

Package leaflet: Information for the user

Dalacin® C Phosphate 150 mg/ml **Concentrate for Solution for Injection/Infusion** clindamycin (as clindamycin phosphate)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- If you get any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Dalacin C Solution is and what it is used for

Dalacin C Solution is a sterile solution for injection into a vein (intravenously) or into a muscle (intramuscularly). The solution contains clindamycin phosphate which is an antibiotic used in the treatment of serious bacterial infections.

2. What you need to know before you use Dalacin C Solution

Do not use Dalacin C Solution:

- If you are allergic to clindamycin, another antibiotic called lincomycin or to any of the other ingredients of this medicine (listed in section 6).
- If you are experiencing diarrhoea or suffer from intestinal inflammatory disease.

Warnings and precautions

Talk to your doctor or pharmacist before using Dalacin C Solution if you have any of the following conditions:

- have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered from problems with your stomach or intestines (bowel disease). If you develop diarrhoea during or after using Dalacin C Solution **tell your doctor immediately** since it will be necessary to stop treatment. This may be a sign of bowel inflammation (*pseudomembranous colitis*) which can occur following treatment with antibiotics.
- you suffer from problems with your kidneys or liver.
- you suffer from asthma, eczema or hayfever.
- develop any severe skin reactions or hypersensitivity to Dalacin.
- you develop signs of an allergic reaction to this medicine, including breathing problems and chest pain. Stop clindamycin immediately and contact your doctor or medical emergency services right away if you notice any of these signs.

- have recently taken or been given a lincosamide medicine such as clindamycin, or a macrolide medicine such as erythromycin. This is important, because there is an increased chance that Dalacin will not work as well as it should.

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.

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.

Other medicines and Dalacin C Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. These include:

- muscle relaxants used during operations.
- oral contraceptive pills. You should use extra contraception such as condoms whilst receiving Dalacin C and for seven days after receiving Dalacin C.
- warfarin or similar medicines – used to thin the blood. You may be more likely to have a bleed. Your doctor may need to take regular blood tests to check how well your blood can clot.
- CYP3A4 or CYP3A5 inducers like Rifampicin may impact effectiveness of the medicine.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or think you might be pregnant or are planning to have baby, discuss with your doctor before Dalacin C Solution is prescribed.

Dalacin C contains benzyl alcohol (see "Dalacin C Solution contains benzyl alcohol and sodium").

Breast-feeding

Tell your doctor if you are breast-feeding as the active substance in this medicine may be passed into breast milk. Your doctor will decide if Dalacin C is appropriate for you.

Dalacin C contains benzyl alcohol (see "Dalacin C Solution contains benzyl alcohol and sodium").

Driving and using machines

No effects on the ability to drive or use machines have been seen with Dalacin C Solution.

Dalacin C Solution contains benzyl alcohol and sodium

Dalacin C Solution contains 9 mg benzyl alcohol in each 1 ml of solution, which is equivalent to 9 mg/ml. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called “gasping syndrome”) in babies and young children. Do not use medicines containing benzyl alcohol in newborn babies (up to 4 weeks old), and do not use these medicines for more than a week in young children (less than 3 years old), unless advised by the doctor. Ask your doctor or pharmacist for advice if you have a liver or kidney disease, or if you are pregnant or breast-feeding. This is because large amounts of

benzyl alcohol can build-up in your body and may cause side effects such as an increased amount of acid in your blood (called “metabolic acidosis”).

Dalacin C Solution contains less than 1 mmol sodium (23 mg) in each ampoule (2 ml or 4 ml), that is to say essentially ‘sodium-free’.

3. How to use Dalacin C Solution

Your doctor or nurse will give you your medicine as an injection into your vein (intravenous) or your muscle (intramuscular). When giving you Dalacin C, your doctor will ensure that the concentration of clindamycin does not exceed 18 mg per ml and the rate it is given to you does not exceed 30 mg per minute. If Dalacin is given too fast it could rarely cause a heart attack.

Adults/Elderly

The recommended dose of Dalacin C Solution is 600 to 2700 mg clindamycin per day in 2 to 4 equal doses, depending on the severity of your infection. Higher doses than this (up to 4800 mg daily) may be given by your doctor for very severe infections.

Use in children

The recommended dosage for children (over 1 month of age) is 15 to 40 mg clindamycin per kg bodyweight each day in three or four equal doses. Clindamycin should be dosed based on total body weight regardless of obesity. Higher doses of at least 300 mg per day (regardless of body weight) may be given by your doctor for very severe infections until a full response to treatment is observed.

Neonates

The recommended dosage for neonates (under 1 month of age) is 15-20 mg clindamycin per kg bodyweight each day in three or four equal doses. The lower dosage may be adequate for small premature infants.

Normally Dalacin C is only given to patients in hospital. The medical staff will be keeping a close eye on you during your treatment. If you need to have more than one course of treatment with clindamycin, your doctor may want to check that the clindamycin is not having any effect on your blood and the way your kidneys and liver are functioning.

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

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you develop:

- signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, dizziness, swelling of the eyelids or face or lips or throat or tongue, rash or itching (especially affecting the whole body).

