

*Your doctor is the best resource for medical advice and information. The health information contained herein is provided for educational / awareness purposes only and is not intended to replace discussions with a medical practitioner and/or medical advice or be construed as a promotional information.*

---

# Package Leaflet: Information for the user

## Clindamycin

### Capsules I.P. and Injection I.P.

### DALACIN C<sup>®</sup>

---

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

- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

#### **1. What Dalacin C (Clindamycin) is and what it is used for**

Clindamycin is an antibiotic, a medicine for fighting against certain pathogens. It belongs to the group of the lincosamides.

Clindamycin is indicated in the treatment of serious infections, when caused by clindamycin susceptible strains of gram-positive aerobes such as streptococci, pneumococci and staphylococci, or by susceptible anaerobic bacteria. In cases of aerobic infections clindamycin is an alternative if other antimicrobial drugs are inactive or contraindicated. In cases of anaerobic infections clindamycin can be considered as a first choice drug.

1. Upper respiratory tract infections: chronic sinusitis caused by anaerobic strains. Clindamycin can be used for selected cases of chronic suppurative otitis media or as adjunctive therapy along with an antibiotic active against aerobic gram-negative organisms. Infections caused by *H. influenzae* are not an indication (see section 5.2). Clindamycin can also be used in cases of recurrent pharyngotonsillitis.
2. Lower respiratory tract infections including infectious exacerbation of chronic bronchitis and pneumonia.

---

<sup>\*</sup> Trademark Proprietor: Pfizer Inc

3. Serious skin and soft tissue infections caused by susceptible organisms.
4. Bone and joint infections including osteomyelitis and septic arthritis.
5. Serious gynaecological infections of the pelvis including pelvic inflammatory disease (PID). Clindamycin can also be used in a single therapy in cases of cervicitis due to *Chlamydia trachomatis*.
6. Intra-abdominal infections including peritonitis and abdominal abscess. In simultaneous administration associated with a suitable Gram-negative antibiotic such as an aminoglycoside, clindamycin appears to be effective in preventing peritonitis or intra-abdominal abscesses after perforation and bacterial contamination following trauma.
7. Septicaemia and endocarditis.  
  
Selected cases of septicaemia and/or endocarditis due to susceptible organisms have responded well to clindamycin. However, bactericidal drugs are often preferred for these infections.
8. Dental infections including periodontal abscess and periodontitis.
9. Toxoplasmic encephalitis in patient with AIDS. In patients who cannot tolerate the usual treatment, clindamycin may be used in combination with pyrimethamine.
10. *Pneumocystis jirovecii* pneumonia in patients with AIDS. In patients who cannot tolerate the usual treatment, clindamycin may be used in combination with primaquine.
11. Malaria, including multi-resistant *Plasmodium falciparum*, in combination with quinine.
12. Prophylaxis of infection in neck and head surgery. Clindamycin phosphate, diluted in normal saline, is used as an intraoperative irrigant of the surgical field.

## **2. What you need to know before you take Dalacin C (Clindamycin)**

### **Do not take Dalacin C (Clindamycin)**

- If you are allergic to clindamycin, lincomycin or any of the other ingredients of this medicine (listed in section 6)
- In cases of meningitis (infection of the meninges)

### **Warnings and precautions**

Talk to your doctor before using Dalacin C (Clindamycin).

- This medicine has been prescribed to you as part of a medicinal treatment. It must not be used by others. Consult your doctor first before using this medicine for other conditions.
- Tell your doctor if you have bowel problems, severe kidney function disorders, severe liver function disorders or if you are hypersensitive. This may be important for you.
- Tell your doctor if you experience signs of hypersensitivity, such as irritation, itching, inflammation or skin reactions. It may be necessary to stop the treatment.

