

This document is approved by Saudi Food and Drug Authority

**Direct Healthcare Professional Communication (DHPC)**

**Clindamycin Hikma 150 mg/mL Injection Solution for Injection / Infusion**

*Dear Healthcare provider,*



In agreement with the Saudi Food and Drug Authority (SFDA), **Nasaq El-Enjaz Company** would like to inform you of a quality discrepancy identified in one batch of **Clindamycin Hikma 150 mg/mL Injection** marketed in the Kingdom of Saudi Arabia.

**Summary**

This communication is regarding the absence of the English Package Leaflet (PIL) inside the product pack for one batch. The quality, safety, and efficacy of the product remain unaffected. Affected batch:

**Clindamycin Hikma 150 mg/mL Injection – Batch No.: 24/165**

**Further information on the safety concern and the recommendations**

The following information is intended for medical or healthcare professionals only.

1. Kindly identify and segregate the affected batch.
2. Ensure patients receive appropriate instructions for use by providing the attached English PIL or through verbal counseling if required.
3. Report any suspected adverse events or quality complaints.

**Call For Reporting**

Please report any suspected adverse drug reactions or quality complaints to:

**Ahmed Maged**

Email: ahmed.maged@nasaq-sa.com

Phone: +966 50 043 2073

**The National Pharmacovigilance Centre (NPC) – SFDA**

SFDA Call Center: 19999

Email: npc.drug@sfda.gov.sa

Website: <http://ade.sfda.gov/>

## **Instructions for use: Information for users**

### **Clindamycin Hikma 150 mg/ml solution for injection** Clindamycin

**Read the entire package leaflet carefully before you start using this medicine as it contains important information.**

- Keep the package leaflet. You may want to it again later.
- If you have any further questions, ask your doctor, pharmacist or healthcare professional.
- This medicine has been prescribed for you personally. Do not pass it on to third parties. It may harm other people, even if they have the same complaints as you.
- If you notice any side effects, contact your doctor, pharmacist or healthcare professional. This also applies to side effects not listed in this package leaflet. See section 4.

#### **What this leaflet says:**

1. What is Clindamycin Hikma and what is it for?
2. What should you consider before using Clindamycin Hikma?
3. How should Clindamycin Hikma be used?
4. What side effects are possible?
5. How should Clindamycin Hikma be stored?
6. Contents of the pack and further information

#### **1. What is Clindamycin Hikma and what is it for?**

Clindamycin Hikma is an antibiotic for parenteral administration by injection or infusion.

For the treatment of acute and chronic bacterial infections (infectious diseases) caused by pathogens sensitive to clindamycin, such as

- Infections of the bones and joints,
- Infections of the ear, nose and throat area,
- Infections of the tooth and jaw area,
- Infections of the deep respiratory tract,
- Infections of the pelvic and abdominal cavity,
- Infections of the female reproductive organs,
- Infections of the skin and soft tissues,
- Scarlet fever,
- Blood poisoning (septicemia),
- bacterial inflammation of the heart valves (endocarditis).

#### **2. What should you consider before using Clindamycin Hikma?**

##### **Clindamycin Hikma must not be used,**

- if you are allergic (hypersensitive) to clindamycin or lincomycin or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to benzyl alcohol or local anesthetics (such as lidocaine or drugs related to lidocaine)

- for premature babies or newborns

### **Warnings and precautions**

Please talk to your doctor, pharmacist or healthcare professional before using Clindamycin Hikma.

Acute kidney disease may occur. Please inform your doctor of any medication you are currently taking and of any existing kidney problems. If you notice reduced urine output, water retention with swelling in the legs, ankles or feet, shortness of breath or nausea, you should contact your doctor immediately.

### **Particular caution is required when using Clindamycin Hikma in the following cases**

- impaired liver function,
- disorders of neuromuscular transmission (e.g. myasthenia gravis: pathological muscle weakness; Parkinson's disease: so-called shaking palsy) and
- History of gastrointestinal diseases (e.g. previous inflammation of the colon).

In the case of long-term treatment (longer than 3 weeks), the blood count and liver and kidney function should be checked at regular intervals.

