Package leaflet: Information for the user

Clindamycin Abcur 150mg/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, pharmacist or nurse.
- 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 <Product Name> is and what it is used for

<Product Name> contains the active substance clindamycin and belongs to a group of medicines called antibiotics. Antibiotics are used to treat infections. <Product Name> is used to clear certain serious bacterial infections, such as:
- Bone and joint infections
- Chronic sinus infections
- Lower respiratory tract infections
- Complicated abdominal infections
- Infections of the reproductive organs
- Complicated skin and soft tissue infections

<Product Name> is usually reserved for the treatment of severe infections in adults and adolescents older than 12 years when the infection is caused by bacteria that are sensitive to clindamycin, and other antibiotics have been unable to clear the infection.

2. What you need to know before you are given <Product Name>

You should not be given <Product Name>:
- if you are allergic to clindamycin or lincomycin (another antibiotic) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given <Product Name>:
- 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 gastrointestinal 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 in people with a known penicillin hypersensitivity.

Serious skin reactions
Serious skin reactions, such as those with increased number of eosinophils (type of blood cells) and symptoms affecting the whole body (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and acute generalized exanthematous pustulosis (AGEP) have been reported in patients treated with clindamycin.

- SJS/TEN can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also, ulcers of mouth, throat, nose, genitals and eyes (red swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications.
- DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.
- AGEP can appear as areas of red skin studded with small pustules (small blisters filled with white/yellow fluid).

If you develop a serious rash or any of these skin symptoms, clindamycin should be discontinued and you should contact your doctor or seek medical attention immediately.

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

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

In long-term therapy (more than 10 days), the doctor may need to monitor the blood count and the liver and renal function.

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 administration of clindamycin may cause an infection of skin and mucous membranes caused by micro-organisms insensitive to clindamycin. This may result in occurrence of fungal infections.

During treatment with clindamycin, a severe infection of the colon (colitis) may occur. Therefore, you should immediately inform your doctor if you suffer from diarrhoea during or after treatment, especially when mucus or blood are in the stools.

Children
<Product name> should not be given to children.

Other medicines and <Product Name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can affect the way <Product name> works, or <Product name> itself can reduce the effectiveness of other medicines taken at the same time.
These include:

- warfarin or similar medicines (e.g. acenocoumarol and fluindione) – 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.

- muscle relaxants used during operations. Clindamycin may increase the effect of muscle relaxants which may lead to unexpected, life-threatening incidents during surgery.
- medicines that slow down the metabolic activity of liver enzymes (CYP3A4 inhibitors) such as: itraconazole, voriconazole (used to treat fungal infections); clarithromycin and telithromycin (antibiotics); ritonavir and cobicistat (antivirals used to treat HIV/AIDS), as this may result in increased levels of clindamycin in the body and may cause side effects.
- medicines that increase the metabolic activity of liver enzymes (CYP3A4 or CYP3A5 inducers) such as rifampicin (an antibiotic to treat tuberculosis), St John's wort (a herbal product used to treat depression) and carbamazepine, phenytoin, phenobarbital (medicines used to treat epilepsy) as this may result in loss of the antibacterial effect of clindamycin.

Pregnancy and breast-feeding
If you are pregnant, think you may be pregnant or are planning to have a baby you should contact your doctor before being given <Product name>.

Breast-feeding women should not be given <Product name> unless strictly necessary. This medicine can pass into breastmilk. In the breast-fed infant diarrhoea, fungal infections (oral thrush) and allergic reaction can occur. The infant should be closely monitored for any signs of side effects especially traces of blood in the stool or diarrhoea (colitis). Special attention is necessary when <Product name> is used for longer periods of time or in high doses in the nursing mother.
Your doctor will decide whether to use <Product name> if you are pregnant or breastfeeding.

Driving and using machines
This medicine may cause mild to moderate side effects that can affect your ability to drive and use machines. You may feel dizzy, sleepy or suffer from headaches when taking this medicine. If you are affected, do not drive or use any tools or machines.

<Product Name> contains sodium.
This medicine contains less than 1 mmol sodium (23 mg) per ampoule, (prior to dilution) that is to say essentially 'sodium-free'.

3. How <Product Name> is given to you

<Product Name> is administered by intravenous infusion (into a vein using a drip) or into muscle (intramuscularly). It will usually be given by a doctor or a nurse. If it is given into a vein, it is always mixed with a glucose or saline (salt) solution before use. Your doctor will decide on the correct dose of clindamycin for you. The infusion will take 10 – 60 minutes.

When giving you <Product name>, your doctor will ensure that the concentration of clindamycin does not exceed 18 mg per ml and the rate it is given to you does not exceed 30 mg per minute. Your doctor and nurse will monitor you carefully during your treatment.

Adults and adolescents older than 12 years are usually given:
- for the treatment of severe infections: 1800 – 2700 mg/day of clindamycin in two or three equal doses.
- for the treatment of less complicated infections: 1200 – 1800 mg/day of clindamycin in two, three or four equal doses.

The maximum daily dose for adults and adolescents over 12 years of age is 2700 mg clindamycin in two to 2-3 equal doses. For life-threatening infections, doses of up to 4800 mg clindamycin can be given daily.

Dosage adjustment is generally not necessary in patients with kidney and liver impairment. Monitoring of the level of clindamycin in the blood is recommended.

Clindamycin is not removed by haemodialysis (removal of waste products from the blood by means of artificial filtration, used to treat kidney failure). Therefore, no additional dose is necessary before or after haemodialysis.

Use in children
This medicine should not be given to children.

If you are given more <Product Name> than you should
If you think you have received too much medicine, speak to your doctor or nurse.

If you forget to use <Product Name>
As you will be given this medicine by a doctor or nurse, you are unlikely to miss a dose. If you think you have missed a dose, speak to 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.

Contact a doctor immediately if you develop:

- serious skin reactions
    - including *Stevens-Johnson syndrome* (SJS) and *toxic epidermal necrolysis* (TEN). These can appear initially as reddish target-like spots or circular patches often with central blisters on the trunk. Also ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes) can occur. These serious skin rashes are often preceded by fever and/or flu-like symptoms. The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal. The frequency of these side effects is rare (may affect up to 1 in 1 000 people).
    - a red, scaly widespread rash with bumps under the skin and blisters accompanied by fever at the initiation of treatment (*Acute generalized exanthematous pustulosis* – AGEP). The frequency of this side effect is not known (cannot be estimated from the available data).
    - flu-like symptoms and a rash on the face then widespread with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia), enlarged lymph nodes and other body organs involvement (*Drug Reaction with Eosinophilia and Systemic Symptoms -DRESS which is also known as drug hypersensitivity syndrome*). The frequency of this side effect is not known (cannot be estimated from the available data).
    - an extensive red skin rash with small pus-containing blisters (*exfoliative dermatitis bullous*). The frequency of this side effect is rare (may affect up to 1 in 1 000 people).

Stop using <Product name> if you develop these symptoms and contact your doctor or seek medical attention immediately. See also section 2.

- signs of a severe inflammation of the colon (pseudomembranous colitis) such as persistent or bloody diarrhoea with stomach pain or fever. This is a common side effect (may affect up to 1 in 10 people) which may occur during or after completing treatment with antibiotics that may be life-threatening and requires immediate appropriate treatment.
- 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).
- yellowing of the skin and whites of the eyes (jaundice). The frequency of this side effect is not known (cannot be estimated from available data).
- more frequent infections with fever, severe chills, sore throat or mouth ulcers (these may indicate you have a low number of white blood cells in your body). These are common side effects (may affect up to 1 in 10 people).
- Decrease in number of platelets which may cause bruising or bleeding (thrombocytopenia). This common side effect (may affect up to 1 in 10 people).
- Fluid retention causing swelling in your legs, ankles or feet, shortness of breath or nausea.

Other side effects which may occur are listed by frequency:

Very common side effects (may affect more than 1 in 10 people)
- Gastrointestinal disorders, such as nausea, abdominal pain, vomiting, diarrhoea.

