# **DALACIN® V Cream 2%**

### **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 using DALACIN V Cream 2%?

DALACIN V Cream 2% contains the active ingredient clindamycin phosphate. Dalacin V is used to treat vaginal infection.

For more information, see Section 1. Why am I using DALACIN V Cream 2%? in the full CMI.

# 2. What should I know before I use DALACIN V Cream 2%?

Do not use if you have ever had an allergic reaction to DALACIN medicines, clindamycin, lincomycin, or any of the ingredients listed at the end of the CMI or have/have previously had inflammatory bowel disease or antibiotic-associated colitis. Talk to your doctor if you have had any bowel problems, 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 I use DALACIN V Cream 2%? in the full CMI.

# 3. What if I am taking/using other medicines?

Some medicines may interfere with DALACIN V Cream 2% and affect how it works.

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

# 4. How do I use DALACIN V Cream 2%?

Vaginal use only, insert one applicator-full of cream, once-a-day, at bedtime, for seven days in a row.

More instructions on how to use DALACIN V Cream 2% can be found in Section 4. How do I use DALACIN V Cream 2%? in the full CMI.

# 5. What should I know while using DALACIN V Cream 2%?

Things you should do

 Remind any doctor, dentist, or

pharmacist you visit that you are using **DALACIN V** Cream 2%. • If you get severe diarrhoea, tell your doctor or seek medical treatment immediately. Do this even if it occurs several weeks after you have stopped using **DALACIN V** Cream 2%. Do not stop Things you using this should not medicine do without talking to your doctor.

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not use condoms or vaginal diaphragm contraceptive devices as methods of contraception while using **DALACIN** V Cream 2% or within 72 hours after the end of your treatment.
- Do not have vaginal sex or use other vaginal products (such as tampons or

	douches) while using this medicine.
Driving or using machines	<ul> <li>No information available.</li> </ul>
Drinking alcohol	<ul> <li>No information available.</li> </ul>
Looking after your medicine	<ul> <li>Store it in a cool dry place below 25°C, away from moisture, heat, or sunlight.</li> <li>Keep it where young children cannot reach it.</li> </ul>

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

# 6. Are there any side effects?

Vaginal pain/discomfort or unusual smell; skin rash, swellings, itching, redness; headache; dizziness, spinning sensation; stomach pain, indigestion, bloating, excessive wind; constipation; diarrhoea; nausea, vomiting; bad breath; change in taste; back pain; pelvic pain; nosebleed; abnormalities during or in-between periods. Uncommon but serious side effects that may need immediate medical attention: severe diarrhoea which may have blood and mucus; severe pelvic pain; signs of an allergic reaction; discomfort when urinating; irregular heart activities; slow or no progress in labour; abnormal infections.

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® V Cream 2%**

Active ingredient(s): Clindamycin phosphate

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

This leaflet provides important information about using DALACIN V Cream 2%. 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 V Cream 2%.

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

- 1. Why am I using DALACIN V Cream 2%?
- 2. What should I know before I use DALACIN V Cream 2%?
- 3. What if I am taking/using other medicines?
- 4. How do I use DALACIN V Cream 2%?
- 5. What should I know while using DALACIN V Cream 2%?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I using DALACIN V Cream 2%?

DALACIN V Cream 2% contains the active ingredient clindamycin phosphate. DALACIN V Cream 2% is an antibiotic cream used in the vagina to treat vaginal

infection. It works by stopping the growth of the bacteria causing the vaginal infection.

Ask your doctor if you have any questions about why DALACIN V Cream 2% has been prescribed for you. Your doctor may have prescribed DALACIN V Cream 2% for another reason.

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

# 2. What should I know before I use DALACIN V Cream 2%?

# **Warnings**

You should not be having vaginal sex or using other vaginal products (such as tampons or douches) while using this product.

Do not use condoms or vaginal contraceptive devices as methods of contraception while using DALACIN V Cream 2% or within 72 hours after the end of your treatment with DALACIN V Cream 2%.

