APPROVED
leshania , 2021/12/29 ,12:22:35

KLIDAR P1529349

KLIDAR P1529349

Professional Information for Medicines for Human Use

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

KLIDAR 150 mg (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains clindamycin hydrochloride USP equivalent to clindamycin 150 mg.
Contains sugar: 53,76 mg lactose monohydrate.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Light blue opaque/light green transparent size '1' hard gelatin capsule filled with white to off-white powder imprinted with 'C' on light blue opaque cap & '39' on light green transparent body with black ink.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

KLIDAR is indicated in serious infections caused by organism's susceptible (anaerobic bacteria) to its action. *In vitro* susceptibility studies should be performed. Infections due to sensitive organisms (serious infections due to susceptible strains of streptococci, pneumococci and staphylococci) which responds to an effective dose of this oral preparation include infections of the:

- **Upper respiratory tract** including pharyngitis, tonsillitis, sinusitis, otitis media.
- **Lower respiratory** including bronchitis, and pneumonia.
- **Skin and soft tissue** including, abscesses, cellulitis, infected wounds, and dental infections (peri- apical abscesses and gingivitis).
- **Bones and joints** including acute and chronic osteomyelitis.

Bacteraemia has responded to the usually recommended dosages.

4.2. Posology and method of administration

Posology

- **Adults:**

Mild to Moderately Severe Infection: 150 mg approximately every six hours.
Severe Infections: Up to 450 mg every six hours.

- **Paediatric population:**

Mild Infections: 8-12 mg/kg/day divided into 3 or 4 equal doses.
Moderately Severe infections: 13-16 mg/kg/day divided into 3 or 4 equal doses.
Severe Infections: 17-25 mg/kg/day divided into 3 or 4 equal doses.
Do not give **KLIDAR** capsules to children weighing less than 10 kg.
Note: With ß-haemolytic streptococcal infections, treatment should continue for at least ten days to diminish the likelihood of subsequent severe complications such as rheumatic fever or glomerulonephritis.

Method of administration

KLIDAR capsules should be taken with a full glass of water to avoid the possibility of oesophageal irritation.
KLIDAR is not appreciably modified by the presence of food (see section 5.2).

4.3. Contraindications

- Patients previously found to be hypersensitive to clindamycin, lincomycin or doxorubicin, or any of the excipients in **KLIDAR** listed in section 6.1.
- Do not use in patients with diarrhoeal states or gastro-intestinal disease, particularly those with a history of colitis.
- Safety for use in pregnancy has not been established.
- Clindamycin has been reported to appear in breast milk. Do not use in lactation.

4.4. Special warnings and precautions for use

Prescribers must adhere to the principles of antibiotic stewardship.
Severe hypersensitivity reactions, including severe skin reactions such as medicine reactions with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and Acute Generalised Exanthematous Pustulosis (AGEP) have been reported in patients receiving clindamycin therapy. If a hypersensitivity or severe skin reaction occurs, clindamycin should be discontinued and appropriate therapy should be initiated (see sections 4.3 and 4.8).

KLIDAR should only be used in the treatment of serious infections. In considering the use of **KLIDAR,** the practitioner should bear in mind the type of infection and the potential hazard of the diarrhoea which may develop, since cases of colitis have been reported during, or even two or three weeks following, the administration of clindamycin.

Studies indicate a toxin(s) produced by clostridia (especially *Clostridium difficile*) is the principal direct cause of antibiotic-associated colitis. These studies also indicate that this toxigenic clostridium is usually sensitive *in vitro* to vancomycin. When 125 mg to 500 mg of vancomycin are administered orally four times a day for 7 - 10 days, there is a rapid observed disappearance of the toxin from faecal samples and a coincident clinical recovery from the diarrhoea (see section 4.8). (Where the patient is receiving cholestyramine in addition to vancomycin, consideration should be given to separating the times of administration).

Colitis is a disease which has a clinical spectrum from mild, watery diarrhoea to severe, persistent diarrhoea, leucocytosis, fever, severe abdominal cramps, which may be associated with the passage of blood and mucus. If allowed to progress, it may produce peritonitis, shock and toxic megacolon. This may be fatal.

The appearance of marked diarrhoea should be regarded as an indication that **KLIDAR** should be discontinued immediately. The disease is likely to follow a more severe course in older patients or patients who are debilitated. Diagnosis is usually made by the recognition of the clinical symptoms, but can be substantiated by endoscopic demonstration of pseudomembranous colitis. The presence of the disease may be further confirmed by culture of the stool for *C.difficile* on selective media and assay of the stool specimen for the toxin(s) of *C. difficile.*
Clostridium Difficile Associated Diarrhoea (CDAD) has been reported with use of nearly all antibacterial medicines, including clindamycin, and may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial medicines alters the normal flora of the colon leading to overgrowth of *C difficile. C. difficile* produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhoea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial medicines.

