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Package leaflet: Information for the user

Clindamycin 150 mg/ml solution for injection/infusion

clindamycin

Read all of this leaflet carefully before you are given 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 nurse.
- If you get any side effects, talk to your doctor or nurse. 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

This medicine contains the active substance clindamycin (as clindamycin phosphate), which is an antibiotic. It is used to treat infections.

Clindamycin is used for the treatment of the following severe infections in adults and children from the age of 1 month:
- bone and joint infections
- chronic sinusitis caused by anaerobic microorganisms
- infections of the lower respiratory tract
- complicated abdominal infections
- pelvic and female genital infections
- complicated skin and soft tissue infections.

Clindamycin may be used for prophylaxis in surgery in case of allergy to beta-lactams.

2. What you need to know before you are given Clindamycin

You must not be given Clindamycin
- if you are allergic to clindamycin, lincomycin (another antibiotic) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before you are given this medicine, if:
- you suffer from impaired liver or kidney function;
- you have problems with your muscle function (e.g. you suffer from muscle weakness called ‘myasthenia gravis’ or Parkinson’s disease);
- you have previously had gastrointestinal diseases (e.g. inflammation of the colon);
- 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 suffer from asthma, eczema or hay fever.

If you are not sure if any of the above apply to you, ask your doctor for advice.

Tell your doctor or nurse immediately if during treatment you experience:
- signs of severe allergic reaction such as wheeziness, breathing difficulties, swelling of eyelids, face or lips, rash or itching (see section 4). These can occur even after the first administration. In this case, your doctor will discontinue the treatment with clindamycin immediately and will initiate the standard emergency measures;
- severe skin rash with irregular red spots or with pus filled blisters and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips (see section 4);
- diarrhoea during or up to 3 weeks after treatment, especially when mucus or blood is in the stool. It may be a sign of severe infection of the colon (colitis). It is more likely to occur in debilitated and/or elderly patients (over 60 years).

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 mucosa with pathogens not sensitive to clindamycin. It may also lead to the development of a fungal infection.

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

During long-term treatment, your doctor will regularly monitor your liver and kidney function.

In order to avoid undesirable effects, clindamycin will be given as slow infusion into a vein.

Children
Safety and dosage in infants less than one month of age have not been established.

Other medicines and Clindamycin
Tell your doctor or nurse if you are using, have recently used or might use any other medicines.
It is particularly important if you are using any of the following medicines:
- muscle relaxants (used during operations to help your muscles relax). Concomitant use with clindamycin may lead to unexpected, life-threatening incidences during surgery. Therefore, if you are in hospital to have an operation or a hospital procedure, tell your doctor you are receiving clindamycin.
- warfarin or similar medicines – used to thin the blood. You may be more likely to bleed. Your doctor may want to take regular blood tests to check how well your blood can clot;
- erythromycin (an antibiotic);
- rifampicin (to treat tuberculosis);
- ciclosporin/tacrolimus (used after organ transplants).

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 for advice before you are given this medicine.
Your doctor will prescribe you clindamycin during pregnancy only if absolutely necessary. This medicine can have a negative effect on the intestinal flora of the breast-fed infant. The doctor will thoroughly outweigh the benefits of breast-feeding for the infant and expected benefits and risks from clindamycin treatment for the mother.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines.

Clindamycin contains sodium
This medicine contains 6.5 mg sodium (main component of cooking/table salt) per ml of solution. This is equivalent to 0.33 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How Clindamycin is given

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

You will be given this medicine by a doctor or nurse, as an injection into a muscle or as a slow infusion into a vein (using a drip). The medicine will be diluted prior infusion into a vein. The infusion will take 10-60 minutes.

Adults
- For the treatment of less complicated infections: the usual dose is 1200-1800 mg daily given in 3 or 4 equal doses.
- For the treatment of severe infections: the usual dose is 2400-2700 mg daily given in 2, 3 or 4 equal doses.

In life-threatening infections the dose given into a vein may be increased up to 4800 mg daily.