Common side effects (may affect up to 1 in 10 people):
- Blood vessels disorder such as inflammation of the veins (thrombophlebitis).
- Skin lesions, such as those with large blistering skin rash (maculo-papular exanthema, morbilliform exanthema), 'nettle rash' (urticaria).
- The results of liver tests may be affected

Uncommon side effects (may affect up to 1 in 100 people):
- Nervous system disturbances, such as an inhibit nerve impulse progression (neuromuscular blocking effect) and altered taste (dysgeusia).
- Difficulty breathing, low blood pressure.
- Pain and abscess (ulcer) at the site of injection.

Rare side effects (may affect up to 1 in 1,000 people):
- Fever.
- Itchy skin (pruritus).
- Inflammation of the vaginal mucosa (vaginitis).

Very rare side effects (may affect up to 1 in 10,000 people):
- Severe acute allergic reaction (anaphylactic reaction).
- Inflammation of the liver (hepatitis) with yellowing of the skin and whites of the eyes (jaundice).
- Allergic reaction with skin rash and blisters formation.
- Joint pain/tenderness (polyarthritis).

Not known (frequency cannot be estimated from the available data):

- Inflammation of the colon (colitis caused by an infection with Clostridium difficile).
- Vaginal infection.
- Severe acute allergic reactions, such as significant drop in blood pressure, paleness, increased heart rate, clammy skin, reduced consciousness (anaphylactic shock, anaphylactoid reaction, hypersensitivity).
- Sleepiness.
- Dizziness.
- Headache.
- Jaundice.
- Irritation at the site of injection.

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. You can also report side effects directly via via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product Name>

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 carton and ampoule after EXP. The expiry date refers to the last day of that month.
Do not store above 25°C.
Do not refrigerate or freeze.

Once your doctor or nurse has opened the ampoule it should be used immediately. Any remaining <Product Name> must be thrown away by the doctor or nurse.

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 <Product Name> contains
- The active substance is clindamycin phosphate. Each ml contains 150mg clindamycin.
- The other ingredients are disodium edetate, sodium hydroxide and water for injections.

What <Product Name> looks like and contents of the pack
<Product Name> is a clear, colourless solution in a glass ampoule containing 2ml or 4ml of the solution for injection. This product is available in cartons containing 1 x 2ml, 1 x 4ml, 5 x 2ml or 5 x 4 ml ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Abcur AB
P.O. Box 1452
251 14 Helsingborg
Sweden

Manufacturer
Vianex SA,12th Km Athens Lamia National Road, Metamorfosi, Athens, Greece

For any information about this medicinal product, please contact the Marketing Authorisation Holder, details provided above.

This leaflet was last revised in 2022-07-13.

The following information is intended for healthcare professionals only:

<Product Name> 150 mg/ml solution for injection/infusion

Administration

Intramuscular injection
<Product Name> is for single use only. Any unused content should be discarded.

Intravenous infusion
<Product Name> must **not** be administered as an intravenous bolus injection as rapid intravenous injection of undiluted clindamycin may lead to cardiac arrest.

Dilution
For use via intravenous infusion, <Product Name> **must** be diluted with 9 mg/ml (0.9%) sodium chloride solution or 50 mg/ml (5%) glucose solution.

The concentration of clindamycin should not exceed 18 mg/ml and the rate of infusion should not exceed 30 mg/min.

The usual infusion rates are as follows:

Dose:	Diluent:	Minimum infusion-time:
300mg	50ml	10 min
600mg	50ml	20 min
900mg	50-100ml	30 min
1200mg	100ml	40 min

Special precautions for storage

Unopened product: Do not store above 25°C.

Opened ampoules: The product should be used immediately after opening. Dispose of any remaining solution after a single use.

Diluted solution: Chemical and physical in-use stability has been demonstrated for 24 hours at 25ºC. 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 the responsibility of the user and would normally be no longer than 24 hours at 2 to 8ºC, unless dilution has taken place in controlled and validated aseptic conditions. The dilution should be made under aseptic conditions. The solution should be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Shelf life
Unopened: 2 years

Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with local requirements.

Each ml of solution contains 6.57mg (0.286mMol) of sodium, prior to dilution.