- chest pain which can be a sign of a potentially serious allergic reaction called Kounis syndrome (frequency not known cannot be estimated from the available data).
- 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.
- blistering and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips.
- yellowing of the skin and whites of the eyes (jaundice).
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea.

Other possible side effects may include:

Common: may affect up to 1 in 10 people

- blood clot (vein inflammation).
- liver function tests may be affected (poor liver function).
- rash characterised by a flat, red area on the skin that is covered with small bumps.
- inflammation of the lining of large intestine (pseudomembranous colitis).

Uncommon: may affect up to 1 in 100 people

- change of sense of taste.
- low blood pressure (feeling light headed, dizzy or faint), heart and lungs stop functioning (when the heart suddenly stops pumping blood around the body).
- feeling sick, diarrhoea.
- 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*)).
- itchy skin.
- hives.
- pain, abscess (boil).

Not known: frequency cannot be estimated from available data

- a marked decrease in the number of blood cells which may cause bruising or bleeding or weaken the immune system (agranulocytosis), a slight decrease in the number of white blood cells (leukopenia), reduced blood platelet (thrombocytopenia).
- an increase in the number of white blood cells (eosinophilia).
- severe allergic reactions.
- stomach pain, being sick (throwing up).
- infection inside and around the vagina.
- inflammation of the large intestine which causes abdominal pain, fever or diarrhoea due to infection by *Clostridium difficile*.
- 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 red skin rash with small pus-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 Clindamycin.

- a rare skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP)).
- irritation at the site of the injection.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Dalacin C Solution

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and ampoule after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not refrigerate or freeze.

Do not throw away any medicines via wastewater. Any unused liquid should be disposed of safely. These measures will help protect the environment.

6. Contents of the pack and other information

What Dalacin C Solution contains

The active substance is clindamycin. Each ml of solution contains clindamycin phosphate equivalent to 150 mg of clindamycin.

The other ingredients are benzyl alcohol (E1519), disodium edetate, sodium hydroxide (for pH adjustment), dilute hydrochloric acid (for pH adjustment) and sterilised water for injections (see section 2 "Dalacin C Solution contains benzyl alcohol and sodium").

What Dalacin C Solution looks like and contents of the pack

Dalacin C Solution is a clear, colourless solution, it is supplied in glass ampoules containing either 2 ml or 4 ml of solution. Each ampoule is packed in a cardboard carton with a leaflet.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Ireland:

Pfizer Healthcare Ireland Unlimited Company,
The Watermarque Building,

Ringsend Road,
Dublin 4,
D04 K7N3,
Ireland

Malta:
Pfizer Hellas S.A.
243 Messoghion Ave.
Neo Psychiko 15451,
Greece

Manufacturer:

Pfizer Manufacturing Belgium NV
Rijksweg 12,
2870 Puurs-Sint-Amands,
Belgium

Company contact address:

For further information on your medicine contact Medical Information at the following address:
Pfizer Healthcare Ireland Unlimited Company, The Watermarque Building, Ringsend Road,
Dublin 4, D04 K7N3, Ireland. Telephone 1800 633 363.

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The following information is intended for healthcare professionals only:

PHYSICIAN LEAFLET

Dalacin® C Phosphate 150 mg/ml Concentrate for Solution for Injection/Infusion
clindamycin (as clindamycin phosphate)

FOR FURTHER INFORMATION PLEASE REFER TO THE SUMMARY OF PRODUCT CHARACTERISTICS.

Posology and method of administration

Posology

Parenteral (IM or IV administration).

Dalacin C Phosphate **must** be diluted prior to IV administration and should be infused slowly and should be infused over at least 10-60 minutes (see '**Dilution for IV use and IV infusion rates**' at the end of the section).

Dalacin C Phosphate IM administration should be used undiluted.

Method of administration

Dilution for IV use and IV infusion rates

The concentration of clindamycin in diluent for infusion should not exceed 18 mg per ml and INFUSION RATES SHOULD NOT EXCEED 30 MG PER MINUTE. The usual infusion rates are as follows:

<u>Dose</u>	<u>Diluent</u>	<u>Time</u>
300 mg	50 ml	10 min
600 mg	50 ml	20 min
900 mg	50-100 ml	30 min
1200 mg	100 ml	40 min

Special precautions for disposal and other handling

Dalacin C Phosphate has been known to be physically and chemically compatible for at least 24 hours in dextrose 5% water and sodium chloride injection solutions containing the following antibiotics in usually administered concentrations: Amikacin sulfate, aztreonam, cefamandole nafate, cephazolin sodium, cefotaxime sodium, ceftazidime sodium, ceftazidime sodium, ceftizoxime sodium, gentamicin sulfate, netilmicin sulfate, piperacillin and tobramycin.

The compatibility and duration of stability of drug admixtures will vary depending upon concentration and other conditions.

Dalacin C Phosphate is a single dose use only and any unused contents should be discarded.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Incompatibilities

Solutions of clindamycin salts have a low pH and incompatibilities may reasonably be expected with alkaline preparations or drugs unstable at low pH. Incompatibility has been reported with: ampicillin sodium, aminophylline, barbiturates, calcium gluconate, ceftriaxone sodium, diphenyl

hydanton, ciprofloxacin, idarubicin hydrochloride, magnesium sulphate, phenytoin sodium and ranitidine hydrochloride.

Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze.