dalacin C injection?</u> in the full CMI.

## 6. Are there any side effects?

Side effects may include discomforts at injection site; pain/stiffness/swelling in joints; skin rash; stomach ache; vomiting; nausea; change/loss of taste; vaginal infection; red rash on folds of the buttocks, groin, armpit or behind the knee.

Serious side effects may include low blood pressure; 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; little or no urine; yellowing of the eyes or skin; severe swelling and redness along a vein; chest and heart discomfort, fast/pounding/irregular heartbeat.

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

# **DALACIN® C Injection**

**Active ingredient(s):** [Clindamycin phosphate]

# **Consumer Medicine Information (CMI)**

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

#### Where to find information in this leaflet:

- 1. Why am I being treated with Dalacin C injection?
- <u>2.</u> <u>What should I know before treatment with Dalacin C injection?</u>
- 3. What if I am taking other medicines?
- 4. How is Dalacin C injection given?
- <u>5.</u> What should I know during or after treatment with Dalacin C injection?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I being treated with Dalacin C injection?

Dalacin C injection contains the active ingredient clindamycin phosphate. Dalacin C injection 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 injection is recommended for patients who are allergic to penicillin or for whom penicillin is not suitable.

Ask your doctor if you have any questions about why Dalacin C injection has been prescribed for you. Your doctor may have prescribed Dalacin C injection for another reason.

# 2. What should I know before treatment with Dalacin C injection?

#### Warnings

You should not be given Dalacin C Injection if you have ever had an allergic reaction to clindamycin, lincomycin or any of the ingredients listed at the end of this leaflet.

#### Tell your doctor if you:

- have had severe diarrhoea associated with the use of antibiotics
- have liver disease
- have kidney disease
- have or have a history of bowel disease or any gastrointestinal (stomach or gut) problems
- have a history of allergic reactions to different things
- 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</u>. <u>Are there any side effects</u>?

#### **Pregnancy**

Tell your doctor if you are pregnant or intend to become pregnant. Clindamycin and benzyl alcohol contained in Dalacin C injection cross the placenta. Your doctor will discuss the benefits and risks of using Dalacin C injection in pregnancy.

### **Breastfeeding**

Tell your doctor if you are breastfeeding or intend to breastfeed. Dalacin C injection may affect your baby and is not recommended during breastfeeding.

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

#### Use in children

Dalacin C injection contains benzyl alcohol. Benzyl alcohol has been associated with serious side effects in newborns and infants. Your doctor will decide if treatment is appropriate.

### Use in the elderly

Patients over 60 years of age are more likely to have severe gastrointestinal effects. It is important to tell your doctor immediately if you suffer from severe stomach pain or diarrhoea which may also involve blood in your stool (poo). This may occur more than 2 months after treatment with Dalacin C injection is stopped.

# 3. What if I am taking other medicines?

Tell your doctor or nurse 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 injection and affect how it works including:

- erythromycin, ciprofloxacin, clarithromycin,
   rifampicin, rifaximin used to treat bacterial infections
- fluconazole, itraconazole, ketoconazole, voriconazole used to treat fungal infections
- carbamazepine, phenobarbital, phenytoin, primidone
   used to manage seizures
- imatinib, enzalutamide, apalutamide, midostaurin used to treat certain cancers
- aprepitant used to treat nausea and vomiting associated with cancer treatment
- lumacaftor 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
- diltiazem, verapamil used to treat angina or high blood pressure
- ritonavir used to treat HIV/AIDS
- some medicines that may be used during surgery in an intensive care setting.

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

# 4. How is Dalacin C injection given?

## How much Dalacin C injection is given

Your doctor will decide the dose, how often, and how long it should be given according to your age, condition and body weight.

#### How is Dalacin C injection given

Dalacin C injection may be given as an intravenous infusion (as a slow drip into a vein) or as an injection into a muscle. It is given by a doctor or trained nurse.

#### If you receive too much Dalacin C injection

As Dalacin C injection is usually given to you in hospital under the close supervision of your doctor, it is unlikely that you will receive too much. However, if you experience severe side effects after being given Dalacin C injection, including severe diarrhoea which may include blood, severe stomach pain, feeling dizzy or faint, unusual heartbeat or chest pain tell your doctor or nurse immediately.