- Also tell your doctor if you experience diarrhoea, especially if it is severe, persistent or bloody, during or after the treatment. This may be a sign of severe inflammation of the colon due to infection by a bacterium called *Clostridioides difficile*. It may be necessary to stop the treatment.
- Undiluted Dalacin C (Clindamycin) must never be administered intravenously. Therefore, intravenous administration is by infusion over 10 to 60 minutes.
- Dalacin C (Clindamycin) solution for injection must not be used in new-borns, whether or not premature, unless absolutely necessary, due to the risk of serious toxic reactions, including abnormal breathing (“gasping syndrome”). See “Dalacin C (Clindamycin) solution for injection contains 9.45 mg of benzyl alcohol per ml” below.
- As with any antibiotic preparation, it is important to remain alert to potential signs of infection by non-susceptible organisms, including fungi.
- If you are already taking other medicines, please also read the section “Other medicines and Dalacin C (Clindamycin)”.
- Oral capsules: Due to the risk of inflammation of the oesophagus (oesophagitis) and oesophageal ulcer, it is important to always take Dalacin C hard capsules exactly as described in section 3.
- 
- If you have a kidney or liver disorder (also see “Dalacin C (Clindamycin) solution for injection contains 9.45 mg of benzyl alcohol per ml”).
- 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.

Talk to your doctor if any of the warnings above applies to you or has applied to you in the past.

In cases of long-term treatment with this medicine, your doctor may carry out further tests on your liver or kidney function.

### **Other medicines and Dalacin C (Clindamycin)**

Tell your doctor if you are taking/using, have recently taken/used or might take/use any other medicines.

Taking multiple medicines can influence the reciprocal activities and/or side effects of these medicines, for example, when other medicines against infections (specifically rifampicin or erythromycin and similar medicines) or medicines used in general anaesthesia during surgery are administered at the same time as Dalacin C (Clindamycin).

If you are using warfarin or similar medicines (used to thin the blood), you might be more susceptible to bleeding. Your doctor may prescribe blood tests in order to check that your blood is clotting properly.

Dalacin C (Clindamycin) may increase the effect of muscle relaxants. Therefore, take Dalacin C (Clindamycin) with caution and with the advice of a doctor when taking it at the same time as muscle relaxants.

Talk to your doctor about using other medicines at the same time as this medicine.

## **Dalacin C (Clindamycin) with food, drink and alcohol**

Talk to your doctor about consuming alcohol at the same time as this medicine.

Swallow the gel capsule whole with a full glass of water and no less than 30 minutes before lying down to avoid possible irritation of the oesophagus.

## **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

This medicine and the benzyl alcohol contained in the solution for injection both cross the placenta.

This medicine is not recommended during the first trimester of pregnancy. Dalacin C (Clindamycin) should only be used during the second and third trimesters of pregnancy under the advice of your doctor (also see: “Dalacin C (Clindamycin) solution for injection contains 9.45 mg of benzyl alcohol per ml”).

Small amounts of this medicine are excreted in breast milk. As serious side effects can occur to the gastrointestinal flora in breast-fed infants, such as diarrhoea or blood in the stools, or rash (skin rash), a decision must be made when you use Dalacin C (Clindamycin) while breast-feeding, the risks and benefits should be carefully weighed against each other, taking into account the importance of the treatment for the mother and the potential side effects for the breastfed infant from this medicine.

Ask your doctor about using this medicine while breast-feeding.

## **Driving and using machines**

Dalacin C (Clindamycin) has little to no influence on the ability to drive and use machines.

## **Dalacin C (Clindamycin) solution for injection contains 9.45 mg of benzyl alcohol per ml**

Dalacin C (Clindamycin) solution must not be used in new-borns and young children, unless advised to do so by your doctor.

Benzyl alcohol is associated with a risk of serious side effects, including breathing issues (known as “gasping syndrome”). Benzyl alcohol can cause allergic reactions.

Ask your doctor for advice if you are **pregnant or breast-feeding** or if you have **liver or kidney problems**. Large amounts of benzyl alcohol can accumulate in your body and cause side effects (known as “metabolic acidosis”).

## **Dalacin C (Clindamycin) gelatin capsules contain lactose**

The gelatin capsules contain lactose. If your doctor has told you that you are intolerant to some sugars, contact him/her before taking this medicine.

