

PATIENT INFORMATION LEAFLET

KLINDAVER 600 mg/4 mL Injectable Solution

Sterile

Administered intramuscularly or intravenously

- **Active ingredient:** Each ampoule (4mL) contains clindamycin phosphate equivalent to 600 mg clindamycin.
- **Excipients:** Benzyl alcohol, disodium edetate, water for injection.

Before using this medicine, read all of this PATIENT INFORMATION LEAFLET carefully. Because, this leaflet includes important information for you.

- *Keep this PATIENT INFORMATION LEAFLET. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *During the use of this medicine, tell that you are using this medicine when you go to a doctor or hospital.*
- *Follow these instructions exactly as written. Do not use **higher or lower** dose other than your recommended dose.*

In this patient information leaflet:

1. *What KLINDAVER is and what it is used for?*
2. *Before you are given KLINDAVER*
3. *How to use KLINDAVER?*
4. *Possible side effects*
5. *How to store KLINDAVER*

Headings are included.

1. What KLINDAVER is and what it is used for?

- KLINDAVER is a clear, colorless sterile solution that is administered intramuscularly or intravenously.
- KLINDAVER contains clindamycin (in the form of clindamycin phosphate), an antibiotic from the lincosamide group. It is available in the form of type I glass ampoule of 4 mL in carton box.
- If your doctor deems appropriate, KLINDAVER is used in the treatment of the following infections caused by susceptible strains of bacteria sensitive to clindamycin, susceptible *Chlamydia trachomatis* strains:
- Upper respiratory tract infections: Tonsillitis, pharyngitis, sinusitis, middle ear inflammation and scarlet fever.
- Lower respiratory tract infections: Bronchitis, lung inflammation, empyema and lung abscess.

- Various skin infections: Acne, furuncle, cellulitis, infectious superficial microbial infection of the skin (impetigo), abscess and scar, erysipelas and entanglement (paronychia).
- Bone and joint infections: Bone and bone marrow inflammation (osteomyelitis) and blood inflammation (septic arthritis).

Gynecological (female reproductive system) diseases

- Abdominal infections: Inflammation of the peritoneum (peritonitis) and abdominal abscess.
- Tooth and gum infections: Gum abscess and gingivitis (periodontitis).

KLINDAVER can also be used in the treatment of more serious cases such as infection in the blood (septicemia), inflammation of the inner lining of the heart (endocarditis) or some infections in AIDS patients.

KLINDAVER does not reach to the brain and is not suitable for the treatment of serious infections in the brain.

In the treatment of malaria, the capsule or oral form of clindamycin is effective when used alone or in combination with other drugs.

2. Before you are given KLINDAVER

DO NOT USE KLINDAVER in the following cases:

If;

- You are hypersensitive (allergic) to clindamycin or other substances contained in KLINDAVER.

Use KLINDAVER CAREFULLY in the following cases:

If;

- You have diarrhea or if you generally have diarrhea when taking antibiotics, or if you have stomach and intestinal problems. If you have severe, prolonged or bloody diarrhea while using the drug or after treatment, inform your doctor immediately; Do not take diarrhea medication without consulting your doctor. This may be an indication of bowel inflammation (pseudomembranous colitis) that may occur after treatment with antibiotics, and treatment may need to be discontinued.
- As with other antibiotics, resistant bacterial and fungal infections may develop in long-term use of KLINDAVER (super infection). This occurs in the form of thrush in the mouth or vagina. For this possibility and emergency intervention, your treatment must be done under the control of a doctor. If you are using KLINDAVER or immediately after using it, please inform your doctor immediately if you have white mouth or tongue, pain or itching and discharge in your genital organs.
- If you have kidney or liver problems (if you are going to use KLINDAVER for a long time, your doctor may request kidney, liver and blood tests from you. Make sure that these checks are done regularly and without missing).
- If you have asthma, eczema or hay fever
- Safety and proper dosage have not been established in infants younger than 1 month.

If these warnings are valid for you, even at any time in the past, please consult your doctor.

Using KLINDAVER with food and drinks

It can be administered to a hungry or full stomach because it does not interact with food and drinks.

Pregnancy

Consult your doctor or pharmacist before using this drug.

It is not known whether KLINDAVER is safe to use during pregnancy. For this reason, do not use KLINDAVER unless your doctor recommends it during pregnancy.

Please consult your doctor or pharmacist if you notice that you are pregnant during your treatment.

Lactation

Consult your doctor or pharmacist for before using this drug.

It is known that KLINDAVER passes into breast milk. For this reason, do not use KLINDAVER during breastfeeding unless your doctor recommends it.

Driving and using machines

Special studies have not been done on the effect of KLINDAVER on the use of cars and dangerous machines.

Although KLINDAVER treatment is not thought to have an effect on the ability to drive, if you have any questions, consult your doctor.

Important information about some of the excipients contained in KLINDAVER content

This medicinal product contains less than 1 mmol of sodium per mL; so essentially "does not contain sodium".

This product contains 9.45 mg benzyl alcohol per mL. It should not be administered to premature babies and newborns (babies less than 1 month old). May cause toxic reactions and allergic reactions in infants and children up to 3 years old.

Using other medicines

When taken with other medicines, the effect of KLINDAVER or other medication may change.