Tell your doctor or nurse immediately if you are concerned that you may have been given too much Dalacin C injection.

# 5. What should I know during or after treatment with Dalacin C injection?

# Things you should do

Tell your doctor or nurse immediately while receiving or after Dalacin C injection has been stopped as you may need urgent medical care:

- If you develop severe stomach pain or severe diarrhoea. Do this even if it occurs several weeks after Dalacin C injection has been stopped. Diarrhoea may mean that you have a serious condition affecting your bowel.
- If you get a severe skin rash. A severe skin rash may mean you are having an allergic reaction to Dalacin C injection.
- If you have chest pain, shortness of breath, nausea and vomiting, sweating and fast or irregular heartbeats. This may mean you are having an allergic reaction to Dalacin C injection.
- If you feel lightheaded or dizzy.

#### Tell your doctor:

- If you get a sore, white mouth or tongue, vaginal itching or discharge. This may mean you have a fungal/yeast infection called thrush. Sometimes the use of Dalacin C injection allows fungi/yeast to grow and the above symptoms to occur. Dalacin C does not work against fungi/yeast.
- If the symptoms of your infection do not improve within a few days, or if they become worse.
- If you are about to have any blood tests. Dalacin C injection 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 stop receiving Dalacin C injection because you are feeling better, unless advised by your doctor.
- Do not take any medicines for diarrhoea without first checking with your doctor.

#### **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

Dalacin C injection will be stored in the hospital pharmacy or on the ward.

#### Disposal of the medicine

The hospital staff will dispose of any leftover Dalacin C injection.

# 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
<ul> <li>pain, swelling, itching, redness, warmth, tenderness, lump under the skin at injection site</li> <li>pain, stiffness or swelling in your joints</li> <li>skin rash which may be red or itchy</li> <li>vomiting, nausea</li> <li>stomach ache</li> </ul>	Speak to your doctor or nurse if you have any of these side effects and they worry you.
<ul> <li>change or loss of taste</li> </ul>	

Side effects	What to do
<ul> <li>vaginal infection (itching, burning and a thick, white discharge)</li> <li>red rash on the folds of the buttocks, groin, armpit or behind the knee</li> </ul>	
<ul> <li>low blood pressure (dizziness, lightheadedness)</li> <li>marks on the skin that do not fade when pressed</li> <li>diarrhoea which may have blood and mucus, stomach pain, fever</li> <li>weight loss and fevers, night sweats, fatigue, cough, chest pain, swelling, stomach pain, rash, pain, weakness, confusion</li> <li>frequent infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>bleeding or bruising more easily than normal</li> <li>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</li> <li>painful red area of skin with blistering or peeling, or bleeding in the lips, eyes, mouth, nose and genitals</li> <li>high fever quickly followed by a skin rash</li> <li>little or no urine with drowsiness, nausea, vomiting, breathlessness</li> <li>yellowing of the eyes or skin, also called jaundice</li> <li>severe swelling and redness along a vein which is extremely tender when touched</li> </ul>	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.

Side effects	What to do
Chest pain, shortness of breath, nausea and vomiting, sweating and fast or irregular heartbeats	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.

# Rare instances following too rapid intravenous administration

Serious side effects		What to do
•	chest discomfort, shortness of breath, weakness, fast-beating, fluttering or pounding heart	Tell your doctor or nurse straight away.

Tell your doctor or nurse 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 <a href="https://www.tga.gov.au/safety/reporting-problems">www.tga.gov.au/safety/reporting-problems</a>. 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 nurse or pharmacist before you decide to stop receiving/taking any of your medicines.

# 7. Product details

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

## What Dalacin C injection contains

Active ingredient	clindamycin phosphate
(main ingredient)	
Other ingredients	benzyl alcohol
(inactive	disodium edetate
ingredients)	hydrochloric acid
	sodium hydroxide
	water for injections

Tell your doctor or nurse if you are allergic to any of these ingredients.

# What Dalacin C injection looks like

Dalacin C injection appears as a clear colorless solution and comes in 2 mL or 4 mL ampoules

AUST R 12294 DALACIN C clindamycin 300mg/2mL (as phosphate) injection ampoule

AUST R 47636 DALACIN C clindamycin 600mg/4mL (as phosphate) injection ampoule

#### Who distributes Dalacin C injection

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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