PATIENT INFORMATION LEAFLET

CLINDAMYCIN VIANEX BA FREE
Clindamycin
Solution for Injection or Infusion 600mg/4ml AMP

1. DETERMINATION OF THE MEDICINAL PRODUCT

1.1. Name: CLINDAMYCIN VIANEX BA FREE

1.2 Composition
Active ingredient: Clindamycin
Excipients: Disodium edentate, sodium hydroxide, water for injections

1.3 Pharmaceutical form
Solution for injection or infusion.

1.4 Strength
Each 4ml ampoule contains clindamycin phosphate equivalent to 600mg of clindamycin.

1.5 Description-Packing
Carton containing 1 ampoule of 4ml.

1.6 Therapeutic classification
Antibiotic

1.7 Marketing Authorization Holder
VIANEX S.A. – Tatoiou Str., 146 71 Nea Erithrea, Attiki, Greece, Tel.: 0030 210 8009111-120

1.8 Manufacturer
VIANEX S.A. – Plant A', Metamorphossi, Attiki, Greece

2. WHAT YOU SHOULD KNOW ABOUT THE MEDICINE PRESCRIBED BY YOUR DOCTOR

2.1 General information
The active substance of CLINDAMYCIN VIANEX BA FREE is clindamycin, a semi-synthetic antibiotic produced by the parent compound lincomycin.
Clindamycin may be either bactreriostatic or bactericidal, depending on the susceptibility of the microorganism and the concentration of the antibiotic.

2.2 Indications
Serious infections caused by gram positive cocci (including staphylococci), various anaerobic bacteria, particularly *Bacteroides fragilis* (intra-peritoneal, gynecological infections, e.t.c.), osteomyelitis.

Toxoplasmic encephalitis in patients with AIDS. In patients who do not well tolerate conventional treatment, clindamycin in combination with pyrimethamine has been shown to be effective.
Pneumocystis jirovecii pneumonia in patients with AIDS. In patients who do not well tolerate or do not respond to convential treatment, clindamycin can be used in combination with primaquin.
Clindamycin use should be restricted to absolute indications or when other safer antibiotics cannot be used because of severe undesirable effects, particularly pseudomembranous colitis.

2.3 Contraindications
Hypersensitivity to clindamycin or lincomycin, diarrheal syndrome, history of colitis or enteritis or antibiotic-associated colitis.

2.4 Special precautions and warnings during use
2.4.1 Tell your doctor if you are allergic or if you are suffering from renal or hepatic impairment, from colitis or if you have a history of colitis.
You should also inform your doctor immediately if diarrhoea occurs during treatment with clindamycin.

Treatment with clindamycin has been associated with severe antibiotic-associated colitis which may be fatal. Symptoms vary from mild to severe, persistent diarrhoea, leukocytosis, fever, severe abdominal cramps, blood and mucus in the intestinal, which if allowed to progress, may produce peritonitis, shock and toxic megacolon.
Antibiotic-associated colitis may occur during the administration or even two or three weeks after the administration of the antibiotic. Antibiotic-associated colitis may be more sever in elderly and/or in debilitated patients. In case of mild antibiotic-associated colitis, discontinuation of the clindamycin is recommended.

Your doctor will recommend treatment with cholestyramin and colestipole resins.
Severe cases of antibiotic-associated colitis should be managed with appropriate replenishment of fluids, electrolytes and proteins.
Your doctor may administer to you vancomycin, because vancomycin induces a rapid disappearance of the toxin produced by *Clostridium difficile* from the stool samples and coincidental recovery from diarrhoea.
In rare cases, colitis may relapse after cessation of treatment with vancomycin.

Cholestyramin and colestipole resins bind vancomycin. If both a resin and vancomycin are to be administered concurrently, it may be advisable to separate the time of administration of each drug.
As an alternative treatment, oral bacitracin could be given.
- Medicines which cause intestinal stasis should be avoided.
- Clindamycin should not be used in the treatment of meningitis since the drug does not diffuse adequately into cerebrospinal fluid.
- Periodic liver and kidney function tests should be carried out during prolonged therapy.

2.4.2 Elderly
The same information is valid as for the adults.

2.4.3 Pregnancy

Safety for use in pregnancy has not been established.

2.4.4 Breast-feeding
Clindamycin is excreted in human milk and therefore its use should be avoided or lactation should be discontinued.

2.4.5 Effects on ability to drive and use machines
No effect.

2.5 Interactions with other medicines or substances
Tell your doctor if you are receiving other medicines.
When administered with general anaesthetics or neuromuscular blocking agents, respiratory depression or paralysis may occur (managed by administering calcium salts and anticholinesterasics). Chloramphenicol and erythromycin antagonize clindamycin activity. Adsorbents (kaolin, e.t.c) decrease clindamycin absorption.