You must tell your doctor, and should not use DALACIN V Cream 2% if you:

 have ever had an allergic reaction to Dalacin medicines, clindamycin or lincomycin or any of the ingredients listed at the end of this leaflet.  have, or have previously had inflammatory bowel disease, or antibiotic-associated colitis (severe diarrhoea associated with the use of antibiotics).

## Check with your doctor if you:

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

You should not be using this medicine if the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

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>. Are there any side effects?

# Pregnancy and breastfeeding

Talk to your doctor if you are:

- pregnant or intend to become pregnant.
- breastfeeding or intend to breastfeed.

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

DALACIN V Cream 2% has not been shown to be effective or safe in children.

# 3. What if I am taking/using other medicines?

Tell your doctor or pharmacist if you are taking/using 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 V Cream 2% and affect how it works, including:

- some medicines used during surgery.
- other medicines used in the vagina.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking/using and if these affect DALACIN V Cream 2%.

# 4. How do I use DALACIN V Cream 2%?

## How much to use and how long to use it

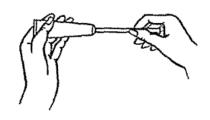
The recommended dose of DALACIN V Cream 2% is one applicator-full (about 5 grams) of cream, once-aday, at bedtime, for seven days in a row.

#### How to use it

The plastic applicators provided with DALACIN V Cream 2% are designed to allow the correct placement of the cream in the vagina. To load and use the applicator correctly, follow these steps:

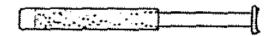
- Wash hands thoroughly with soap and water before and after using the vaginal applicator.
- Remove the cap from the tube of cream.
- Screw the open end of the applicator onto the tube.
   Gently squeeze from the base of the tube, forcing the cream into the applicator (see diagram 1).

#### Diagram 1



 As the cream enters the applicator, the plunger will be pushed back until it reaches the stopping point. At this stage, unscrew the applicator from the tube (see diagram 2) and replace the cap.

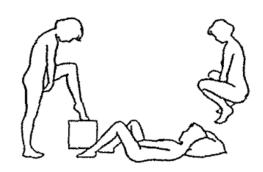
#### Diagram 2



 Choose a position to apply DALACIN V Cream 2% which is comfortable for you, keeping in mind that the applicator must reach as high as is comfortable in the vagina. This may be the position which you usually use for the insertion of a tampon (see diagram 3). For example:

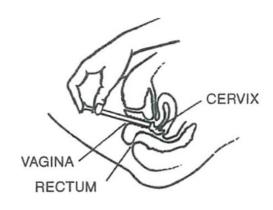
- a) squatting;
- b) standing with your legs apart or with one leg raised on a chair;
- c) lying on your back with your legs raised.

Diagram 3



 The lips of the vagina should be parted with the fingers of one hand. Grasp the applicator between the thumb and middle finger of the other hand and insert it (open end first) into the vagina as deeply as it will comfortably reach (see diagram 4).

Diagram 4



 Holding the applicator in place, slowly push the plunger until it stops, so depositing the cream in the vagina.  Carefully withdraw the applicator from the vagina and dispose of the applicator safely where children cannot find it.

## If you forget to use DALACIN V Cream 2%

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, and then go back to using DALACIN V Cream 2% as you would normally.

Do not use a double dose to make up for the dose that you missed.

# If you use too much DALACIN V Cream 2%

It is important that you do not use more DALACIN V Cream 2% than your doctor has prescribed. If you use too much DALACIN V Cream 2%, you may experience unwanted side effects.

#### If DALACIN V Cream 2% is Swallowed

### 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.

## If DALACIN V Cream 2% gets into eyes

You should immediately rinse the eye with lots of cool tap water.

# 5. What should I know while using DALACIN V Cream 2%?

# Things you should do

- Wash hands thoroughly with soap and water after using the vaginal applicator.
- Tell your doctor immediately if you suffer mild diarrhoea or seek immediate emergency medical attention if you experience severe diarrhoea which may contain blood. Do this even if it occurs several weeks after stopping DALACIN V Cream 2%.
- Tell your doctor if you feel that DALACIN V Cream 2% is not helping your condition.
- Tell your doctor if you have persistent symptoms (infections) following treatment with DALACIN C Cream 2%, as you may be infected with other bacteria.
- Tell your doctor or pharmacist if you do not feel well while using DALACIN V Cream 2%.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using DALACIN V Cream 2%.

