

PACKAGE LEAFLET: INFORMATION FOR THE USER

Clindamycin 150 mg/ml solution for injection/ concentrate for solution for infusion

Clindamycin

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, pharmacist, nurse or healthcare personnel.
- If you get any side effects talk to your doctor, pharmacist, nurse or healthcare personnel. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Clindamycin is and what it is used for

Clindamycin contains the active substance Clindamycin (as phosphate). Clindamycin is an antibiotic.

Clindamycin is used for the treatment of severe infections caused by clindamycin-sensitive pathogens. In case of aerobic infections clindamycin constitutes an alternative treatment in case other antibacterial agents are inactive or contra-indicated (e.g. in case of allergy to penicillins). In case of anaerobic infections a treatment with clindamycin as first choice agent can be envisaged.

Clindamycin is used for the treatment of:

- bone and joint infections
- chronic infections of paranasal sinuses
- infections of the lower respiratory tract
- abdominal infections (peritonitis)
- infections of the reproductive organs
- skin and soft tissue infections

2. What you need to know before you use Clindamycin

You must not be given Clindamycin in the following cases:

- if you are allergic to clindamycin or lincomycin or any of the other ingredients of Clindamycin (listed in section 6)

Warnings and precautions

Talk to your doctor, pharmacist, nurse or healthcare personnel before using Clindamycin

- if you suffer from impaired liver and kidney function,
- if you have problems with your muscle functions caused by e.g. Myasthenia gravis (pathological muscular weakness) or Parkinson disease (so called shaking palsy),
- if you have previously suffered from gastro-intestinal diseases (e.g. earlier inflammation of the colon),

- if you suffer from any kind of allergies, e.g. hypersensitivity to penicillin because in individual cases allergic reactions to Clindamycin have been reported for people with a known penicillin hypersensitivity.

You should consult your doctor if one of the precautions and warnings mentioned above are or were applicable to you in the past.

Severe hypersensitivity reactions, including severe skin reactions such as drug reactions with increased number of eosinophiles (type of blood cells) and symptoms affecting the entire body (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP) have been reported in patients receiving clindamycin therapy. If a hypersensitivity or severe skin reaction occurs, talk to your doctor immediately.

Severe allergic reactions can occur even after the first application. In this event your doctor will discontinue the treatment with Clindamycin immediately and will implement the standard emergency measures.

Rapid intravenous injection causes undesirable effects and must be avoided. Your doctor will dilute the medicine prior to administration into a vein and will ensure that it will be infused over at least 10-60 minutes.

In long-term therapy (more than 10 days) the blood count and the liver and renal function should be monitored regularly.

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.

Long-term and repeated use of Clindamycin may cause an infection of skin and soft mucosa with pathogens not sensitive to clindamycin. It may also lead to the development of a fungal infection. During treatment with clindamycin a severe infection of the colon (colitis) may occur. Therefore, you should **immediately** inform your doctor if you suffer from severe and persisting diarrhoea during or up to two months after treatment, especially when mucus or blood is in the stool.

Clindamycin should not be used in case of acute infections of the respiratory tract, if these are caused by viruses.

Clindamycin is not suitable for the treatment of brain fever (meningitis).

Children

Special care should be taken with children up to 3 years because this medicinal product contains benzyl alcohol (see below).

Other medicines and Clindamycin

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

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.

Clindamycin should not be given in combination with medicinal products containing erythromycin because a mutual reduction of efficacy can not be excluded.

Clindamycin should not be given after treatment with lincomycin.

Clindamycin may increase the efficacy of muscle relaxants which may lead to unexpected, life-threatening incidences during surgery measures.

Rifampicin may increase the elimination of clindamycin from the blood, therefore your doctor should regularly control the blood level of clindamycin.

Pregnancy and breast-feeding

Tell your doctor if:

- you are pregnant or think you might be pregnant. The doctor will decide how to use Clindamycin after comparing risk and benefit of your treatment with Clindamycin.
- you are breast-feeding. This medicine can pass into breast milk. In the breast-fed infant, sensibilisation (creation of hypersensitivity), diarrhoea and fungal infections can occur.

