Dalacin C*

Clindamycin HCl

300 mg Hard Gelatin Capsule

Reference Market: Belgium

AfME Markets using same as LPD: Egypt

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Dalacin C 300 mg hard gelatin capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Dalacin C 300 mg hard gelatin capsules
The active substance is clindamycin. This is present in the form of clindamycin hydrochloride 325.74 mg equivalent to 300 mg clindamycin.

Excipients with known effect:

Dalacin C hard gelatin capsules
Each 300 mg hard gelatin capsule contains 260 mg lactose monohydrate (see section 4.4).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard gelatin capsules:

Opaque violet hard gelatin capsule filled with white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Clindamycin is indicated in the treatment of serious infections, when caused by clindamycin susceptible strains of gram-positive aerobes such as streptococci, pneumococci and staphylococci, or by susceptible anaerobic bacteria (see section 5.1):

1. Upper respiratory tract infections: chronic sinusitis caused by anaerobic strains.
   Clindamycin can be used for selected cases of chronic suppurative otitis media or as adjunctive therapy along with an antibiotic active against aerobic gram-negative organisms.
   Infections caused by *H. influenzae* are not an indication (see section 5.1).
   Clindamycin can also be used in cases of recurrent pharyngotonsillitis.
2. Lower respiratory tract infections including infectious exacerbation of chronic bronchitis and pneumonia.
3. Serious skin and soft tissue infections caused by susceptible organisms.
4. Bone and joint infections including osteomyelitis and septic arthritis.
5. Serious gynaecological infections of the pelvis including pelvic inflammatory disease (PID).
   Clindamycin can also be used in a single therapy in cases of cervicitis due to *Chlamydia trachomatis*.
6. Intra-abdominal infections including peritonitis and abdominal abscess.
7. Septicaemia and endocarditis.
   Selected cases of septicaemia and/or endocarditis due to susceptible organisms have responded well to clindamycin. However, bactericidal drugs are often preferred for these infections.

8. Dental infections including periodontal abscess and periodontitis.
9. Toxoplasmic encephalitis in patient with AIDS. In patients who cannot tolerate the usual treatment, clindamycin may be used in combination with pyrimethamine.
10. *Pneumocystis jirovecii* pneumonia in patients with AIDS. In patients who cannot tolerate the usual treatment, clindamycin may be used in combination with primaquine.
11. Malaria, including multi-resistant *Plasmodium falciparum*, in combination with quinine.

Like other antibiotics information regarding the prevention of local resistance as well as the official recommendations regarding prescription of antibiotics must be reviewed before prescribing clindamycin.

4.2 Posology and method of administration

Posology

The posology and the mode of administration should be determined by the seriousness of the infection, the patient's condition and the sensitivity of the disease causing germ.

It is recommended to swallow the capsules with a glass of water in order to avoid irritation of the oesophagus.

Clindamycin hydrochloride capsules (oral administration):
The usual daily dose is 600-1800 mg divided in 3 or 4 administrations.
In the exceptional case of a treatment for recurrent β haemolytic streptococcal infection: 300 mg, twice daily for at least 10 days.
Cervicitis due to *Chlamydia trachomatis*: 1800 mg per day, divided over several administrations for 10-14 days.

Paediatric population

Clindamycin hydrochloride capsules (*for children who are able to swallow capsules*) in children older than 1 month:
8-25 mg/kg/day in 3 or 4 equal administrations.

Clindamycin capsules are not suitable for children who are unable to swallow them. The capsules do not provide exact mg/kg doses.

Posology in cases of renal and/or liver function impairment:

Dose adjustment is not necessary in patients with an impaired renal function. Haemodialysis and peritoneal dialysis are not effective to remove clindamycin from the blood.

In patients with moderately to seriously reduced liver function, a prolonged half-life of clindamycin was seen. Accumulation is rare if clindamycin is administered every 8 hours. A dose reduction is, therefore, not considered necessary.

Dosage in specific indications:

Toxoplasmic encephalitis in patients with AIDS:
Dalacin C hard capsules in a dose of 600-1200 mg every 6 hours for 2 weeks, followed by oral administration of 300-600 mg every 6 hours. The total treatment usually lasts 8 to 10 weeks.
Oral administration of 25 mg to 75 mg of pyrimethamine per day for 8 to 10 weeks is necessary.
With higher doses of pyrimethamine one should administer 10 to 20 mg of folic acid per day.

Pneumocystis jirovecii pneumonia in patients with AIDS:
Dalacin C hard capsules in a dose of 300 to 450 mg every 6 hours for 21 days, combined with 15 to 30 mg of oral primaquine per day for 21 days.

