



LINCOCIN™

Lincomycin

Lincocin 300 mg – 600 mg solution for Injection

Reference Market: Belgium

Package leaflet

**Package Leaflet: information for the patient
Lincocin 300 mg – 600 mg solution for injection**

lincomycin

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.

- Ask your doctor, pharmacist or nurse if you need more information or advice.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Lincocin is and what it is used for

Lincocin contains the active substance lincomycin. Lincomycin is an antibiotic, a medicine used to combat certain microbes that cause disease. It belongs to the group of medicines called lincosamides.

Lincocin is used in cases of bacterial infection of the nose, ears, respiratory tract, skin, bones, joints, heart and blood.

2. What you need to know before you use Lincocin

Do not use Lincocin:

- if you are allergic to lincomycin, clindamycin or any of the other ingredients of this medicine listed in section 6;
- if you suffer from an inflammation of the meninges (the thin lining that surrounds the brain and the spinal cord) (meningitis).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Lincocin.

- Tell your doctor if you have intestinal problems, severe kidney or liver function disorders.
- If you notice an allergic reaction to the medicine, tell your doctor.
- If you have a severe skin reaction, see your doctor immediately.
- You should also tell your doctor if you have diarrhoea, especially if it is severe, persistent or bloody, either during or after the treatment. This may be a sign of severe inflammation of the colon due to infection by a bacterium called *Clostridium difficile*. It may be necessary to discontinue treatment if this is the case.
- In case of prolonged treatment with this medicine, your doctor may ask you to undergo further examinations to assess the functioning of your liver and/or kidneys. If you are being treated with high doses, your doctor may ask you to undergo a blood test.
- Lincocin solution for injection should not be used in pre-term or full-term newborn infants, unless it is absolutely necessary due to the risk of serious toxic reactions, including abnormal breathing ("gasping syndrome"). See the section below "Lincocin 300 mg and 600 mg solution for injection contains benzyl alcohol".
- As with any antibiotic treatment, vigilance is required for any signs of superinfection by non-susceptible organisms, including fungi.
- If you are taking other medicines, please also read the section "Other medicines and Lincocin".

Lincocin must never be administered intravenously when undiluted. Intravenous administration must therefore take the form of an infusion of at least 1 hour.

Use in children and adolescents

The injectable form of this product contains benzyl alcohol. Lincocin 300 mg and 600 mg solution for injection should not be given to newborn infants (up to 4 weeks) and should not be used for more than one week in young children (less than 3 years old), unless advised by a doctor (see “**Lincocin 300 mg and 600 mg solution for injection contains benzyl alcohol**”).

Patients with kidney and/or liver disorders

If you have a kidney and/or liver disorder, inform your doctor, pharmacist or nurse. Your dose should be reduced.

Other medicines and Lincocin

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

Different medicines used together may influence each other's activity and/or their side effects, for example when certain other medicines for infections (including erythromycin and analogues), certain medicines used in general anaesthesia during operations, and certain medicines for diarrhoea (including kaolin / pectin), are used at the same time as Lincocin.

Certain medicines can also affect the results of blood tests. With Lincocin, this may be the case for tests of liver function.

Lincocin with food, drink and alcohol

Consult your doctor or pharmacist about drinking alcohol while you are using this medicine.

Pregnancy, breastfeeding and fertility

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

Talk with your doctor about the possible use of this medicine during pregnancy. Lincomycin should not be used during pregnancy unless the treatment is absolutely necessary.

Benzyl alcohol can cross the placenta (see below “Lincocin 300 mg and 600 mg solution for injection contains benzyl alcohol”).

This medicine is excreted in small amounts in breast milk. Since the possibility exists that serious adverse effects may occur in breastfed infants, your doctor will decide whether to discontinue either breastfeeding or the medicine, taking into account the importance of the medicine to your treatment.

Lincocin 300 mg and 600 mg solution for injection contains benzyl alcohol, a preservative that is likely to pass into breast milk. (see below “Lincocin 300 mg and 600 mg solution for injection contains benzyl alcohol”).

Driving and using machines

No study aiming to determine the effect of lincomycin on the ability to drive or use machines has been conducted. Although no specific effects have been observed on the ability to drive or use machines, occasional dizziness has been reported.

Lincocin 300 mg and 600 mg solution for injection contain benzyl alcohol.

The solution for injection contains 9.45 mg of benzyl alcohol per mL.

Benzyl alcohol can cause allergic reactions. Benzyl alcohol has been associated with the risk of severe side effects including breathing problems (called “gasping syndrome”) in young children. Lincocin solution for injection should not be given to newborn infants (up to 4 weeks) unless recommended by a doctor. Lincocin solution for injection should not be used for more than one week in young children (less than 3 years old), unless advised by a doctor. Taking large amounts of Lincocin can cause a build-up of benzyl alcohol in your body resulting in an increase in acid levels in

your blood (called “metabolic acidosis”). Patients with liver or kidney disease or women who are pregnant or breastfeeding should be particularly careful and consult their doctor.

Contact your doctor or pharmacist if you have liver or kidney problems or if you are pregnant or breastfeeding as large volumes of this product can cause toxic reactions (disruption in your metabolism).

3. How to use Lincocin

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

The dose of the **solution for injection** will be determined by your doctor, based on the nature and severity of the illness.