Cross-resistance has been demonstrated between lincomycin hydrochloride and clindamycin hydrochloride. Antagonism with erythromycin has been demonstrated *in vitro*, therefore it is not recommended that the two medicines be given at the same time. Staphylococci resistant to erythromycin may also develop resistance to clindamycin. Since clindamycin does not diffuse adequately into cerebrospinal fluid, it should not be used in the treatment of meningitis.

Precautions: Caution should be used when prescribing **KLIDAR** to individuals with a history of gastro-intestinal disease, especially colitis.

Periodic liver and kidney function tests should be carried out during prolonged therapy.
Patients with very severe renal and/or very severe hepatic disease accompanied by severe metabolic aberrations should be dosed with caution and serum clindamycin levels monitored during high dose.
Prolonged administration of **KLIDAR,** as with any anti-infective, may result in super-infection due to organisms resistant to clindamycin.
Care should be observed in the use of **KLIDAR** in atopic individuals.

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking medicines.
Therefore, it should be used with caution in patients receiving such medicines.

KLIDAR contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine

4.5. Interaction with other medicines and other forms of interaction

Clindamycin has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking medicines. Therefore, it should be used with caution in patients receiving such medicines.

Clindamycin may competitively inhibit the effects of macrolides, ketolides, streptogramins, linezolid, and chloramphenicol because they all bind to the same subunit of the ribosome. Antagonism between clindamycin and erythromycin has been shown in vitro (see section 4.4).

Vitamin K antagonists

Increased coagulation tests (PT/INR) and/or bleeding, have been reported in patients treated with clindamycin in combination with a vitamin K antagonist (e.g. warfarin). Coagulation tests, therefore, should be frequently monitored in patients treated with vitamin K antagonists.

Co-administration of clindamycin with inhibitors of CYP3A4 and CYP3A5

Clindamycin is metabolized predominantly by CYP3A4, and to a lesser extent by CYP3A5, to the major metabolite clindamycin sulfoxide and minor metabolite N-desmethylclindamycin.

Therefore, inhibitors of CYP3A4 and CYP3A5 may reduce clindamycin clearance and inducers of these isoenzymes may increase clindamycin clearance. In the presence of strong CYP3A4 inducers such as rifampicin, monitor for loss of effectiveness.

In vitro studies indicate that clindamycin does not inhibit CYP1A2, CYP2C9, CYP2C19, CYP2E1 or CYP2D6 and only moderately inhibits CYP3A4. Therefore, clinically important interactions between clindamycin and co-administered medicines metabolized by these CYP enzymes are unlikely.

4.6. Fertility, pregnancy and lactation

Pregnancy

Teratogenic effects

Clindamycin crosses the placenta in humans. **KLIDAR** should not be used during pregnancy as safety has not been established (see section 4.3).

Breastfeeding

KLIDAR should not be used during breastfeeding (see section 4.3).

Fertility

Fertility studies in rats treated orally with up to 300 mg/kg/day (approximately 1,6 times the highest recommended adult human dose based on mg/m^2) revealed no effects on fertility or mating ability.

4.7. Effects on ability to drive and use machines

Clindamycin has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Use of clindamycin had been associated with the development of diarrhoea in up to 20 % of patients.
Skin rashes occur in 10 % of patients treated with clindamycin and may be more common in patients with HIV infection.
The table below lists the adverse reactions sorted by system organ class and frequency.
Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

a. Tabulated list of adverse reactions

System Organ Class	Frequency Category
Infections and infestations:	
Pseudomembranous colitis#	Frequent
Clostridium difficile colitis	Frequency unknown
Vaginal infection	
Blood and lymphatic disorders:	
Agranulocytosis	Frequency unknown
Neutropenia	
Thrombocytopenia	
Leukopenia	
Eosinophilia	
Immune system disorders:	
Anaphylactic shock	Frequency unknown
Anaphylactoid reaction	
Anaphylactic reaction	
Hypersensitivity	
Nervous system disorders:	
Dysgeusia	Frequency unknown
Gastrointestinal disorders:	
Diarrhoea	Frequent
Abdominal pain	
Vomiting	Less Frequent
Nausea	
Oesophageal ulcer	Frequency unknown
Oesophagitis	
Hepatobiliary Disorders	
Jaundice	Frequency unknown
Skin and subcutaneous tissues disorders:	
Rash maculo-papular	Less frequent
Urticaria	
Toxic epidermal necrolysis (TEN)	Frequency unknown
Stevens-Johnson syndrome (SJS)	
Medicine reaction with eosinophilia and systemic symptoms (DRESS)	
Acute generalised exanthematous pustulosis (AGEP)	
Angioedema	
Dermatitis exfoliative	
Dermatitis bullous	
Erythema multiforme	
Pruritus	
Rash morbilliform	
Investigations:	
Liver function test abnormal	Frequent

See section 4.4, and section 4.8.b Description of selected adverse reactions

b. Description of selected adverse reactions:

Treatment of antibiotic-associated colitis:

If persistent diarrhoea occurs during therapy, the medication should be discontinued. Significant diarrhoea occurring up to several weeks post-therapy should be managed as if antibiotic associated.

- Mild colitis: may respond to discontinuation of clindamycin alone.
- Moderate to severe colitis: discontinue clindamycin and treat with fluid, electrolyte and protein replacement.
- Severe colitis: In cases not responding to the above discontinue clindamycin and treat with appropriate fluid electrolyte and protein supplementation and with one of the following:
  - vancomycin 125 to 500 mg orally, every 6 hours for 5 to 10 days
  - metronidazole 250 to 500 mg orally, every 8 hours,
  - bacitracin 25 000 units orally, 4 times a day or
  - cholestyramine 4 grams orally, 4 times a day.

Relapses must be treated with a second course of the above medication.

DETACH BEFORE DISPENSING

- signs of a severe allergic reaction such as sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, throat or tongue, rash or itching (especially affecting the whole body)
- a widespread rash with blistering and peeling of large areas of skin, particularly around the mouth, nose, eyes or genitals, known as Stevens-Johnson Syndrome, or Toxic Epidermal Necrolysis
- a rare skin eruption that is characterised by the rapid appearance of areas of red skin studded with small pustules (small blisters filled with white/yellow fluid) (Acute Generalised Exanthematous Pustulosis (AGEP))
- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge - erythema multiforme)
- widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)
- fever, swollen lymph nodes or skin rash, these may be symptoms of a condition known as DRESS (Drug Reaction with Eosinophilia and Systemic Symptoms)

These are all very serious side effects. If you have them, you may have had a serious reaction to **KLIDAR.** You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Vomiting
- Nausea (feeling sick)
- Abdominal cramps or stomach pains.
- Rash maculo-papular (presence of flat and papules rash)
- Urticaria 'itchy rash or swellings

Less frequent side effects:

- *Clostridium difficile* colitis (mild diarrhoea to fatal colitis)
- Vaginal infection
- Agranulocytosis (deficiency of granulocytes in the blood)
- Neutropenia (a low level of neutrophils)
- Eosinophilia (n increase in the number of eosinophils in the blood)
- Leukopenia (a reduction in the number of leucocytes) blood cells that fight for infection in the blood
- Thrombocytopenia (a reduction in the number of platelets in the blood)
- Dysgeusia (taste disturbance)
- Oesophageal ulcer
- Oesophagitis (inflammation of the lining of the oesophagus)
- Pruritus (itchy skin)
- Rash morbilliform (skin rash)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 via https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store KLIDAR

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Store at or below 25 °C.
Keep in original packaging until required for use.
Do not use after the expiry date stated on the label.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What KLIDAR contains

The active substance in **KLIDAR** is clindamycin hydrochloride USP equivalent to clindamycin 150 mg.
The other ingredients are:
Lactose Monohydrate USNF
Corn Starch USNF
Talc USP
Magnesium Stearate USNF
Empty Hard Gelatin Capsule Shell (Light blue opaque/light green transparent, size '1')

What KLIDAR looks like and contents of the pack

KLIDAR

Light blue opaque/light green transparent size 1 hard gelatin capsule filled with white to off-white powder and imprinted with 'C' on light blue opaque cap and '39' on light green transparent body with black ink.

HDPE

20s:
White opaque round 40 mL HDPE container with 33 mm neck finish closed with 33 mm white opaque polypropylene RS closure with wad having induction sealing liner. Each HDPE container also contains 1 gm of silica gel sachet.

100s:
White opaque round 120 mL HDPE container with 38 mm neck finish closed with 38 mm white opaque polypropylene CR closure with wad having induction sealing liner.
Each HDPE container also contains 1 gm of silica gel sachet.
HDPE bottles shall be further packed in preprinted carton with a packaging leaflet.

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AUROGEN SA (Pty) Ltd
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

REGISTRATION NUMBER:

52/20.1.1/0029

This leaflet was last revised in

12 October 2021

SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

KLIDAR

150 mg capsules

Clindamycin hydrochloride

Contains sugar: 53,76 mg lactose monohydrate

Read all of this leaflet carefully before you start taking KLIDAR

- Keep this leaflet. You may need to read it again.
- **KLIDAR** has been prescribed for you personally and you should not share your **KLIDAR** with other people. It may harm them, even if their symptoms are the same as yours.
- If you have any further questions, ask your doctor or pharmacist, nurse or other healthcare provider.

What is in this leaflet:

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

1. What KLIDAR is and what it is used for

KLIDAR belong to a group of medicines called antibiotics. It is used to treat serious bacterial infections.
KLIDAR can be prescribed to you if you have any of the following:

- Upper respiratory tract infections such as inflammation of the lining of bronchial tubes, lung infection.
- Lower respiratory tract infections such as pain or irritation in the throat and inflammation of the nasal cavities.
- Skin and soft tissue infections, infected wounds, and dental infections.
- Inflammation of bone or bone marrow infections.