- Do not use any medicines for diarrhoea or strong pain unless you have spoken to your doctor, nurse or pharmacist first.
- Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.
- If you become pregnant or plan to breastfeed while using DALACIN V Cream 2%, tell your doctor immediately.
- Keep all your doctor's appointments so that your progress can be checked.

## Things you should not do

- DALACIN V Cream 2% must only be used in the vagina. It must not be used on skin, in the mouth or in eyes.
- You should not be having vaginal sex or using other vaginal products (such as tampons or douches) while using this product.
- Do not use condoms or vaginal diaphragm contraceptive devices as methods of contraception while using DALACIN V Cream 2% or within 72 hours after the end of your treatment with DALACIN V Cream 2%.
- Do not stop using this medicine without talking to your doctor.
- Do not take/use any medicines/products for diarrhoea without first checking with your doctor.
- Do not give your medicine to anyone else, even if they have the same condition as you.

 Do not use DALACIN V Cream 2% to treat any other illnesses unless your doctor tells you to.

# **Driving or using machines**

No information available.

## **Drinking alcohol**

No information available.

# Looking after your medicine

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 meters 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
<ul> <li>vaginal itching, burning, irritation, pain, discharge, bad smell or unusual smell</li> </ul>	Speak to your doctor if you have any of these side effects and they worry you.
<ul> <li>skin rash, swellings, itching, redness</li> </ul>	
<ul><li>headache</li></ul>	
<ul><li>dizziness, spinning sensation</li></ul>	
<ul> <li>stomach pain, indigestion, bloating, passing excessive wind</li> </ul>	
<ul><li>constipation</li></ul>	
<ul><li>diarrhoea</li></ul>	
<ul><li>nausea, vomiting</li></ul>	
<ul><li>bad breath</li></ul>	
<ul><li>change in taste</li></ul>	

Side effects	What to do
<ul> <li>back pain, pelvic pain, general pain</li> </ul>	
<ul><li>nosebleed</li></ul>	
<ul> <li>abnormal bleeding in- between periods,</li> </ul>	
<ul><li>painful or irregular periods</li></ul>	

# **Serious side effects**

Serious side effects	What to do
<ul> <li>severe diarrhoea which may have blood and mucus, stomach pain, fever</li> <li>severe pain in pelvis, especially during your period, during sex or using the bathroom</li> <li>signs of allergy (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> </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.

Serious side effects	What to do
<ul> <li>discomfort when urinating, change in urinary color/frequency/ urgency</li> </ul>	
<ul> <li>increase in appetite, loss of weight, intolerance to heat, increased sweating, tremors, rapid heart rate</li> </ul>	
<ul><li>slow or no progress in labour</li></ul>	
<ul> <li>abnormal infections in skin, urinary tract, respiratory tract, or fungal infections.</li> </ul>	

# 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 sideeffects 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 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 V Cream 2% contains

Active ingredient (main ingredient)	clindamycin phosphate
Other ingredients	benzyl alcohol
(inactive ingredients)	cetostearyl alcohol
	cetyl esters wax
	liquid paraffin
	polysorbate 60
	propylene glycol
	purified water
	sorbitan monostearate
	stearic acid

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

#### What DALACIN V Cream 2% looks like

DALACIN V Cream 2% is a white semi-solid cream. It is available in a 40g tube. Each DALACIN V Cream 2% pack also contains 7 disposable applicators.

AUST R 48431 - DALACIN V clindamycin 2% (20mg/g) (as phosphate) cream tube

# Who distributes DALACIN V Cream 2%

# Pfizer Australia Pty Ltd

Level 17, 151 Clarence Street SYDNEY NSW 2000

Toll Free Number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in July 2025.

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