

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lincocin

500 mg hard capsules

LINCOMYCIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 pharmacist • 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

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

1. WHAT LINCOICIN IS AND WHAT IT IS USED FOR

Lincocin contains the active substance lincomycin. Lincomycin is an antibiotic, a medicine for combating certain organisms that cause diseases. It belongs to the group of lincosamides.

Lincocin is used for bacterial infections of the nose, ears, airways, skin, bones, joints, heart and blood.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE/USE LINCOICIN

Do not take/use Lincocin:

- if you are allergic to lincomycin or any of the other ingredients of this medicine (listed in section 6);
- if you have meningitis.

Warnings and precautions

Talk to your doctor, pharmacist, or a medical professional before taking/using Lincocin.

- Tell your doctor if you have intestinal problems or have serious kidney or liver failure.
- Tell your doctor if you are allergic to the medicine.

- Also let your doctor know when diarrhoea occurs, especially if it is severe, persistent or bloody during or after treatment. This may be a sign of severe inflammation of the colon due to superinfection by a bacterium called *Clostridium difficile*. It may be necessary to discontinue treatment.
- In case of long-term treatment with this medicine, your doctor may carry out further tests to monitor your liver or kidney functions. In case of treatment with doses, your doctor may have your blood tested.
- As with any antibiotic treatment, it is advisable to stay alert for any signs of a superinfection by non-susceptible organisms, including fungi.
- If you are already taking other medicines, please also read the section “Other medicines and Lincocin”.

Other medicines and Lincocin

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Some medicines may specifically affect the effects and/or side effects each other. For example, when certain other medicines for infections (in particular erythromycin and similar agents), certain medicines administered during surgeries for general anaesthesia, or certain medicines for diarrhoea (in particular kaolin/pectin) are used together with Lincocin.

Certain medicines may affect the results of a blood test: this can be the case for Lincocin in liver function tests.

Use of Lincocin with food, drink, and alcohol

You should ask your doctor or pharmacist for advice about taking/using this medicine simultaneously with alcohol.

Pregnancy, breast-feeding and fertility

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

Discuss the possible use of this medicine with your doctor if you are pregnant. Lincomycin should only be used during pregnancy if the treatment is truly necessary.

This medicine is excreted into breast milk in small amounts. Since there is a possibility for severe side effects to occur in breast-fed infants, your doctor will decide whether breast-feeding or treatment should be discontinued, taking into consideration the importance of the medicine for you.

Driving and using machines

Although no specific effect on driving and using machines has been observed, occasional dizziness has been reported.

Lincocin 500 mg hard capsules contain lactose

Only take Lincocin after consulting your doctor, if you know that you have a sugar intolerance.

3. HOW TO TAKE/USE LINCOCIN

Always take/use Lincocin exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The hard capsules are to be taken whole with a glass of water.

The dose will be determined by your doctor. The following dosages usually apply, depending on the severity and type of disease: 1 x 500 mg hard capsule 3 to 4 times daily, at least 1 hour before or 1 hour after meals.

Your doctor will tell you how long you must take Lincocin. Do not prematurely interrupt your treatment, because symptoms can occur again when an antibiotic treatment is ended too soon and all the bacteria are therefore not destroyed.

If you use more Lincocin than you should

If you take more Lincocin than you should, contact your doctor, your pharmacist or the poison control centre immediately.

Stomach aches, nausea, vomiting and diarrhoea may occur when too high a dose is taken. Your doctor will induce vomiting or conduct a gastric lavage.

If you forget to use Lincocin

If you have forgotten a dose, take the next one at the scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop using Lincocin

Always consult with your doctor if you are thinking about stopping treatment.

When an antibiotic treatment is ended too soon and all the bacteria are therefore not destroyed, symptoms can occur again.

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

4. POSSIBLE SIDE EFFECTS

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

The following side effects may occur with the use of Lincocin:

- Gastrointestinal disorders: such as stomach aches, nausea, vomiting, diarrhoea and potential inflammation of the oesophagus. If severe and long-term episodes of diarrhoea occur during treatment, the treatment must be stopped. These effects can occur up to 2-3 weeks after the end of treatment. A specific treatment of the diarrhoea is sometimes required.
- Blood disorders: Deficiency or reduction in white blood cell count (neutropoenia, agranulocytosis or leukopoenia), blood platelet deficiency (thrombocytopenia), anaemia, reduction of all types of blood cells (pancytopenia).
- Hypersensitivity reactions: angioneurotic syndrome (itching and swelling of the skin), serum sickness (fever, swelling and joint pain, which may lead to shock), morbilliform rash (rash on clearly delineated, pink, small areas of skin, between which healthy areas of skin can be seen).
- Skin and mucous membrane disorders: Itching, rash, redness, inflammation of the vagina, skin inflammation with flaking (top layer of skin falling off in scales) and blisters.
- Liver disorders: Jaundice, abnormal liver function tests.
- Cardiac disorders: Hypotension (low blood pressure) after too fast an intravenous administration, which in rare cases may lead to cardiopulmonary arrest.
- Local reactions: with injection into a vein: Inflammation, usually at the injection site, accompanied by swelling and pain.
- Other: Superinfection with non-susceptible organisms, especially fungi.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or to a medical professional. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE LINCOCIN

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

Do not store above 25 °C.

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

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lincocin contains

- The active substance is lincomycin (as lincomycin hydrochloride). Each hard capsule contains 500 mg lincomycin.
- The other ingredients are Lactose, talc and magnesium stearate in a hard capsule, the components of which are: Indigotindisulfonate sodium, titanium oxide and gelatin.

What Lincocin looks like and contents of the pack

- Dark blue (top side) and light blue (bottom side) hard capsules, filled with a white powder and with the inscription "P&U 500" on both parts.
- Pack with 12 hard capsules at 500 mg

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Pfizer S.A., 17 Boulevard de la Plaine, 1050 Brussels, Belgium.

Manufacturer:

Pfizer Manufacturing Belgium N.V., Rijksweg 12, 2870 Puurs, Belgium; or Pfizer Italia S.r.l., Località Marino del Tronto, 63100 Ascoli Piceno (AP), Italy

Status: Only available by prescription.

This package leaflet was last revised in 07/2015.