2. What you need to know before you take KLIDAR

Do not take KLIDAR:

- If you are hypersensitive (allergic) to clindamycin, lincomycin or doxorubicin, or any of the other ingredients of **KLIDAR** (listed in section 6).
- If you are suffering from diarrhoeal states or gastro-intestinal disease, particularly those with a history of colitis.
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special care with KLIDAR

- Tell your doctor immediately if you have hypersensitivity skin reactions like fever, unexplained widespread skin pain, a red or purple skin rash that spreads or blisters on your skin and mucous membranes of your mouth, nose, eyes and genitals, **KLIDAR** should be discontinued and appropriate therapy should be initiated by your doctor .
- Tell your doctor immediately if you have diarrhoea or usually get diarrhoea when you take antibiotics or have ever suffered from problems with your stomach or intestines. If you develop severe or prolonged or bloody diarrhoea during or after using **KLIDAR** tell your doctor immediately since it may be necessary to stop the treatment. This may be a sign of bowel inflammation (pseudomembranous colitis) which can occur following treatment with antibiotics up to several weeks after discontinuation of treatment.
- If you have to take **KLIDAR** for a long time, your doctor may arrange regular liver, kidney and blood tests.
- If you suffer from problems with your kidneys or liver.
- If you have rare hereditary problems of galactose intolerance or total lactase deficiency or glucose-galactose malabsorption you should not take this **KLIDAR**.

Other medicines and KLIDAR:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

Do not take KLIDAR if:

- If you are taking or using any nerves and muscle pain blocking medicines.
- If you are taking or using any medicines related to any bacterial infections such as macrolides, ketolides, streptogramins, linezolid, and chloramphenicol.
- If you are taking or using a blood thinner or anti-blood clotting medicines such as warfarin.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby or think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before **KLIDAR** is administered to you.
Safety and efficacy in pregnancy have not been established for **KLIDAR**.
KLIDAR is contraindicated in pregnancy There are no adequate and well-controlled studies in pregnant women during the first trimester of pregnancy.

Breastfeeding:

You should not use **KLIDAR** if you are breastfeeding. Safety and efficacy in lactation have not been established. **KLIDAR** is excreted in the breast milk.

Effects on fertility:

KLIDAR does not have any effects on fertility or mating ability.

Driving and using machines

KLIDAR has no or negligible influence on the ability to drive and use machines. It is not always possible to predict to what extent **KLIDAR** may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which **KLIDAR** affects you.

KLIDAR contains lactose. Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this **KLIDAR**.

3. How to take KLIDAR

Do not share medicines prescribed for you with any other person. Always take **KLIDAR** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and Elderly patients

The recommended dose is 150 mg - 450 mg (1-3 capsules) every six hours, depending on the severity of your infection.
The capsules should be taken with a full glass of water.

Children:

The recommended dose in children is between 3 mg and 6 mg per kg of body weight every six hours, depending on the severity of the infection. Your doctor will work out the number of capsules that your child should have.
Your doctor will tell you how long your treatment with **KLIDAR** will last. Do not stop treatment early. If you have the impression that the effect of **KLIDAR** is too strong or weak, tell your doctor or pharmacist.

Taking KLIDAR with food and drink

KLIDAR can be taken with food and water.

If you take more KLIDAR than you should

In the event of over dosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take KLIDAR

It is important that you continue to take **KLIDAR** according to the instructions on the label and that you do not miss any doses. However, if you do miss a dose, take it as soon as you remember and take the next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

Effects if KLIDAR is stopped:

You must not stop taking **KLIDAR** unless your doctor tells you to. If you have any further questions on the use of **KLIDAR**, ask your doctor or pharmacist.

4. Possible side effects

KLIDAR can have side effects.
Not all side effects reported for **KLIDAR** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **KLIDAR**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **KLIDAR** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Inflammation in the colon, loose stools, and abdominal pain, hypersensitivity, SJS (severe illness with ulceration of the mouth, lips and skin), TEN (severe illness and sloughing of the skin), AGEP (skin reactions), DRESS (a rash, involvement of internal organs, hematologic abnormalities, and systemic illness)
- Severe, persistent or bloody diarrhoea (which may be associated with stomach pain or fever). This is a common side effect which may occur after treatment with antibiotics and can be a sign of serious bowel inflammation (pseudomembranous colitis)

A/s: 315 x 480 mm ■ Black

AUROBINDO Packaging Development		Product Name	Component	Item Code	Date & Time
		KLIDAR capsules	Leaflet	P1529349	29.12.2021 & 02.40 pm
		Country	Version No.	Reason Of Issue	Reviewed / Approved by
		South Afric_U3_APL	05	Commercial	
Team Leader	Kiran K	Dimensions (mm)	Colours: 01		
Initiator	Bhogi	315 x 480 mm	29349		
Artist	Sree Designers	Pharma Code: 29349			
Additional Information					