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

Driving and using machines

You may feel dizzy, tired or suffer from headaches when taking this medicine. If you are affected, do not drive or use any tools or machines.

Clindamycin contains sodium chloride and benzyl alcohol

Sodium chloride

This medicine contains 8.5 mg sodium (main component of cooking/table salt) in each ml solution. This is equivalent to 0.43% of the recommended maximum daily dietary intake of sodium for an adult.

Benzyl alcohol

This medicine contains 9 mg benzyl alcohol in each ml solution.

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 young children.

Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor.

Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice 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 (called “metabolic acidosis”).

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

3. How to use Clindamycin

Clindamycin is administered by intramuscular injection (into a muscle) of the undiluted solution or by intravenous infusion (into a vein) of the diluted solution. It will usually be given by a doctor or a nurse.

Your doctor will decide on the correct dose of clindamycin therapy for you.

Adults and adolescents older than 12 years usually obtain

- for the treatment of less complicated infections:
8 to 12 ml Clindamycin daily (corresponding to 1.2 to 1.8 g clindamycin),
- for the treatment of severe infections:
12 to 18 ml Clindamycin (corresponding to 1.8 to 2.7 g clindamycin)

in two to four equal doses.

Normally the maximum daily dosage for adults and adolescents older than 12 years is 18 ml Clindamycin (corresponding to 2.7 g clindamycin) in two to four equal doses. In life-threatening infections doses up to 4.8 g/day can be given.

In patients with liver and renal diseases the metabolism of clindamycin is reduced. However, in most cases a dosage adaption is not necessary. Monitoring of the blood level of Clindamycin is recommended.

Clindamycin is not haemodialysable. Therefore, no additional dose is necessary before or after haemodialysis.

Use in Children

Depending on the severity and site of infection children aged older than 4 weeks up to 12 years obtain 15 – 40 mg Clindamycin per kg body weight in three to four equal doses.

The duration of treatment depends on the disease and its development.

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

4. Possible side effects

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

Very common: may affect more than 1 in 10 people

- Gastrointestinal disorders in the form of diarrhoea, abdominal pain, vomiting, nausea.

Common: may affect up to 1 in 10 people

- Pseudomembranous colitis (inflammation of the large intestine) may be caused by antibiotics, can be life threatening and requires **immediate** appropriate treatment.
- Blood abnormalities like marked decrease of blood granulocytes (agranulocytosis), neutropenia (lack of neutrophils), tendency to bleed (thrombocytopenia), leucopenia (lack of white blood cells) and eosinophilia (increase of eosinophilic cells).
- Disorders of the blood vessels like thrombophlebitis (inflammation of the vein).
- Skin disorders like exanthema (widespread rash with small nodules), urticaria (nettle rash).
- Liver function tests may be affected.

Uncommon: may affect up to 1 in 100 people

- Disorders of the nervous system like a neuromuscular-blocking effect (blocking of the rendering of nerve impulses on a muscle) and distortion of the sense of taste (dysgeusia).
- Cardiac and vascular disorders like cardiorespiratory arrest and drop in blood pressure (hypotension).
- General disorders and disorders at the administration site like pain and abscess (boil) at the injection site.

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

- Drug fever, hypersensitivity reaction to a specific ingredient of the medicine (benzyl alcohol)
- Serious skin reactions:
 - a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (toxic epidermal necrolysis)
 - widespread red skin rash with small pus-containing blisters (exfoliative dermatitis bullous)
 - angioedema (swelling, particularly around the face and neck, wheezing and/or difficulty breathing)
- Pruritus
- Vaginitis (inflammation of the vaginal mucosa)

Very rare: may affect up to 1 in 10,000 people

- Severe allergic reaction (anaphylactic reaction)
- Temporary hepatitis with cholestatic jaundice.
- Hypersensitivity reaction with rash and formation of blisters
- Inflammation of joints (polyarthrititis).