2.6 Dosage
Adults:
By intramuscular injection or by slow intravenous infusion: 600 mg to 2400 mg/day given in 2 - 4 doses.
Must be diluted with isotonic solution of sodium chloride or dextrose. Single IM injection of greater than 600 mg is not recommended.
Children: 15 to 40 mg/kg/day given in 3 - 4 doses.

TOXOPLASMIC ENCEPHALITIS IN PATIENTS WITH AIDS:
Clindamycin phosphate I.V. 600-1200 mg every 6 hours for two weeks followed by orally given clindamycin 300-600 mg every 6 hours. The usual total duration of therapy is 8 to 10 weeks. The dose of pyrimethamine is 25-75 mg daily given orally for 8 to 10 weeks. Folinic acid 10-20 mg daily should be given with higher doses of pyrimethamine.

***Pneumocystis jirovecii* pneumonia in patients with AIDS:**
Clindamycin phosphate I.V. 600-900 mf every 6 hours or 900 mg I.V. every 8 hours for 21 days and primaquin in a single oral dose 10-30 mg daily for 21 days.

Method of administration
No special cut tool is needed to open the ampoule. The neck of the ampoule is pre-scored at the point of constriction.

DILUTION AND INFUSION RATE
The concentration of clindamycin in diluent for infusion should not exceed 18 mg per ml and THE INFUSION RATE SHOULD NOT EXCEED 30 mg PER MINUTE.

The usual infusion rate is as following:

Dose	Diluent	Time
300 mg	50 ml	the first 10 minutes
600 mg	50 ml	the first 20 minutes
900 mg	50-100 ml	the first 30 minutes
1200 mg	100 ml	the first 40 minutes

Administration of more than 1200 mg in a single 1-hour infusion is not recommended.

Incompatibilities
Solutions of clindamycin salts have a low pH and incompatibilities may reasonably be expected with alkaline preparations or drugs unstable at low pH. Incompatibility has been reported with: ampicillin sodium, aminophylline, barbiturates, calcium gluconate, ceftriaxone sodium, ciprofloxacin, diphenylhydantoin, idarubicin hydrochloride, magnesium sulphate, phenytoin sodium and ranitidine hydrochloride. This pharmaceutical product must not be mixed with other pharmaceutical products except those mentioned in section 2.6.

2.7 Overdosage – Treatment
In case of overdosage treatment is symptomatic. Corticosteroids, adrenaline may be administered.

2.8 Side Effects
Vomiting, diarrhea, which impose the immediate discontinuation of treatment, pseudomembranous colitis often life threatening.

- **Gastrointestinal system**

Abdominal pain, nausea, vomiting and diarrhea (see section 2.4)

- **Hypersensitivity reactions**

Maculopapular rash and urticaria have been observed during drug therapy. Generalized mild to moderate morbilliform-like skin rashes are the most frequently reported reactions. Rare instances of erythema multiform, some of which resembling to Stevens-Johnson syndrome, have been associated with clindamycin. A few cases of anaphylactoid reactions have been reported.

- **Liver**

Jaundice and abnormalities in liver function tests have been observed during clindamycin therapy.

- Renal
Renal dysfunction has rarely been reported (causative relationship of clindamycin to this effect has not been established).

- **Skin and mucous membranes**

Pruritus, vaginitis and rare instances of exfoliative and vesiculobullous dermatitis have been reported.

- **Haemopoietic system**

Transient neutropenia (leucopenia) and eosinophilia have been reported. Cases of agranulocytosis and thrombocytopenia have been reported.

- **Cardiovascular**

Rare cases of cardiopulmonary arrest and hypotension have been reported following rapid intravenous administration.

- **Local reactions**

Local irritation, pain, abscess formation have been observed with intramuscular injection. Thrombophlebitis has been reported with intravenous infusion. These reactions can be minimized by deep intramuscular injection and avoidance of indwelling intravenous catheter. You should inform your doctor immediately, if you experience any problem (especially diarrhoea) during treatment.

- Nervous system

Dysgeusia

2.9 Expiry date

It is written on the outer and inner package. Do not use the product after this date.

2.10 Special precautions for storage

Keep at temperature $\leq 25^{o}C$.

2.11 Date of Patient Information Leaflet last revision

27-3-2013

3. INFORMATION ON THE RATIONAL USE OF MEDICINES

- Your doctor prescribed this medicine only for your specific medical problem. Never give it to others or use it for another disease before consulting your doctor.
- If, during treatment, you experience any problem, inform immediately your doctor or pharmacist.
- If you have any questions about your medicine or you need some additional information on your medical problem, consult your doctor or pharmacist.
- Take this medicine according to your doctor's instructions, so as to be effective and safe.
- For your health and safety, please read all information about your medicine in this leaflet very carefully.
- Do not keep medicines in bathroom's cupboards because heat and moisture may alter them and make them harmful for your health.
- Do not keep medicines you need no more or medicines after their expiry date.
- Keep all medicines safely out of reach of children.

4. WAY OF DISPENSING

Under medical prescription.