Cholestyramine or colestipol resins bind to *C. difficile* toxin *in vitro*. If it is administered concurrently with vancomycin, it may be advisable to administer the medicines several hours apart, since the resins have been shown to bind to oral vancomycin (see section 4.4).
Antiperistaltic antidiarrhoeals are not recommended since they may delay the removal of toxins from the colon, thereby prolonging and/or worsening the condition.

c. Other special population

Elderly Use

Reported clinical experience indicates that antibiotic-associated colitis and diarrhoea (due to *C.difficile*) seen in association with most antibiotics occur more frequently in the elderly (> 60 years) and may be more severe. These patients should be carefully monitored for the development of diarrhoea.

Pharmacokinetic studies with clindamycin have shown no clinically important differences between young and elderly subjects with normal hepatic function and normal (age-adjusted) renal function after oral or intravenous administration (see section 5.2).

d. Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the '**6.04 Adverse Drug Reactions Reporting Form**' found under SAHPRA's publications: https://www/sahpra.org.za/Publications/Index/8

4.9. Overdose

The incidence of gastrointestinal side-effects is greater with higher doses. Haemodialysis and peritoneal dialysis are not effective means of removing the compound from the blood. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and class: A 20.1.1 Broad and medium spectrum antibiotics

Pharmacotherapeutic group: Lincocosamide antibiotics, ATC Code D10AF01

Mechanism of Action

Clindamycin inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the ribosome. Clindamycin is bacteriostatic.

Antimicrobial Activity

Clindamycin has been shown to be active against most of the isolates of the following microorganisms, both *in vitro* and in clinical infections.

Gram-positive bacteria

Staphylococcus aureus (methicillin susceptible strains), *Streptococcus pneumoniae* (penicillin susceptible strains), *Streptococcus pyogenes.*

Anaerobic bacteria

Clostridium perfringens, Fusobacterium necrophorum, Fusobacterium nucleatum, Peptostreptococcus anaerobius, Prevotella melaninogenica.

Resistant

Streptococcus faecalis, Escherichia coli, Shigella spp., Samlmonella spp.,
Proteus spp. and Pseudomonas spp.

5.2. Pharmacokinetic properties

Absorption

Clindamycin is rapidly absorbed after oral administration (peak blood levels occurred in 45 minutes). Bone and other body fluid levels are obtained rapidly.
About 90 % of a dose of clindamycin hydrochloride is absorbed from the gastro-intestinal tract; concentrations of 2 to 3 micrograms per mL occur within one hour after a 150 mg dose of clindamycin, with average concentrations of about 0,7 micrograms per mL after 6 hours. After doses of 300 and 600 mg peak plasma concentrations of 4 and 8 micrograms per ml, respectively, have been reported. Absorption is not significantly diminished by food in the stomach but the rate of absorption may be reduced.

Distribution

Clindamycin is widely distributed in body fluids and tissues including bone, but it does not reach the cerebrospinal fluid in significant concentrations. It diffuses across the placenta into the foetal circulation and has been reported to appear in breast milk. High concentrations occur in bile. It accumulates in leucocytes and macrophages. Over 90 % of clindamycin in the circulation is bound to plasma proteins. The half-life is 2 to 3 hours, although this may be prolonged in patients with severe renal impairment.

Metabolism

In vitro studies in human liver and intestinal microsomes indicated that clindamycin is predominantly oxidized by CYP3A4, with minor contribution from CYP3A5, to form clindamycin sulfoxide and a minor metabolite, N-desmethylclindamycin. Clindamycin undergoes metabolism, presumably in the liver, to the active N-demethyl and sulphoxide metabolites, and also some inactive metabolites.

Excretion

About 10 % of a dose is excreted in the urine as active medicine or metabolites and about 4 % in the faeces; the remainder is excreted as inactive metabolites. Excretion is slow and takes place over several days. It is not effectively removed from the blood by dialysis.

Special Populations

Patients with Renal Impairment

Serum half-life of clindamycin is increased slightly in patients with markedly reduced renal function. Haemodialysis and peritoneal dialysis are not effective in removing clindamycin from the serum.

Elderly Patients

The half-life, volume of distribution and clearance, and extent of absorption after administration of clindamycin hydrochloride are not altered by increased age. Analysis of data from clinical studies has not revealed any age-related increase in toxicity. Dosage requirements in elderly patients, therefore, should not be influenced by age alone.