**Dalacin C (Clindamycin) solution for injection contains less than 1 mmol (23 mg) of sodium per dose, meaning it is essentially “sodium-free”.**

## **3. How to use Dalacin C (Clindamycin)**

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The dose is determined by your doctor. In general, the doses below apply according to the severity and nature of the condition:

**Adults:**

Clindamycin hydrochloride capsules (oral administration):

The usual daily dose is 600-1800 mg divided in 3 or 4 administrations.

In the exceptional case of a treatment for recurrent  $\beta$ -haemolytic streptococcal infection: 300 mg, twice daily for at least 10 days.

Cervicitis due to *Chlamydia trachomatis*: 1800 mg per day, divided over several administrations for 10-14 days.

Clindamycin phosphate solution for injection (IM or IV administration):

The usual daily dose of clindamycin phosphate is 2400-2700 mg in 2, 3 or 4 equal doses for intra-abdominal infections, pelvic infections in women and other serious infections, usually combined with a suitable Gram-negative aerobic antibiotic.

Treatment of Pelvic Inflammatory Disease (PID):

Clindamycin phosphate I.V. 900 mg every 8 hours, associated to a suitable Gram-negative spectrum antibiotic (e.g. gentamicin 2 mg/kg, followed by 1.5 mg/kg every 8 hours) in patients with a normal renal function. This treatment should be administered for at least 4 days. From the moment clinical improvement occurs, the treatment should be continued for another 2 days. Then 1800 mg of clindamycin hydrochloride per day should be administered orally, divided over several administrations, up to a total treatment duration of 10 to 14 days.

Dalacin C hard capsules should be taken whole with a full glass of water and no less than 30 minutes before lying down to avoid possible irritation of the oesophagus.

**Use in children:**

Dalacin C should be dosed based on total body weight regardless of obesity.

Clindamycin hydrochloride capsules (for children who are able to swallow capsules) in children older than 1 month:

8-25 mg/kg/day in 3 or 4 equal administrations. Dalacin C capsules should be taken whole with a full glass of water and no less than 30 minutes before lying down to avoid possible irritation of the oesophagus.

Clindamycin capsules are not suitable for children who are unable to swallow them.

Clindamycin phosphate (IM or IV administration) in children older than 1 month:

20-40 mg/kg/day in 3 or 4 equal administrations.

The dose of solution for injection is determined by your doctor according to the nature and severity of the condition. Intramuscular (IM) Dalacin C (Clindamycin) must not be diluted. Intravenous (IV) Dalacin C (Clindamycin) must be diluted.

Your doctor will tell you how long you need to use Dalacin C (Clindamycin). Do not stop treatment early because your infection may not be cured.

### **If you use more Dalacin C (Clindamycin) than you should**

There are no specific symptoms of overdose.

If you have used or taken too much Dalacin C (Clindamycin), contact your doctor immediately.

### **If you forget to take Dalacin C (Clindamycin)**

It is important to take your capsules regularly at the same time each day. If you miss a dose, take the next one at the scheduled time. Do not take a double dose to make up for a forgotten dose.

As you receive the Dalacin C (Clindamycin) solution for injection under close medical supervision, it is unlikely that you will forget to take a dose. However, if you think this is the case, tell your doctor.

### **If you stop taking Dalacin C (Clindamycin)**

Do not stop your treatment early. If all the bacteria have not been killed, the symptoms may return.

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

## **4. Possible side effects**

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

The side effects of Dalacin C (Clindamycin) may include:

*Common side effects* (may affect up to 1 in 10 people)

- Inflammation with obstruction of a vein (thrombophlebitis) (after intravenous administration)
- Diarrhoea, abdominal pain (see section 2, “Warnings and Precautions”)
- Large intestine disorders (pseudomembranous colitis and *C. difficile* colitis)
- Abnormal liver function tests
- Spotty skin rash (maculopapular rash)
- Increase in the level of one type of white blood cells (eosinophilia)

*Uncommon side effects* (may affect up to 1 in 100 people)

- Taste disorders (dysgeusia)
- Heart problems such as heart failure (after intravenous administration)
- Decrease in blood pressure (after intravenous administration)
- Vomiting, nausea
- Skin irritation, acute skin and mucous membrane disorder (erythema multiforme), itching
- Pain and abscess formation at the injection site (after intramuscular injection)