Long-term and repeated use of Clindamycin Hikma on skin and mucous membranes can lead to infection with pathogens against which Clindamycin Hikma is ineffective, as well as to colonization with fungal sprouts.

Clindamycin Hikma should not be used for acute respiratory tract infections caused by viruses.

Clindamycin Hikma is not suitable for the treatment of meningitis, as the concentrations achievable in the cerebrospinal fluid (CSF) are too low.

Clindamycin treatment may be a possible alternative treatment for penicillin allergy (penicillin hypersensitivity). A cross-allergy between clindamycin and penicillin is not known and is not to be expected due to the structural differences between the substances. However, in individual cases there is information about anaphylaxis (hypersensitivity) to clindamycin in people with a pre-existing allergy to penicillin. This should be taken into account when treating patients with penicillin allergies with clindamycin.

Very rarely, severe, persistent diarrhea occurs during or in the first few weeks after treatment. In this case, a severe intestinal disease (pseudomembranous enterocolitis) should be considered (in most cases caused by *Clostridium difficile*). This intestinal disease triggered by antibiotic treatment can be life-threatening and requires immediate and appropriate treatment. In this case, be sure to consult your doctor.

Very rarely, a life-threatening anaphylactic shock may occur (circulatory failure due to hypersensitivity). These reactions sometimes occur after the first application. In this case, please contact your doctor.

### **Use of Clindamycin Hikma together with other medicines**

Tell your doctor or pharmacist if you are taking/using other medicines, have recently taken/used other medicines or intend to take/use other medicines, even if they are non-prescription medicines.

#### *Medicines that influence the effect of Clindamycin Hikma*

- Erythromycin (antibiotic): reciprocal reduction in effectiveness

#### *Medicinal products whose effect is influenced by Clindamycin Hikma:*

- Muscle relaxants (drugs for muscle relaxation), e.g. ether, tubocurarine, pancuronium halide: increased effect
- Warfarin and similar blood-thinning medication: The likelihood of bleeding may be increased. Regular blood tests may be necessary to check blood clotting.

The pathogens are cross-resistant to clindamycin, the active ingredient in Clindamycin Hikma, and lincomycin-containing drugs.

#### *Medicinal products that are incompatible with Clindamycin Hikma (chemical incompatibility)*

Clindamycin Hikma must not administered together with ampicillin, phenytoin sodium, barbiturates, aminophylline, calcium gluconate and magnesium sulphate in a mixed syringe. These medicinal products must be administered separately.

### **Pregnancy and breastfeeding**

If you are pregnant or breastfeeding, or if you think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before using this medicine.

When used during pregnancy and breastfeeding, the benefits and risks must carefully weighed against each other. Observations in humans have so far shown no evidence of adverse effects on fertility.

In breastfed infants, sensitization (production of hypersensitivity), diarrhoea and fungal colonization of the mucous membranes cannot be ruled out.

### **Roadworthiness and ability to operate machinery**

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

### **Clindamycin Hikma contains benzyl alcohol**

This medicine contains 9 mg benzyl alcohol per ml. Benzyl alcohol can cause allergic reactions.

Benzyl alcohol has been associated with a risk of serious side effects, including breathing problems (known as 'gaspings syndrome') in young children. Do not use this medicine in young children (under 3 years of age) for more than one week unless advised by your doctor or pharmacist.

If you are pregnant or breastfeeding, ask your doctor or pharmacist for advice, as large amounts of benzyl alcohol can accumulate in your body and cause side effects (so-called "metabolic acidosis").

If you suffer from liver or kidney disease, ask your doctor or pharmacist for advice, as large amounts of benzyl alcohol can accumulate in your body and cause side effects (so-called "metabolic acidosis").

### **Clindamycin Hikma contains sodium**

This medicine contains up to 8.32 mg sodium (main component of table salt) per ml solution. This corresponds to 0.42% of the maximum recommended daily dietary sodium intake for an adult.

### **3. How should Clindamycin Hikma be used?**

Clindamycin is usually administered by a doctor or healthcare professional. It is administered undiluted as an intramuscular injection (into the muscle) or diluted as an intravenous infusion (into a vein). Clindamycin must never be injected undiluted into a vein, but only as an infusion after dilution.