After oral administration of clindamycin hydrochloride, the average elimination half-life is increased to approximately 4 hours (range 3,4 - 5,1 hours) in the elderly compared to 3,2 hours (range 2,1 - 4,2 hours) in younger adults. The extent of absorption, however, is not different between age groups and no dosage alteration is necessary for the elderly with normal hepatic function and normal (age-adjusted) renal function.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose Monohydrate USNF
Corn Starch USNF
Talc USP
Magnesium Stearate USNF
Empty Hard Gelatin Capsule Shell (Light blue opaque/light green transparent, size '1')

6.2. Incompatibilities

Not applicable

6.3. Shelf life

36 months

6.4. Special precautions for storage

Store at or below 25 °C.
Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5. Nature and contents of container

HDPE

20s:

White opaque round 40 mL HDPE container with 33 mm neck finish closed with 33 mm white opaque polypropylene RS closure with wad having induction sealing liner. Each HDPE container also contains 1 gm of silica gel sachet.

100s:

White opaque round 120 mL HDPE container with 38 mm neck finish closed with 38 mm white opaque polypropylene CR closure with wad having induction sealing liner. Each HDPE container also contains 1 gm of silica gel sachet.

HDPE bottles shall be further packed in preprinted carton with a packaging leaflet.

6.6. Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

AUROGEN SA (Pty) Ltd
Woodhill Office Park, Building 1, First Floor
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12, 1448
Johannesburg
South Africa

8. REGISTRATION NUMBER

52/20.1.1/0029

9. DATE OF FIRST AUTHORISATION

12 October 2021

P1529349

DETACH BEFORE DISPENSING

SKEDULERINGSTATUS

S4

PASIËNTINLIGTINGSTUK
KLIDAR
150 mg kapsules
Klindamisien hidrochloried
Bevat suiker: 53,76 mg laktosemonohidraat

Lees hierdie hele pamflet sorgvuldig deur voordat u KLIDAR begin neem

- Hou hierdie pamflet. U moet dit dalk weer lees.
- **KLIDAR** is vir u persoonlik voorgeskryf en u moet nie u **KLIDAR** met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al het hulle dieselfde simptome as u.
- Indien u enige verdere vrae het, vra u dokter of apteker, verpleegster of ander gesondheidsorgverskaffer.

Wat is in hierdie pamflet

1. Wat **KLIDAR** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **KLIDAR** neem
3. Hoe om **KLIDAR** te neem
4. Moontlike newe-effekte
5. Hoe om **KLIDAR** te berg
6. Inhoud van die verpakking en ander inligting

1. Wat KLIDAR is en waarvoor dit gebruik word

KLIDAR behoort aan 'n groep medisyne wat antibiotika genoem word. Dit word gebruik om ernstige bakteriële infeksies te behandel.

KLIDAR kan aan u voorgeskryf word as u een van die volgende het:

- Boonste respiratoriese kanaalinfeksies soos inflammasie van die voering van bronggiale buise, longinfeksie.
- Onderste respiratoriese kanaalinfeksies soos pyn of irritasie in die keel en inflammasie, inflammasie van die neusholtes.
- Vel- en sagteweegselinfeksies, besmette wonde, en tandheelkundige infeksies.
- Inflammasie van been of beenmurginfeksies.

2. Wat u moet weet voordat u KLIDAR neem

Moenie KILDAR neem nie:

- Indien u hipersensitief (allergies) is vir klindamisien, linkomisien of doksorubisien, of enige van die ander bestanddele van **KLIDAR** (gelys in afdeling 6).
- Indien u ly aan diaretiese toestande of gastrointestinale siekte, veral diegene met 'n geskiedenis van kolitis.
- Indien u swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met KLIDAR

- Vertel u dokter onmiddelik indien u hipersensitiviteit vetreaksies het, soos koors, onverklaarbare wydverspreide velpyn, 'n rooi of pers veluitslag wat versprei of blase op u vel en slymvliese van u mond, neus, oë en geslagsdele, **KLIDAR** moet gestaak word en die toepaslike behandeling moet deur u dokter begin word.
- Vertel u dokter onmiddelik indien u diarree het of gewoonlik diarree kry wanneer u antibiotika neem of ooit probleme met u maag of ingewande gehad het. Indien u ernstige of langdurige of bloederige diarree ontwikkel, tydens of na die gebruik van **KLIDAR**, vertel u dokter onmiddelik, aangesien dit nodig mag wees om behandeling te staak. Dit kan 'n teken wees van derminflammasie (pseudomembrane kolitis) wat kan voorkom na behandeling met antibiotika tot 'n paar weke na die beëndiging van behandeling.
- Indien u **KLIDAR** vir 'n lang tyd moet neem, kan u dokter gereeld lewer-, nier- en bloedtoetse reël.
- Indien u ly aan probleme met u niere of lewer.
- Indien u seldsame ooerflike probleme of galaktose-intoleransie of totale laktase-tekort of glukose-galaktose wanabsorpsie het, moet u nie **KLIDAR** gebruik nie.

Ander medisyne en KLIDAR:

Vertel altyd u gesondheidsorgkundige as u enige ander medisyne neem (dit sluit alle komplementêre of tradisionele medisyne in).