Your doctor will tell you how long you need to use Lincocin for. Do not stop your treatment prematurely. When antibiotic treatment is stopped too early, not all bacteria are destroyed and the symptoms may return.

If you use more Lincocin than you should

If you have used or taken too much Lincocin, immediately contact your doctor, pharmacist.

When excessive amounts have been taken, stomach aches, nausea, vomiting and diarrhoea can occur. Your doctor may induce vomiting or perform a gastric lavage.

If the medicine is injected too rapidly into a vein without dilution, you may experience heart problems. However, this does not occur when Lincocin is administered correctly.

If you forget to use Lincocin

If you miss a dose, take your next dose as scheduled. Do not take a double dose to make up for a forgotten dose.

If you forget to use Lincocin

Always consult your doctor if you are considering stopping treatment.

When antibiotic treatment is stopped too early, not all bacteria are destroyed and the symptoms may return.

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

4. Possible side effects

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

The following side effects can occur when using Lincocin:

Common: may affect up to 1 in 10 people

- Nausea, vomiting, diarrhoea (see section 2 “Warnings and precautions”)

Uncommon: may affect up to 1 in 100 people

- Vaginal infection
- Rash, redness to the skin

Rare: may affect up to 1 in 1,000 people

- Itching

Not known: cannot be estimated from the available data

- Large intestine disorder (pseudomembranous colitis), inflammation of the colon due to bacteria (colitis)
- Deficit or reduction in the number of white blood cells (neutropenia, agranulocytosis or leucopenia), red marks on the skin due to a platelet deficit (thrombocytopenic purpura), anaemia, reduction in all blood cell components (pancytopenia)
- Potentially fatal severe allergic reaction (anaphylactic reaction), angioedema (allergic reaction characterised by swelling on the face and neck), serum sickness (fever, joint pain and stiffness that may result in shock)
- Heart problems such as palpitations, low blood pressure and heart attack (following intravenous administration)
- Inflammation with potential obstruction of a vein (thrombophlebitis) (following intravenous administration)
- Abdominal discomfort
- Jaundice, liver function test anomalies
- Severe acute reactions of the skin (toxic epidermal necrolysis (TEN), generalised acute exanthematous pustulosis (AGEP) and mucous membranes (erythema multiforme), inflammation of the skin with peeling (shedding of the outer layer of the skin in sheets) and blisters, potentially fatal rash (Stevens-Johnson syndrome)

If diarrhoea occurs during treatment, treatment must be suspended. Specific treatment is sometimes required.

When taking treatment, a yeast cross-infection can occur.

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.

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 wastewater 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**

Lincocin 300 mg - 600 mg solution for injection:

- The active substance is lincomycin (as lincomycin hydrochloride). Each mL of solution for injection contains 300 mg of lincomycin.
- The other ingredients are benzyl alcohol (see section 2 “Lincocin 300 mg and 600 mg solution for injection contain benzyl alcohol”), water for injections.

What Lincocin looks like and contents of the pack

Lincocin 300 mg/mL solution for injection - vials:

- The solution for injection is a colourless solution
- Packs with 1, 2, 3, 5, 6, 10, 25 and 100 vials

Lincocin 600mg/mL solution for injection vials: 1 vial/pack

Not all pack sizes may be marketed.

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

Status: Only available by prescription.

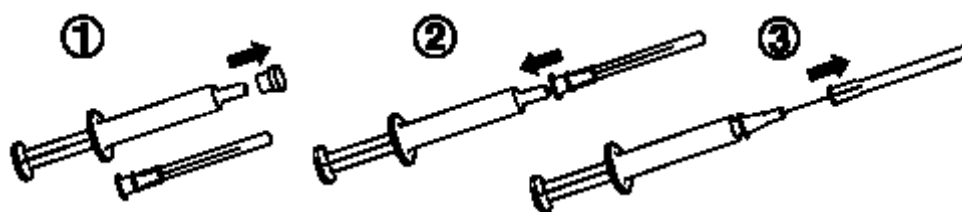
This leaflet was last revised in January 2021.

The following information is intended for healthcare professionals only:

In a solution for infusion, the following medicines are physically incompatible with lincomycin: novobiocin, kanamycin and phenytoin.

INSTRUCTIONS FOR THE DISPOSABLE SYRINGE:

1. Remove the protective cap
 2. Attach needle to syringe
 3. Remove needle guard
- The syringe is ready for use.



Discard the syringe after use; do not reuse.

Lincomycin must never be injected as an undiluted IV bolus but must be infused over a period of at least 1 hour (see section below, “Methods of dilution and infusion”).

METHODS OF DILUTION AND INFUSION

IV doses are administered on the basis of 1 gram of lincomycin diluted in at least 100 mL of an appropriate solution (e.g. 0.9% sodium chloride or 5% glucose) and infused over the course of at least one hour.

<u>Dose</u>	<u>Volume</u>	<u>Time</u>
600 mg	100 mL	1 hour
1 g	100 mL	1 hour
2 g	200 mL	2 hours
3 g	300 mL	3 hours
4 g	400 mL	4 hours

These doses may be repeated as often as necessary, not exceeding 8 grams of lincomycin per day.

Note:

Serious cardiopulmonary reactions have been observed when the recommended administration concentration and speed were exceeded.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach and sight of children

**Council of Arab Health Ministers
Union of Arabic Pharmacists**