Malaria:

Uncomplicated Malaria/*P falciparum*:
Adults:
Quinine sulfate: 650 mg orally three times daily for 3 or 7 days plus clindamycin:
20 mg base/kg/day orally divided three times daily for 7 days.

Paediatric population:
Quinine sulfate: 10 mg/kg orally three times daily for 3 or 7 days plus clindamycin:
20 mg base/kg/day orally divided three times daily for 7 days.

Severe malaria:
Adults:
Quinidine gluconate: 10 mg/kg loading dose IV over 1-2 hrs, then 0.02 mg/kg/min continuous infusion for at least 24 hours (for alternative dosing regimen please refer to quinidine label). Once parasite density < 1% and patient can take oral medication, complete treatment with oral quinine, dose as above, plus clindamycin: 20 mg base/kg/day orally divided three times daily for 7 days.
If patient is not able to take oral medication, give 10 mg base/kg clindamycin loading dose IV followed by 5 mg base/kg IV every 8 hours. Avoid rapid IV administration. Switch to oral clindamycin (oral dose as above) as soon as patient can take oral medication. Treatment course = 7 days.

Paediatric population:
Quinidine gluconate: Same mg/kg dosing and recommendations as for adults plus clindamycin: 20 mg base/kg/day orally divided three times daily for 7 days. If patient is not able to take oral medication, give 10 mg base/kg clindamycin loading dose IV followed by 5 mg base/kg IV every 8 hours. Avoid rapid IV administration. Switch to oral clindamycin (oral dose as above) as soon as patient can take oral medication. Treatment course = 7 days.

4.3 Contraindications

- Hypersensitivity to the active substance, to lincomycin, to any component of the formulation, or to any of the excipients listed in section 6.1.
- In case of infectious meningitis (see section 4.4).

4.4 Special warnings and precautions for use

- Severe hypersensitivity reactions, including severe skin reactions such as drug reaction with eosinophilia and systemic symptoms (DRESS), Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and acute generalized 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).

- Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *Clostridium difficile*. This has been reported with use of nearly all antibacterial agents, including clindamycin, and may range in severity from mild diarrhoea to fatal colitis. *C. difficile* produces toxins A and B which contribute to the development of *Clostridium difficile* associated diarrhoea (CDAD) and is a primary cause of "antibiotic-

associated colitis". Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. This form of colitis is characterized by mild, watery diarrhoea that may develop to serious, chronic diarrhoea, leukocytosis, fever, serious abdominal cramps that may be accompanied by loss of blood and mucus. Without further treatment peritonitis, shock and toxic megacolon may develop. Antibiotic induced colitis can occur with clindamycin up to 2 to 3 weeks after discontinuation of the treatment. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

- It is important to consider the diagnosis of CDAD in patients who present with diarrhoea during or after the administration of antibacterial agents. This may progress to colitis, including pseudomembranous colitis (see section 4.8), which may range from mild to fatal colitis. If antibiotic-associated diarrhoea or antibiotic-associated colitis is suspected or confirmed, ongoing treatment with antibacterial agents, including clindamycin, should be discontinued and adequate therapeutic measures should be initiated immediately. In moderate-to-severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis. Drugs inhibiting peristalsis are contraindicated in this situation. The diagnosis of an antibiotic induced colitis is usually made based on clinical symptoms. The diagnosis can be confirmed by endoscopic demonstration of pseudomembranous colitis or by demonstrating the presence of Clostridium difficile and toxins in the faeces.

- Medicinal products which discontinue intestinal motility must be avoided.

- Clindamycin should be prescribed with caution to individuals with a history of gastro-intestinal conditions, particularly colitis. Antibiotic induced colitis and diarrhoea occur more frequently and in more serious forms in debilitated and/or older patients.

- Since clindamycin does not diffuse adequately in the cerebrospinal fluid, this drug should not be used to treat meningitis (see section 4.3).

- Antagonism between clindamycin and erythromycin was demonstrated *in vitro*. Because of th*e possible clinical si*gnificance, both drugs should not be used simultaneously (see section 4.5).

- If therapy is prolonged, liver and kidney functions tests should be performed.

- Clindamycin appears to have neuromuscular blocking properties that can enhance the effects of other neuromuscular blocking drugs. In patients that are treated with these drugs, clindamycin should, therefore, be used with caution (see section 4.5).