These are;

- Erythromycin (an antibiotic); The two drugs counteract each other.
- Muscle relaxants (KLINDAVER may increase the effect of these drugs)
- Birth control pills (you should try other birth control methods such as condoms during KLINDAVER treatment or for 7 days after stopping KLINDAVER treatment).
- Patients who do not respond to clindamycin may not benefit from lincomycin.

If you are currently using or have recently used any prescribed or non-prescribed medicine, please inform your doctor or pharmacist.

3. How to use KLINDAVER

Instructions for use and dose/frequency of administration:

Your doctor will decide in what dosage and how often you should take KLINDAVER.

In adults, 600-2700 mg per day are administered in 2, 3 or 4 equal doses, depending on the severity of the infection.

Higher doses (up to 4800 mg per day) may be given in very serious infections.

Your doctor may increase or decrease the dosage depending on the severity of the infection.

Clindamycin concentration should not be more than 18 mg / mL and the administration rate should not exceed 30 mg per minute. If applied too quickly, it may rarely cause a heart attack.

Follow your doctor's instructions exactly and never change the dose yourself.

Prolonged use can lead to other infections.

Route of administration and method:

It is administered intramuscularly and intravenously. When administered intravenously, it is mixed with sugar or saline (salt) solution and administered dropwise.

Different age groups:

Use in children:

In children (over 1 month of age) the recommended dose is 15-40 mg of clindamycin per kg body weight in 3 or 4 equal doses per day.

In severe infections, your doctor may administer high doses of up to 300 mg per day, regardless of body weight, until a complete response to treatment is observed.

Your doctor will decide in what dosage and how often you should take KLINDAVER.

Use in the elderly:

There is no need for dose restriction in the elderly. It is the same as the dose administered in adults.

Conditions of special use:

Renal impairment:

There is no need for any dose adjustment.

Hepatic impairment:

There is no need for any dose adjustment.

When long-term use is necessary, your doctor may order regular liver, kidney and blood tests.

If you have the impression that the effect of KLINDAVER is too strong or too weak, talk to your

doctor or pharmacist.

If you use more KLINDAVER than you should:

If you use more KLINDAVER than you should, talk to a doctor or pharmacist.

If you forget to use KLINDAVER:

If you have completely missed a dose of KLINDAVER, inform your doctor.

Do not take double doses to make up for forgotten doses.

If KLINDAVER treatment ends, effects may occur:

Use KLINDAVER regularly and exactly as recommended by your doctor.

Do not stop treatment even if you feel well; Because if the treatment is terminated early, the medicine may not have killed all the germs and the infection may recur.

4. Possible side effects

Like all other medicines, KLINDAVER may cause side effects in patients with hypersensitivity to any component of the drug.

If you notice any of the following, stop using KLINDAVER tell your doctor immediately or consult nearest hospital emergency room:

- Sudden sneezing, difficulty in breathing, swelling of the face, eyelid and lips, rash on the skin, itching (especially if it affects the whole body)

These are all very serious side effects.

If you have one of these, you have a serious allergy to KLINDAVER. You may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare.

The frequency of adverse events is reported using the following categories;

Very common	: can be seen at least 1 out of 10 patients.
Common	: can be seen less than one in 10 patients, but more than one in 100 patients.
Uncommon	: can be seen less than one in 100 patients, but more than one in 1,000 patients.
Rare	: can be seen less than one in 1.000 patients, but can be seen more than 10,000 patients in one.
Very rare	: can be seen less than one in 10,000 patients.
Unknown	: cannot be estimated from available data.

Common:

- Abnormal liver function tests
- Abdominal pain, diarrhea

- Thrombophlebitis (blood clot formation due to inflammation of the veins) (after intravenous injection)

Uncommon:

- Deterioration in sense of taste
- Low blood pressure (dizziness or fainting), rarely heart attack (if the injection is given quickly)
- Nausea and vomiting
- Maculopapular (slightly raised skin) rashes
- Pain, abscess formation (after intramuscular injection)

Rare:

- Swelling, pain, tenderness in more than one joint
- Increased blood urea nitrogen (BUN) and serum creatinine levels
- Decrease in daily urine output (oliguria) and / or protein detection in urine (proteinuria)

Unknown:

- Inflammation in the female genitalia
- Transient neutropenia (leukopenia), eosinophilia, agranulocytosis and thrombocytopenia
- Allergic reactions
- Esophagitis, esophageal ulcer (inflammation and wound in the esophagus)
- Jaundice (seen as yellowing of the skin or whites in the eyes)
- Erythema multiforme (inflammation of the skin and around the eyes, swelling and redness), rash, itching
- Steven Johnson Syndrome (inflammation of the skin and around the eyes with swelling and redness), toxic epidermal necrosis (a serious disease with fluid-filled blisters on the skin), exfoliative dermatitis (a type of skin disease), morbilliform-like skin redness, vesiculobullous dermatitis (a type of skin disease), serious skin adverse reaction (SCAR)
- Swelling, redness, hardening, irritation at the administration site (after intramuscular administration)

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

Reporting of the side effects:

If you get any side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to your doctor or pharmacist. You can also report side effects directly to your country's related health authority. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store KLINDAVER

*Keep KLINDAVER in places out of sight and reach of children and within the packaging.
Store at room temperature at 15-30°C.*

Use in accordance with the expiry date.

Do not use KLINDAVER after the expiration date which is stated on the package.

Marketing Authorization Holder and Manufacturing Site:

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This leaflet was approved on .../.../....