The dose for prophylaxis of post-operative infections will be determined by your doctor. It will depend on type and duration of the surgical procedure.

Into a muscle, the maximum recommended single dose is 600 mg. Into a vein, the maximum recommended dose for a single one-hour infusion is 1200 mg.

Elderly
No dose adjustment is required in the elderly with normal liver and kidney function.

Patients with liver and/or kidney impairment
Dose adjustment is generally not necessary in mild to moderate liver or kidney impairment.
The doctor will monitor kidney function in patients with severe kidney impairment.
In patients with severe liver impairment, the doctor will monitor liver function, and, where possible, plasma levels of the medicine. The doctor will adjust the dose or dosing intervals, if necessary.

The following information is intended for healthcare professionals only:

Please refer to the Summary of Product Characteristics for full prescribing information.

Method of administration
Intramuscular injection (IM) or intravenous infusion (IV).

For intramuscular administration, clindamycin should be used undiluted. Intramuscular administration of more than 600 mg at once is not recommended. Intramuscular administration is indicated when intravenous infusion is not possible for any reasons.

For intravenous administration, clindamycin **must be diluted prior IV administration** and should be infused over at least 10-60 minutes. The concentration should not exceed 18 mg clindamycin per ml solution and the infusion rate should not exceed 30 mg/min. **It must never be given as intravenous bolus injection** (may cause serious adverse events). Intravenous infusions of more than 1200 mg in one hour are not recommended.

The usual infusion rates

Dose	Diluent	Concentration of clindamycin	Minimum infusion-time
300 mg	50 ml	6 mg/ml	10 minutes
600 mg	50 ml	12 mg/ml	20 minutes
900 mg	50-100 ml	9 mg/ml to 18 mg/ml	30 minutes
1200 mg	100 ml	12 mg/ml	40 minutes

For compatible diluents, see ‘Instructions for use, handling and disposal’.

Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned below under ‘Instructions for use, handling and disposal’.
The following medicinal products are physically incompatible with

Place for bleedmarks

Pharmacode

Pharmacode

Pharmacode

Use in children and adolescents
Children over 1 month to 12 years of age
20-40 mg/kg body weight daily given in 3 or 4 equal doses.
The dose of clindamycin in children should be based on total body weight regardless of obesity. In severe infections, it is recommended that children be given no less than 300 mg/day regardless of body weight. The total daily dose should not exceed the maximum recommended daily dose for adults.

Adolescents over 12 years of age
Doses in adolescents over 12 years of age should be the same as in adults, taking into account possible dose adjustments based on liver function. In underweight adolescent patients, between the ages of 12 and 18 it is not recommended to exceed the maximum dose of 40 mg/kg/day. The total daily dose should not exceed the maximum recommended daily dose for adults.

If you receive more Clindamycin than you should
This medicine will always be given under carefully controlled conditions. However, if you think that you have been given too much medicine, tell a doctor or a nurse immediately.

If you missed a dose of Clindamycin
This medicine will be given to you by a doctor or nurse. However, if you think that you have missed a dose, tell your doctor or nurse.

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

4. Possible side effects

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

Serious side effects

Tell your doctor or nurse **immediately** if you develop any of the following side effects as you may require immediate medical attention:

Common (may affect up to 1 in 10 people)
- **Stomach and gut disorders**
  Severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). It may occur during or after treatment with antibiotics and can be a sign of serious bowel inflammation (pseudomembranous colitis).

Uncommon (may affect up to 1 in 100 people)
- **Heart and blood vessels disorders**
  Low blood pressure (feeling lightheaded, dizzy or faint) or sudden chest pain or pressure, shortness of breath, dizziness, fainting, nausea or vomiting (signs of cardiac arrest). These may occur if the medicine is given too fast.