When administered intramuscularly, a single dose of 600 mg clindamycin should not be exceeded.

The following information applies unless your doctor has prescribed Clindamycin Hikma otherwise.

Adults and young people over the age of 14 receive

- for moderately severe infections 8 to 12 ml Clindamycin Hikma daily (equivalent to 1.2 to 1.8 g Clindamycin),
- For severe infections, 16 to 18 ml Clindamycin Hikma (equivalent to 2.4 to 2.7 g Clindamycin) daily in 2 to 4 single doses.

The maximum daily dose for adults and adolescents over 14 years of age is 32 ml Clindamycin Hikma (equivalent to 4.8 g Clindamycin) in 2 to 4 single doses.

#### Dosage for children

Children aged between 4 weeks and 14 years receive 20 - 40 mg clindamycin per kg body weight in 3 to 4 single doses, depending on the location and severity of the infection.

#### Dosage for liver diseases

In patients with moderate to severe liver disease, the elimination half-life (measure of the metabolic function of the liver) of clindamycin is prolonged. A dose reduction is not necessary if Clindamycin Hikma is administered every eight hours. However, the blood concentration (plasma level) of clindamycin should be monitored in patients with severely impaired liver function (severe hepatic insufficiency). Depending on the results of this measure, it may be necessary to reduce the dose or extend the dosing interval.

#### Dosage for kidney disease

In renal disease, the elimination half-life (measure of renal function) of clindamycin is prolonged; however, a dose reduction is recommended in mild to moderately severe renal disease.

Restriction of renal function not required. However, the blood concentration (plasma level) of clindamycin should be monitored in patients with severely impaired renal function (severe renal insufficiency) or no urine excretion (anuria). Depending on the results of this measure, a dose reduction or alternatively an extended dosing interval 8 or even 12 hours may be necessary.

#### Dosage for hemodialysis

Clindamycin is not hemodialyzable. Therefore, no additional dose is required before or after dialysis.

#### Duration of use

The duration of treatment depends on the underlying disease and the course of the disease.

If a larger amount of Clindamycin Hikma has been used than it should Overdose symptoms have not been observed so far. Hemodialysis (so-called blood washing) and peritoneal dialysis (peritoneal lavage) are not effective. A specific antidote is not known.

#### If you want to stop using Clindamycin Hikma

In the event of side effects, your doctor will discuss with you what countermeasures are available and whether other medicines could be considered for treatment.

If you have any further questions about the use of the medicine, ask your doctor or pharmacist.

#### **4. What side effects are possible?**

Like all medicines, Clindamycin Hikma can side effects, although not everybody gets them. Inform your doctor immediately if you experience the following:

- Water retention leading to swelling in the legs, ankles or feet, shortness of breath or nausea

#### **Other possible side effects**

##### **Very common (may affect more than 1 in 10 people treated)**

- soft stools and diarrhea, sometimes associated with nausea, vomiting or abdominal pain. These symptoms are usually mild in nature and often subside during treatment, otherwise after discontinuation. They depend on the dosage form and the amount used.

##### **Common (may affect up to 1 in 10 people treated)**

- Temporarily slightly elevated liver values (serum transaminases).
- Irritation, pain, induration and sterile abscesses (tissue melting) after injection of Clindamycin Hikma in the muscle at the site of injection.
- Pain and inflammation of the vein with formation of a blood clot (thrombophlebitis) after administration into a vein.

##### **Occasionally (may affect up to 1 in 100 people treated)**

- Allergies in the form of a measles-like rash, itching and hives.
- Leukopenia, eosinophilia, neutropenia, granulocytopenia and thrombocytopenia (reduction in various types of white blood cells or platelets).
- Blockade of the transmission of nerve stimuli to the muscle (neuromuscular blocking effect).
- Serious cardiovascular disorders (e.g. drop in blood pressure and cardiac arrest) if administered rapidly into a vein (see also 3. under "Route of administration")

**Rare (may affect up to 1 in 1,000 people treated)**

- Swelling (Quincke's oedema, joint swelling), erythema exsudativum multiforme (e.g. Stevens-Johnson syndrome) and Lyell syndrome (both life-threatening skin diseases, sometimes with blistering or extensive detachment of the skin).
- Itching, exfoliating and blistering skin inflammation.
- Drug fever
- Vaginal catarrh (discharge)
- Hypersensitivity reactions due to benzyl alcohol