Not known: frequency cannot be estimated from the available data

- Colitis (severe infection of the large intestine caused by *Clostridium difficile*)
- Vaginal infection
- Severe acute allergic reactions like strong fall of blood pressure, paleness, weak fast pulse, clammy skin, reduced conscience (anaphylactic shock), anaphylactoid reaction, hypersensitivity
- Sleepiness
- Dizziness
- Headaches
- Jaundice
- Fever, swollen lymph nodes or skin rash, these may be symptoms of a condition known as DRESS (Drug reaction with eosinophilia and systemic symptom) can be severe and life-threatening.
- A rare skin eruption that is characterised by the rapid appearance of areas of red skin with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP)).
- Irritation at the site of the injection.
- fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, nurse or healthcare personnel. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance. Website: www.hpra.ie.

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

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5. How to store Clindamycin

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 label. The expiry date refers to the last day of the month.

Do not store above 25°C.

Do not use Clindamycin if you notice that it shows any discoloration, precipitation or any other particles.

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 Clindamycin contains

- The active substance is clindamycin.

Each ml of solution for injection/concentrate for solution for infusion contains 150 mg clindamycin (as phosphate).

Each ampoule with 2 ml contains 300 mg clindamycin.

Each ampoule with 4 ml contains 600 mg clindamycin.

Each ampoule with 6 ml contains 900 mg clindamycin.

- The other ingredients are benzyl alcohol (9 mg in each ml solution), disodium edetate, sodium hydroxide for pH-adjustment and water for injections.

What Clindamycin looks like and contents of the pack

Clindamycin is a clear, colourless to slightly coloured solution in colourless glass ampoules containing 2 ml, 4 ml or 6 ml of solution for injection/concentrate for solution for infusion.

Pack sizes: 5 and 10 ampoules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Fresenius Kabi Deutschland GmbH
Else-Kroener Strasse 1
Bad Homburg v.d.H 61352
Germany

Manufacturer:

Labesfal – Laboratórios Almiro, S.A
Lagedo, Santiago de Besteiros
Santiago de Besteiros, 3465-157
Portugal

This medicinal product is authorised in the Member States of the EEA under the following names:

BE Clindamycin Fresenius 150 mg/ml oplossing for injectie
BG Clindamycin 150 mg/ml инжекционен разтвор
CZ Clindamycin 150 mg/ml, injekční roztok
DE Clindamycin 150 mg/ml Injektionslösung
EL Clindamycin 150 mg/ml ενέσιμο διάλυμα
ES Clindamicina Fresenius 150 mg/ml solución inyectable
FI Clindamycin Fresenius 150 mg/ml injektioneste, liuos
HU Clindamycin 150 mg/ml oldatos injekció
IE Clindamycin 150 mg/ml solution for injection
LU Clindamycin 150 mg/ml Injektionslösung
NL Clindamycine 150 mg/ml oplossing voor injectie
PL Clindamycin
SK Clindamycin 150 mg/ml injekčný roztok

This leaflet was last revised in July 2021.

The following information is intended for healthcare professionals only:

Only for single use. Any unused solution shall be discarded.

Do not use Clindamycin if you notice any particles or strong coloration of the solution.

Reconstituted solutions should be inspected visually. Only clear solutions free of visible particles should be used. The reconstituted product is for single use only and any unused solution must be discarded.

Chemical and physical in-use stability has been demonstrated for 48 hours at 25°C. From a microbiological point of view, once diluted, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are in the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Clindamycin must be diluted prior to intravenous infusion with a resulting concentration not exceeding 18 mg clindamycin per ml and should be infused over at least 10 - 60 minutes (not exceeding 30 mg/min).

Unless the compatibility is proven, the solution for infusion should always be administered separately.

Clindamycin may be diluted with 0.9 % sodium chloride solution, 5 % glucose solution or Ringer's lactate.