Moenie KLIDAR neem nie:

- Indien u enige medisyne neem of gebruik wat senuwee- en spierpyn blokkeer.
- Indien u enige medisyne neem of gebruik wat verband hou met bakteriële infeksies soos makroliede, ketoliede, streptogramiene, linezolid en chlooramfenikol.
- Indien u 'n bloedverdunner of medisyne teen bloedstolling, soos warfarien, neem of gebruik.

Swangerskap, borsvoeding en fertiliteit

Indien u swanger is of u baba borsvoed, dink u is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir advies voordat u **KLIDAR** gebruik.

Veiligheid en effektiwiteit tydens swangerskap is nie vir **KLIDAR** vasgestel nie.

KLIDAR is teenaangedui in swangerskap. Daar is geen voldoende en goed gekontroleerde studies in swanger vroue tydens die eerste trimester van swangerskap nie.

Borsvoeding:

U moet nie **KLIDAR** gebruik terwyl u borsvoed nie. Veiligheid en effektiwiteit in laktasie is nie vasgestel nie. **KLIDAR** word in borsmelk uitgeskei.

Effekte op fertiliteit:

KLIDAR het geen effekte op fertiliteit of paringsvermoë nie.

Bestuur en gebruik van masjinerie

KLIDAR het geen of 'n onbeduidende invloed op die vermoë om te bestuur en om masjiene te gebruik.
Dit is nie altyd moontlik om te voorspel tot watter mate **KLIDAR** met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie aan enige van bogenoemde aktiwiteite deelneem totdat u weet tot watter mate **KLIDAR** u beïnvloed nie.
KLIDAR bevat laktose. Laktose is 'n tipe suiker. Indien u dokter u meegedeel het dat u 'n intoleransie vir sommige suikers het, kontak u dokter voordat u **KLIDAR** neem.

3. Hoe om KLIDAR te neem

Moenie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie. Neem altyd **KLIDAR** presies soos u dokter u aanbevel het. Raadpleeg u dokter of apteker indien u onseker is.

Volwassenes en Bejaarde pasiënte

Die aanbevole dosis is 150 mg – 450 mg (1 – 3 kapsules) elke ses uur, afhangende van die erns van u infeksie. Die kapsules moet met 'n vol glas water geneem word.

Kinders:

Die aanbevole dosis by kinders is tussen 3 mg en 6 mg per kg liggaamsgewig, elke ses uur, afhangende van die erns van die infeksie. U dokter sal die aantal kapsules bepaal wat u kind moet neem.
U dokter sal u vertel hoe lank u behandeling met **KLIDAR** sal duur. Moenie die behandeling vroeg stop nie. Vertel u dokter of apteker as u die indruk het dat die effek van **KLIDAR** te sterk of te swak is.

Die neem van KLIDAR met voedsel en drank

KLIDAR kan met voedsel en water geneem word.

Indien u meer KLIDAR neem as wat u moet

In die geval van oordosering, raadpleeg u dokter of apteker sonder versuim. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of giftbeheersentrum.

Indien u vergeet om KLIDAR te neem

Dit is belangrik om voort te gaan om **KLIDAR** te neem volgens die instruksies op die etiket en dat u geen dosisse mis nie.
Indien u egter 'n dosis mis, neem dit so gou as wat u onthou en neem die volgende dosis op die normale tyd. Moenie 'n dubbeldosis neem om op te maak vir 'n vergete dosis nie.

Effekte indien KLIDAR gestaak word

U moet nie ophou om **KLIDAR** te neem nie, tensy u dokter u beveel om dit te doen. Indien u enige verdere vrae het oor die gebruik van **KLIDAR**, vra u dokter of apteker.

4. Moontlike newe-effekte

KLIDAR kan newe-effekte hê.

Nie alle newe-effekte wat vir **KLIDAR** aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid agteruitgaan of indien u enige ongewensde effekte ervaar terwyl u **KLIDAR** neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir advies.
Indien enige van die volgende gebeur, staak **KLIDAR** en vertel u dokter onmiddelik of gaan na die ongevalle-afdeling van u naaste hospitaal:

- Inflammasie in die kolon, los stoelgang, en abdominale pyn, hipersensitiwiteit, SJS (ernstige siekte met ulserasie van die mond, lippe en vel), TEN (ernstige siekte en peeling van die vel), AGEP (velreaksies), DRESS ('n uitslag, betrokkenheid van interne organe, hematologiese abnormaliteite, en sistemiese siekte)
- Erge, aanhoudende of bloederige diarree (wat verband kan hou met maagpyn en koors). Dit is 'n algemene newe-effek wat kan voorkom na behandeling met antibiotika en kan 'n teken wees van ernstige derminflammasie (pseudomembrane kolitis)
- tekens van 'n ernstige allergiese reaksie soos skielike hyging, moeilik om asem te haal, swelling van die ooglede, gesig of lippe, keel of tong, uitslag of jeuk (wat veral die hele liggaam aantas)
- 'n wydverspreide uitslag met blaasvorming en afskilfering van groot areas van die vel, veral rondom die mond, neus, oë of geslagdele, bekend as Stevens-Johnson-Sindroom, of Toksiese Epidermale Nekrolise
- 'n seldsame veluitbarsting wat gekenmerk word deur die vinnige voorkoms van areas van rooi vel besaai met klein pustules (klein blasies gevul met wit/geel vloeistof) (Akute Veralgemene Eksantematiese Pustulose (AGEP))
- veluitslag, wat blase kan vorm, en lyk soos klein teikens (sentrale donker kolle omring deur 'n ligter area, met 'n donker ring om die kant – eriteem multiforme)
- wydverspryde rooi veluitslag met klein etter-gevulde blase (bulleuse eksfoliatiewe dermatitis)
- koors, geswelde limfknope of veluitslag, hierdie kan simptome wees van 'n toestand wat bekend is as DRESS (Medisyne reaksie met eosinofilie en sistemiese simptome)

