

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**PFIZER**

**Dalacin® C 75 mg Capsules**

clindamycin hydrochloride

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clindamycin hydrochloride

**PFIZER**

### **Read all of this leaflet carefully before you start taking this medicine**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Dalacin is and what it is used for
2. Before you take Dalacin
3. How to take Dalacin
4. Possible side effects
5. How to store Dalacin
6. Further information

#### **1. What Dalacin is and what it is used for**

Dalacin contains clindamycin hydrochloride which is an antibiotic used in the treatment of serious bacterial infections.

#### **2. Before you take Dalacin**

##### **Do not take Dalacin**

If you are allergic (hypersensitive) to clindamycin, lincomycin or to any of the other ingredients in this medicine.

##### **Take special care with Dalacin**

Tell your doctor if you have any of the following conditions to help him or her decide if Dalacin is suitable for you:

- you have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhoea during or after using Dalacin **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 following treatment with antibiotics.
- you suffer from problems with your kidneys or liver.
- you suffer from asthma, eczema or hayfever.

Dalacin 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.

#### **Taking other medicines**

Some medicines can affect the way this medicine works, or the medicine itself can reduce the effectiveness of other medicines taken at the same time. These include:

- erythromycin (an antibiotic).
- muscle relaxants used for operations (neuromuscular blockers).
- oral contraceptive pills. You should use extra contraception such as condoms whilst taking Dalacin and for seven days after taking Dalacin.
- 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.

Please tell your doctor if you are taking or have recently taken any other medicines including medicines obtained without a prescription.

### **Taking Dalacin with food and drink**

The capsules may be taken either before or after a meal.

### **Pregnancy**

If you are pregnant or think you might be pregnant you should contact your doctor before taking Dalacin.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Breast-feeding**

Tell your doctor if you will be breast-feeding while taking Dalacin as the active substance in this medicine 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.

### **Driving and using machines**

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

### **Important information about some of the ingredients of Dalacin Capsules**

Dalacin Capsules contains lactose a type of sugar. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Dalacin**

Always take Dalacin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure how to take this medicine.

Dalacin Capsules should always be swallowed whole with a full glass of water.

### **Adults and Elderly Patients**

The recommended dose of Dalacin is between 150 and 450mg (2 to 6 capsules) every 6 hours, depending on the severity of your infection.

### **Children**

The recommended dose in children is between 3 and 6mg per kg of bodyweight every six hours, depending on the severity of the infection. Your doctor will work out the number of capsules that your child should have.

### **Long term use of Dalacin**

If you have to take Dalacin for a long time, your doctor may arrange regular liver, kidney and blood tests. Do not miss these check-ups with your doctor.

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

#### **If you take more Dalacin Capsules than you should**

If you accidentally take too many Dalacin Capsules contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there are any Dalacin Capsules left or not. Do not take any more capsules until your doctor tells you to.

#### **If you miss a dose of Dalacin**

If the forgotten dose is just a few hours late, use it straight away. If it is nearly time for your next dose miss out the forgotten one. **Do not take a double dose to make up for a missed dose.**

#### **If you stop taking Dalacin**

If you stop taking the medicine too soon your infection may come back again or get worse.

Do not stop taking Dalacin unless your doctor tells you to.

If you have any further questions on how to take this product, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, Dalacin 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 an uncommon 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, swelling of eyelids, face or lips, rash or itching (especially affecting the whole body).
- 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).

Other possible side effects may include:

- **Effects on your nervous system:** impaired sense of taste
- **Effects on your skin:** reddening of the skin, skin rash, itching (hives)
- **Effects on your stomach and intestines:** throat ulcers, sore throat, feeling sick, being sick, stomach pain and diarrhoea
- **Effects on your blood system:** reduced numbers of blood cells which may cause bruising or bleeding or weaken the immune system
- **Effects on your liver:** poor liver function
- **Effects on your genital area:** inflammation of the vagina.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or 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](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Dalacin**

- Keep out of the reach and sight of children.
- Do not use Dalacin C Capsules after the expiry date which is stated on the carton and blister labels. The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. Further information**

### **What Dalacin C Capsules contain**

The active substance is clindamycin hydrochloride. Each capsule contains clindamycin hydrochloride equivalent to 75mg of clindamycin.

The other ingredients are Lactose, Maize starch, Talc, Magnesium stearate.

Capsule: Gelatin, Indigo carmine (E132), Quinoline Yellow (E104).

Printing ink: Shellac, Soya lecithin, Dimeticone (Antifoam DC 1510), Titanium dioxide (E171).

### **What Dalacin C Capsules look like and contents of the pack**

Dalacin C Capsules are hard capsules coloured green/white and with markings of 'CLIN 75' and 'Pfizer'.

Dalacin C Capsules 75 mg are available in blister packs of 24 and 100 capsules.

### **Marketing Authorisation Holder**

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

### **Manufacturer**

Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Pocé-sur-Cisse, France

### **Company Contact address:**

If you have any comments on the way this leaflet is written, please contact Medical Information at Pfizer Limited in Walton Oaks, Tadworth, Surrey.

Tel: 01304 616161.

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