*Very rare side effects* (may affect up to 1 in 10,000 people)

- Serious, potentially life-threatening allergic reaction (anaphylactic shock) (after intravenous administration)

- Inflammation of the colon caused by a bacterium (colitis)

*Side effects of unknown frequency (cannot be estimated from the available data)*

- Vaginal infection (onset of another infection)
- Disturbance in blood count
- Serious allergic reactions, hypersensitivity
- Inflammation of the oesophagus, oesophageal ulcer (both during oral administration and more likely to occur if Dalacin C hard capsules are taken in a lying position and/or without enough water)
- Jaundice
- Exfoliative skin disease (with scaling) (toxic epidermal necrolysis), Stevens-Johnson Syndrome, serious reactions to medicines such as drug hypersensitivity syndrome with eosinophilia (increased number of a type of white blood cells) and systemic symptoms (DRESS syndrome) and acute generalised exanthematous pustulosis (AGEP), oedema, inflammation of the skin in the form of shreds or blisters
- Irritation at the injection site (after intravenous administration)
- Acute kidney injury

If diarrhoea occurs during treatment, stop the treatment. Specific treatment is sometimes necessary.

During treatment, superimposed yeast infection can occur.

## **5. How to store Dalacin C (Clindamycin)**

*Capsules:* Store below 30°C.

*Injection:* Store at 2°C to 8°C.

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

## **6. Contents of the pack and other information**

### **What Dalacin C (Clindamycin) contains**

- The active substance in Dalacin C 150 and 300 mg gelatin capsules is clindamycin, in the form of clindamycin hydrochloride I.P., which corresponds to 150 or 300 mg of clindamycin respectively.
- The active substance in Dalacin C 300 and 600 mg solution for injection is clindamycin, in the form of clindamycin phosphate U.S.P., which corresponds to 150 mg of clindamycin per ml.
- The other ingredients are:

*Capsules (150 mg/300 mg):*

Magnesium stearate, Maize starch, Talc, Lactose monohydrate

Colour used in 150 mg capsule shell – Titanium dioxide

Colour used in 300 mg capsule shell – Titanium dioxide, Indigocarmine, Erythrosine

*Injection (300 mg/600 mg):*

Benzyl Alcohol (9.45 mg per ml including 5% overages), Disodium Edetate, Sodium Hydroxide (for pH adjustment), Water for injection.

## **What Dalacin C (Clindamycin) looks like and contents of the pack**

### Capsules:

150 mg Capsules - Hard opaque gelatin capsules, size N° 1, with white cap and body, overprinted in black with Pfizer logo and the code "CLIN 150" and containing a white powder.

300 mg Capsules - Hard opaque gelatin capsules, size N° 0, with white cap and body, overprinted in black with Pfizer logo and the code "CLIN 300" and containing a white powder.

### Solution for injection:

An almost colourless solution.

## **Contents of the pack**

### *Capsules (150 mg/300 mg):*

Carton containing 2 blister strips, each blister strip containing 10 capsules.

### *Injection 300 mg:*

Carton containing ampoule pack of 2 ml.

### *Injection 600 mg:*

Carton containing ampoule pack of 4 ml.

Not all pack sizes may be marketed.

## **Imported and Marketed by:**

Capsules -

M/s. Pfizer Products India Private Limited,  
The Capital – B Wing, 1802, 18<sup>th</sup> Floor,  
Plot No. C-70, G Block, Bandra Kurla Complex,  
Bandra (E), Mumbai – 400 051, India

Injection –

M/s. Pfizer Products India Private Limited,  
The Capital – B Wing, 1802, 18<sup>th</sup> Floor,  
Plot No. C-70, G Block, Bandra Kurla Complex,  
Bandra (E), Mumbai – 400 051, India

## **Manufactured by:**

Capsules - M/s. Fareva Amboise, Zone Industrielle 29 Route Des Industries Poce Sur Cisse (France) – 37530

Injection - M/s. Pfizer Manufacturing Belgium NV, Rijksweg 12, B-2870 Puurs, Belgium

*This leaflet was prepared based on LPDDAL112024*