- In patients with serious renal and/or serious liver disorders associated to serious metabolic conditions, clindamycin should be administered cautiously. The serum levels of clindamycin should be monitored if high doses are required (see section 4.2).

- The hard capsules contain lactose and patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

An antagonism was demonstrated between clindamycin, erythromycin and chemically related macrolides.

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 (such as ritonavir, lopinavir, indinavir, cobicistat, ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin, telithromycin, grapefruit juice, nefazodone) 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 drugs metabolized by these CYP enzymes are unlikely.

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, acenocoumarol and fluindione). Coagulation tests, therefore, should be frequently monitored in patients treated with vitamin K antagonists.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data on the use of clindamycin in pregnant women during the first trimester of pregnancy. Clindamycin crosses the placenta. In clinical trials, the use of Dalacin C in pregnant women and the systemic administration of clindamycin during the second and third trimesters, have not been associated with an increased incidence of congenital abnormalities. Animal studies did not reveal any direct or indirect deleterious effects on reproduction (see section 5.3).

As a precautionary measure, it is preferable to avoid the use of Dalacin C during the first trimester of pregnancy. The use of Dalacin C during the second and third trimester of pregnancy may be considered after establishing the proper diagnosis by the doctor.

Breastfeeding

Orally administered clindamycin has been reported to appear in human breast milk in ranges from < 0.5 to 3.8 µg/mL (50 to 100% of the serum level is attained in the breast milk (see section 5.2)).

Clindamycin has the potential to cause adverse effects on the breastfed infant's gastrointestinal flora such as diarrhoea or blood in the stool, or rash. The developmental and health benefits of breastfeeding for the child should be considered along with the mother's clinical need for clindamycin and any potential adverse effects on the breastfed child from clindamycin or from the underlying maternal condition. If possible Dalacin C should not be used during breastfeeding. If a breast-feeding mother needs oral clindamycin, it may be considered to temporarily interrupt breastfeeding for the duration of the mother's treatment.
If oral clindamycin is used during breastfeeding, the infant should be closely monitored for adverse drug reactions. If these occur, breastfeeding should be discontinued.

Fertility

Fertility studies in rats treated orally with clindamycin revealed no effects on fertility or mating ability (see section 5.3). No data are available on man fertility.

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

The table below lists the adverse reactions identified through clinical trial experience and post-marketing surveillance by system organ class and frequency. Adverse reactions identified from post-marketing experience are included in italics. The frequency grouping is defined using the following convention: Very common (≥ 1/10), Common (≥ 1/100, < 1/10), Uncommon (≥ 1/1000, < 1/100), Rare (≥ 1/10000, < 1/1000), Very rare (< 1/10000) and Not known (cannot be estimated from the available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Adverse Reactions Table

System Organ Class	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1000 to < 1/100	Rare ≥ 1/10000 to < 1/1000	Very Rare < 1/10000	Frequency not known (cannot be estimated from available data)
Infections and infestations	*Pseudomembranous colitis* (see section 4.4), *Clostridium difficile colitis*				*Vaginal infection*
Blood and lymphatic system disorders	Eosinophilia[1]				*Agranulocytosis, Neutropenia, Thrombocytopenia, Leukopenia*
Immune system disorders					*Anaphylactoid reaction, Anaphylactic reaction, Hypersensitivity*
Nervous system disorders		Dysgeusia[1]			
Cardiac disorders†		Cardio-respiratory arrest†, Hypotension† (both following rapid IV administration: see section 4.2)			
Gastrointestinal disorders	Abdominal pain Diarrhoea	Nausea Vomiting		Colitis	*Oesophageal ulcer*, Oesophagitis**
Hepatobiliary disorders	Liver function test abnormal				*Jaundice*

System Organ Class	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1000 to < 1/100	Rare ≥ 1/10000 to < 1/1000	Very Rare < 1/10000	Frequency not known (cannot be estimated from available data)
Skin and subcutaneous tissue disorders	*Rash maculo-papular*[6]	*Urticaria* Erythema multiforme[1] Pruritus[1]			*Toxic epidermal necrolysis (TEN), Steven Johnson syndrome (SJS), Drug reaction with eosinophilia and systemic symptom (DRESS), Acute Generalised Exanthematous Pustulosis (AGEP), Angioedema, Dermatitis exfoliative, Dermatitis bullous, Rash morbilliform*

[1] Frequency for hard capsules: not known
[2] Frequency for hard capsules: uncommon
* Only applicable for oral formulations

- If diarrhoea occurs during treatment, the therapy should be discontinued.
- In cases of serious anaphylactoid reactions, immediate measures should be taken with the administration of epinephrine (adrenaline), oxygen and intravenous steroids. Mechanical ventilation, possibly with intubation, should also be applied if necessary.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after marketing 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 according to their local country requirements.