Hierdie is almal baie ernstige newe-effekte. Indien u dit ervaar, het u moontlik 'n ernstige reaksie vir **KLIDAR**. U benodig moontlik dringende mediese behandeling of hospitalisasie.
Vertel u dokter onmiddelik of gaan na die ongevalle-afdeling van u naaste hospitaal indien u enige van die volgende opmerk:

- Vergeling van die vel en oë, donker urine, en moegheid wat simptome van lewerprobleme kan wees.

Hierdie is almal ernstige newe-effekte. U benodig moontlik dringende mediese behandeling.
Vertel u dokter indien u enige van die volgende opmerk:
Gereelde newe-effekte:

- Braking
- Naarheid (siek voel)
- Abdominale krampe of maagpyne
- Uitslag, makulo-papulêr (voorkoms van plat en papules uitslae)
- Neteiroos, jeukerige uitslag of swellings

Minder gereelde newe-effekte:

- *Clostridium difficile* kolitis (ligte diarree tot dodelike kolitis)
- Vaginale infeksie
- Agranulositose (tekort aan granulosiete in die bloed)
- Neuropenie ('n lae vlak van neurtrofiele)
- Eosinofilie ('n toename in die aantal eosinofiele in die bloed)
- Leukopenie ('n vermindering in die aantal plaatjies in die bloed)
- Disgeusie (smaakversteuring)
- Esofageale ulkus
- Esofagitis (inflammasie van die voering van die slukderm)
- Pruritus (jeukerige vel)
- Morbiliforme uitslag (veluitslag)

Indien u enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblief u dokter of apteker in.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegster. Dit sluit enige moontlike newe-effekte in wat nie in hierdie pamflet gelys is nie. U kan ook newe-effekte aanmeld via https://www.sahpra.org.za/Publications/Index/8
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van hierdie medisyne te verskaf.

5. Hoe om KLIDAR te berg

BERG ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

Berg teen of benede 25 °C.
Hou in die oorspronklike verpakking tot benodig vir gebruik.
Moenie na die vervaldatum, wat op die etiket aangedui is, gebruik nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat KLIDAR bevat

Die aktiewe bestanddeel in **KLIDAR** is klindamisien hidrochloried USP gelykstaande aan klindamisien 150 mg.
Die ander bestanddele is:
Laktosemonohidraat USNF
Mieliestysel USNF
Talk USNF
Magnesiumstearaat USNF
Leë Harde Gelatienkapsule Dop (Ligblou ondeursigtige/liggroen deursigtig, grootte '1')

Hoe KLIDAR lyk en inhoud van die verpakking

KLIDAR

Ligblou, ondeursigter/liggroen deursigtige grootte '1' harde gelatienkapsule gevul met wit tot naaswit poeier. en ingedruk met 'C' op die ligblou ondeursigtige doppie en '39' op die liggroen deursigtige romp met swart ink.

HDPE

20s:

Wit, ondeursigtige, ronde 40 mL HDPE-houer met 33 mm nekafwerking met 33 mm wit, ondeursigtige polipropileen RS sluiting met watte en induksie seëlvoering. Elke HDPE-houer bevat ook 'n 1 g silikagel-sakkie.

100s:

Wit, ondeursigtige, ronde 120 mL HDPE-houer met 38 mm nekafwerking met 38 mm wit, ondeursigtige polipropileen CR sluiting met watte en induksie seëlvoering. Elke HDPE-houer bevat ook 'n 1 g silikagel-sakkie.
HDPE-bottels word verder verpak in vooraldgedrukte kartron met 'n pamflet.

NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE REGISTRASIE SERTIFIKAAT

AUROGEN SA (Edms.) Bpk
Woodhill Office Park, Gebou 1, Eerste Vloer
Philip Engelbrechtlaan 53
Meyersdal, Uitbr. 12, 1448
Johannesburg
Suid-Afrika

REGISTRASIENOMMER:

52/20.1.1/0029

Hierdie pamflet is laas hersien in:

12 Oktober 2021