**Very rare (may affect up to 1 in 10,000 people treated)**

- Temporary inflammation of the liver with jaundice caused by a build-up of bile
- Inflammation of the joints (polyarthritis)
- Anaphylactic shock
- Pseudomembranous colitis

**Not known (frequency cannot be estimated based on available data)**

- Inflammation of the esophagus and oral mucosa.
- Intolerance reactions in the form of a feeling of heat, nausea when administered rapidly into a vein (see also 3. under "Route of administration").
- Acute kidney damage

**Reporting of side effects**

If you notice any side effects, contact your doctor, pharmacist or healthcare professional. This also applies to side effects that are not listed in this package leaflet. You can also report side effects directly to the BfArM (Federal Institute for Drugs and Medical Devices, Department of Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, website: [www.bfarm.de](http://www.bfarm.de)). By reporting side effects, you can help to ensure that more information is made available about the safety of this medicine.

**5. How should Clindamycin Hikma be stored?**

this medicine out of the reach of children.

Do not use this medicine after the expiry date shown on the label and carton.

"Do not use the product after the expiry date stated under ". The expiry date refers to the last day of the specified month.

Do not store above 25 °C. Store the medicine in the outer carton to protect the contents from light.

Shelf life after production of the ready-to-use preparation:

The chemical and physical stability after dilution was proven over 48 hours at 20 - 25 °C. From a microbiological point of view, the diluted medicinal product should be used immediately. If not, the storage time and conditions are the responsibility of the user. The diluted medicinal product should not normally be stored at 2-8 °C for more than 24 hours unless the dilution has been carried out under controlled and validated aseptic conditions.

Never dispose of medicines in the waste water (e.g. not in the toilet or sink). Ask your pharmacy how to dispose of the medicine when you have finished using it. This will help to protect the environment. Further information can be found at [www.bfarm.de/arzneimittelentsorgung](http://www.bfarm.de/arzneimittelentsorgung).

## **6. Contents of the pack and further information**

### **What Clindamycin Hikma contains**

The active substance is: clindamycin.

2 ml contain 356.4 mg clindamycin-2-dihydrogen phosphate corresponding to 300 mg clindamycin.

4 ml contain 712.8 mg clindamycin-2-dihydrogen phosphate corresponding to 600 mg clindamycin.

6 ml contain 1069.2 mg clindamycin-2-dihydrogen phosphate corresponding to 900 mg clindamycin.

The other ingredients are: Benzyl alcohol (9 mg/ml), sodium edetate, sodium hydroxide (for pH adjustment), water for injection.

### **What Clindamycin Hikma looks like and contents of the pack**

Glass ampoules with 2 ml, 4 ml, 6 ml or vials with rubber stopper with 6 ml clear solution for injection.

Packs of 5, 10 or 100 ampoules and 1, 5 or 10 vials. Not all pack sizes may be placed on the market.

### **Pharmaceutical company and manufacturer**

Hikma Farmacêutica (Portugal) S.A.

Estrada do Rio da Mó, 8, 8A e 8B - Fervença

2705-906 Terrugem SNT

Portugal

### Co-distribution

Hikma Pharma GmbH

Lochhamer Str. 13

82152 Martinsried Germany

### Manufacturer

Hikma Farmacêutica (Portugal) S.A.

Estrada do Rio da Mó, 8 8a e 8b - Fervença

2705-906 Terrugem SNT

Portugal

Hikma Italia S.p.A.

Viale Certosa 10

27100 Pavia

Italy

**This leaflet was last revised in June 2021.**

The following information is intended for healthcare professionals: Preparation of the

ready-to-use solution:

Before an intravenous infusion, the solution should be diluted so that the concentration does not exceed 12 mg clindamycin per ml solution. The infusion rate should be

Do not exceed 30 mg clindamycin per minute. No more than 1200 mg of clindamycin per hour should be given as a single infusion.

Clindamycin Hikma can be diluted with saline solution (NaCl solution) 0.9 % or with glucose solution 5 %.