

Package leaflet: Information for the patient

Dalacin C® Phosphate Sterile Solution 150 mg/ml 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 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 Sterile Solution is and what it is used for
2. What you need to know before you use Dalacin C Sterile Solution
3. How to use Dalacin C Sterile Solution
4. Possible side effects
5. How to store Dalacin C Sterile Solution
6. Contents of the pack and other information

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

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

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

Do not use Dalacin C Sterile Solution

- If you are allergic to clindamycin, lincomycin or any of the other ingredients of this medicine (listed in section 6).
- In premature babies or neonates.

Warnings and precautions

Talk to your doctor before taking Dalacin C Sterile Solution if you:

- 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 severe or prolonged or bloody diarrhoea during or after using this medicine, **tell your doctor immediately** since it may be necessary to interrupt the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur even after 2 to 3 weeks following treatment with antibiotics.
- suffer from problems with your kidneys or liver.
- suffer from asthma, eczema or hayfever.

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 Sterile Solution

Tell your doctor if you are taking, have recently taken or might take any other medicines. Some medicines can affect the way Dalacin C Sterile Solution works, or Dalacin C Sterile Solution itself can reduce the effectiveness of other medicines taken at the same time. These include:

- muscle relaxants used during operations.
- oral contraceptive pills. You should use extra contraception such as condoms whilst receiving this medicine and for seven days after receiving it.
- 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, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

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

Breast-feeding

Tell your doctor if you will be breast-feeding while taking this medicine as it may be passed into breast milk. Your doctor will decide if Dalacin is appropriate for you. Although it is not likely that a nursing infant will take in very much of the active substance from the milk it drinks, if your baby gets bloodstained diarrhoea or shows any signs of illness, tell your doctor at once. You should stop breast-feeding if this happens.

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

Driving and using machines

No effects on the ability to drive or use machines have been seen with this medicine.

Dalacin C Sterile Solution contains benzyl alcohol and sodium

This medicine contains 18 mg of benzyl alcohol (2 ml ampoule) and 36 mg of benzyl alcohol (4 ml ampoule) which is equivalent to 9 mg/ml benzyl alcohol. 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").

This medicine 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 Sterile Solution

Your doctor will give you your medicine as an injection into your vein (intravenous) or your muscle (intramuscular). If it is given into a vein, it is always mixed with a sugar or saline (salt) solution before use and given using a drip.

When giving you this medicine, 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 is 600 to 2700 mg of clindamycin per day in two to four 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 of clindamycin per kg bodyweight each day in three or four equal doses. This medicine 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.

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 this medicine, your doctor may want to check that it is not having any effect on the way your kidneys and liver are working.

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:

- severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever).
This is a common side effect which may occur during or after completing treatment with antibiotics and can be a sign of serious bowel inflammation.
- 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 if affecting the whole body).
- potentially life-threatening skin rashes:
 - blistering and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips

- a widespread rash with blistering and peeling of large areas of 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**)
- 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), known as erythema multiforme
- 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))
- yellowing of the skin and whites of the eyes (jaundice).
- 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).
- 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)
- abnormalities in liver function tests
- rash characterised by a flat, red area on the skin that is covered with small bumps

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
- itchy skin
- hives
- pain, abscess (boil)

Not known: frequency cannot be estimated from available data

- reduced numbers of blood cells which may cause bruising or bleeding or weaken the immune system
- an increase in the number of white blood cells (eosinophilia)
- stomach pain, being sick (throwing up)
- inflammation of the lining of the oesophagus (gullet), open sores or lesions in the lining of the oesophagus (gullet)
- infection inside and around the vagina
- 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dalacin C Sterile 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 vial label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not refrigerate or freeze.

6. Contents of the pack and other information

What Dalacin C Sterile Solution contains

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

The other ingredients are benzyl alcohol (E1519), disodium edetate and sterilised water for injections (see section 2 “Dalacin C Sterile Solution contains benzyl alcohol and sodium”).

What Dalacin C Sterile Solution looks like and contents of the pack

Dalacin C Sterile 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:

Pfizer Limited,
Ramsgate Road,
Sandwich,
Kent,
CT13 9NJ,
UK.

Manufacturer:

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

Company Contact address

For further information on this medicine, please contact Medical Information at Pfizer Limited, Walton Oaks, Tadworth, Surrey, UK.

Tel: 01304 616161.

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The following information is intended for healthcare professionals only:

Dalacin C® Phosphate Sterile Solution
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 Sterile Solution **must** be diluted prior to IV administration and should be infused over at least 10-60 minutes (see '**Dilution for IV use and IV infusion rates**' below). Dalacin C Phosphate Sterile Solution should be used undiluted for IM administration.

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 shown 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, 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, ciprofloxacin, diphenylhydantoin, idarubicin hydrochloride, magnesium sulfate, phenytoin sodium and ranitidine hydrochloride.

Special precautions for storage

Do not store above 25°C.

Do not refrigerate or freeze.