To Report any Side-effect:

Egypt:

Pharmacovigilance center, Pfizer Pharmaceutical Company: EGY.AEReporting@pfizer.com

Egyptian Pharmacovigilance center (EPVC), CAPA: PV.Center@Eda.mohealth.gov.eg

4.9 Overdose

The toxicity of clindamycin is not linked to the dose. An overdose does not cause specific symptoms. Haemodialysis and peritoneal dialysis are not effective to remove clindamycin from the serum.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antibacterials for systemic administration - lincosamides
ATC code: J01F F 01

The active substance is clindamycin, a semi-synthetic antibiotic obtained by 7-(S)-chloro-substitution of the 7-(R)-hydroxyl group of lincomycin.

Mechanism of action
Clindamycin binds to the 50S subunit of the bacterial ribosome and inhibits protein synthesis. Clindamycin can be either bactericidal or bacteriostatic, depending on the sensitivity of the organisms and the concentration of the antibiotic.

Mechanisms of resistance
Cross resistance between clindamycin and lincomycin is complete. Resistance in staphylococci and streptococci is most often due to methylation of specific nucleotides in the 23S RNA of the 50S ribosomal subunit, which can determine cross resistance to macrolides and streptogramins B (MLS_B phenotype). Macrolide-resistant isolates of these organisms should be tested for inducible resistance to lincomycin/clindamycin using the D-zone test.

Methicilline-sensitive *Staphylococcus aureus* strains are generally sensitive to clindamycin. Clindamycin has a significant activity against many strains of methicilline-resistent staphylococci (MRSA). However, the occurrence of a significant number of clindamycin-resistant MRSA-strains excludes the use of clindamycin for infections due to these organisms without sensitivity tests. *In vitro* some erythromycin-resistant strains of staphylococci rather rapidly develop resistance against clindamycin.

The following germs are usually resistant:
- Aerobic Gram negative bacilli
- *Enterococcus faecalis*
- *Nocardia* species
- *Neisseria meningitidis*
- Strains of *Haemophilus influenzae* (in places where resistance to antibiotics is frequent).

Breakpoints
EUCAST Breakpoints for Clindamycin (from 2014)

Pathogen	**Susceptible**	**Resistant**
Staphylococcus spp.	≤ 0.25 mg/l	> 0.5 mg/l
Streptococcus groups A, B, C, G	≤ 0.5 mg/l	> 0.5 mg/l
Streptococcus pneumoniae	≤ 0.5 mg/l	> 0.5 mg/l
Gram-positive anaerobes (excluding *Clostridium difficile*)	≤ 4 mg/l	> 4 mg/l
Gram-negative anaerobes	≤ 4 mg/l	> 4 mg/l

Prevalence of acquired resistance
The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of the agent on at least some types of infections is questionable. Particularly in severe infections or therapy failure microbiological diagnosis with verification of the pathogen and its susceptibility to lincomycin/clindamycin is recommended.

The following data is available for clindamycin based on European surveillance studies available in 2013.

Commonly susceptible organisms	**Remarks**
Aerobic gram-positive microorganisms	
Actinomyces israelii[a]	
Staphylococcus aureus (methicillin-susceptible)	
Streptococcus agalactiae	
Viridans group streptococci	
Anaerobic microorganisms	
Bacteroides spp.[a] (excluding *B. fragilis*)	
Fusobacterium spp.[a]	
Peptococcus spp.[a]	
Prevotella spp.	
Veillonella spp.[a]	
Other microorganisms	
Chlamydia trachomatis[a]	
Clamydophila pneumoniae[a]	
Gardnerella vaginalis[a]	
Mycoplasma hominis[a]	

Organisms for which acquired resistance may be a problem	**Remarks**
Aerobic gram-positive microorganisms	
Staphylococcus aureus (methicillin-resistant)[b]	
Staphylococcus epidermidis[b]	
Staphylococcus haemolyticus	
Staphylococcus hominis	
Streptococcus pneumoniae	Resistance rates between > 20 and 49% in some European countries
Aerobic gram-negative microorganisms	
Moraxella catarrhalis[c]	
Anaerobic microorganisms	
Bacteroides fragilis	
Clostridium perfringens	Higher resistance rates in Spain (10-20%)
Peptostreptococcus spp.	Higher resistance rates in Spain (10-20%)
Propionibacterium spp.	