Not known (frequency cannot be estimated from the available data)
- **Allergic reactions**
  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)
- **Skin disorders**
  Signs of severe and potentially life-threatening skin reactions such as severe skin rash with irregular red spots or with pus-filled blisters and peeling of large areas of skin, fever, cough, feeling unwell and swelling of the gums, tongue or lips
- **Liver disorders**
  Yellowing of the skin and whites of the eyes (jaundice)
- **Kidney disorders**
  Fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea.
- **Changes in blood counts**
  Increase in infections which you may see as fevers, severe chills, sore throat or mouth ulcers (these may indicate you have a low number of white blood cells in your body)

Other side effects

Common (may affect up to 1 in 10 people)
- Infection or inflammation of the veins in your leg (thrombophlebitis)
- Increase in some white blood cells (eosinophilia)
- Inflammation of the lining inside the mouth
- Diarrhoea
- Red raised skin rash
- Induration at the injection site (after injection into the muscle)
- Changes to liver function (seen in blood test)

Uncommon (may affect up to 1 in 100 people)
- Low number of white blood cells in your body (granulocytopenia)
- Impaired sense of taste
- Muscle relaxing effect
- Abdominal pain
- Inflammation of the lining of the gullet
- Feeling sick
- Being sick
- Hives
- Inflammation and redness of the skin (erythema multiforme)
- Itching
- Pain at the injection site
- Abscess at the injection site (after injection into the muscle)

Rare (may affect up to 1 in 1 000 people)
- Swelling, especially of the face and throat, wheezing and/or difficulty breathing (angioedema)

Very rare (may affect up to 1 in 10 000 people)
- Indigestion

Not known (frequency cannot be estimated from the available data)
- Infection of the large intestine (colon) caused by bacterium
- Infection of the vagina
- Unexplained bruising or bleeding for longer than normal or small red-purple spots on the skin (these may indicate you have a low number of platelets in the blood)
- Allergic reactions
- Changes in smell
- Rose-red flat or slightly elevated skin rash
- Irritation at the injection site

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

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 ampoule label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C. Do not refrigerate or freeze.
Keep the ampoules in the outer carton in order to protect from light.

Shelf life after opening the ampoule:
The product should be used immediately.

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

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 contains 150 mg of clindamycin (as clindamycin phosphate).
Each ampoule of 2 ml solution contains 300 mg clindamycin (as clindamycin phosphate).
Each ampoule of 4 ml solution contains 600 mg clindamycin (as clindamycin phosphate).

– The other ingredients are disodium edetate, sodium hydroxide (for pH adjustment), water for injections.

What Clindamycin looks like and contents of the pack
Clear, colourless to almost colourless solution, practically free from visible particles.

2 ml or 4 ml of solution filled in colourless glass ampoules with one point cut.
Each pack contains 1, 5 or 10 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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Pharmacode

Pharmacode

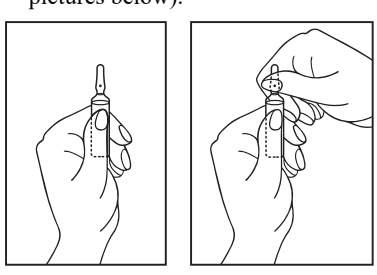
clindamycin phosphate: ampicillin, phenytoin sodium, barbiturates, aminophylline, calcium gluconate, magnesium sulphate, ceftriaxone sodium, ciprofloxacin, idarubicin hydrochloride and ranitidine hydrochloride.

Instructions for use, handling and disposal
For single use only. Discard any unused portion.

The medicinal product should be visually inspected prior to use. Do not use if there are any visible signs of deterioration (e.g. particles). Only clear solutions free from visible particles should be used.

May be diluted with:
– 9 mg/ml (0.9 %) sodium chloride solution for infusion
– 50 mg/ml (5 %) glucose solution for infusion

Instruction of ampoule opening
1) Turn the ampoule with coloured point up. If there is any solution in the upper part of the ampoule, gently tap with your finger to get all the solution to the lower part of the ampoule.
2) Use both hands to open; while holding the lower part of the ampoule in one hand, use the other hand to break off the upper part of the ampoule in the direction away from the coloured point (see the pictures below).



Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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