Inherently resistant organisms	
Aerobic gram-positive microorganisms	
Enterococcus spp.	
Listeria monocytogenes	
Aerobic gram-negative microorganisms	
Escherichia coli	
Klebsiella spp.	
Neisseria gonorrhoeae	
Pseudomonas aeruginosa	
Anaerobic microorganisms	
Clostridium difficile	
Other microorganisms	
Mycoplasma pneumoniae	

Ureaplasma urealyticum	

[a]Updated information not available.
[b]At least one European region has reported resistance rates higher than 50%.
[c]Most isolates have inherently intermediate resistance.

Antagonism was demonstrated between clindamycin and erythromycin and chemically related macrolides. Clindamycin does not demonstrate any antagonism with penicillins.

Although clindamycin hydrochloride is active both *in vivo* and *in vitro*, clindamycin phosphate and clindamycin palmitate are not active *in vitro*. However, both compounds are *in vivo* rapidly hydrolysed to the active base.

5.2 Pharmacokinetic properties

Absorption

After oral administration clindamycin is rapidly and nearly completely (90 %) absorbed. The following table gives the mean plasma levels after oral administration of 150 mg in adults.

Way of administration and posology	**Time/plasma levels in µg/ml**				
	45 min	1 hr.	2 hr.	3 hr.	6 hr.
Oral, 150 mg HCl	2.5	2.48	1.88	1.51	0.7

The serum peak level of clindamycin palmitate is obtained at the same time as for the hydrochloride. In children clindamycin palmitate was administered in doses of 2, 3 and 4 mg per kg body weight every 6 hours. 1 hour after the first administration serum levels of 1.2, 2.2 and 2.4 µg/ml respectively were obtained. At the fifth administration a steady state was obtained. Using the above dose regimens serum peak levels of 2.5, 3.0 and 3.8 µg/ml respectively are expected. The oral resorption is quantitatively not significantly affected by the simultaneous intake of food. The resorption can, however, be somewhat slowed down.

Distribution

The protein binding is between 40 and 90 % of the administered dose. No accumulation could be demonstrated with oral administration.

Clindamycin easily penetrates in most body fluids and tissues. In bone tissue a level of approx. 40 % (20-75 %) of the serum level is reached, in the mother's milk 50-100 %, in synovial fluid 50 %, in the sputum 30-75 %, in the peritoneal fluid 50 %, in foetal blood 40 %, in pus 30 %, in pleural fluid 50-90 %. Clindamycin does not penetrate however in the cerebrospinal fluid, not even in the event of meningitis.

Biotransformation

Clindamycin has a half-life of approx. 1 1/2 - 3 1/2 hours. This is somewhat longer in patients with a significantly reduced function of the liver or of the kidneys. The dose regimen should however not be adjusted in cases of moderately seriously reduced function of the kidneys or of the liver.

Clindamycin is relatively extensively metabolised.

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**.**

Elimination

The excretion in the urine is 10-20 % and in the faeces some 4 % in microbiologically active form. The remainder is excreted as biologically inactive metabolites.
The excretion is mainly via the bile and the faeces.

5.3 Preclinical safety data

Fertility studies in rats treated orally with up to 300 mg/kg/day (approximately 1.1 times the highest recommended adult human dose based on mg/m^2) revealed no effects on fertility or mating ability.

In oral embryo foetal development studies in rats and subcutaneous embryo foetal development studies in rats and rabbits, no developmental toxicity was observed except at doses that produced maternal toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dalacin C 300 mg hard gelatin capsules:
Capsule content: maize starch, lactose monohydrate, talc, magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Do not use Dalacin C after the expiry date which is stated on the carton / blister after EXP:. The expiry date refers to the last day of that month.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C, in a dry place

6.5 Nature and contents of container

Oral administration

Hard gelatin capsules:
- Carton box containing (Transparent PVC/Aluminium Foil) blister of 10 hard gelatin capsules + Inner Leaflet.

6.6 Special precautions for disposal and other handling

Keep out of sight and reach of children.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. FURTHER INFORMATION

MARKETING AUTHORISATION HOLDER

Pfizer S.A. Boulevard de la Plaine 17, 1050 Brussels – Belgium, a subsidiary of Pfizer Inc., USA

MANUFACTURED, PACKED & RELEASED BY
Pfizer Egypt

8. Provision of the drug: Medicinal product subject to medical prescription

9. DATE OF REVISION OF THE TEXT

November 2019

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach and sight of children

Council of Arab Health Ministers
Union of Arabic Pharmacists