

# INFECTOCURE 250,500MG TAB



Egyptian Group for Pharmaceutical Industries  
الجموعة المصرية للصناعات الدوائية

MEDICAL AND PRODUCT KNOWLEDGE



For patients suffering from

- Lower respiratory infection
- Upper respiratory with lower respiratory infection
- H-pylori infection
- Skin infection

Infectocure 500mg and 250mg tablets focus on the effectiveness, flexibility, and safety of both products, emphasizing their value in treating a wide range of bacterial infections.

Unlike other macrolides that has lower efficacy because of bacterial resistance

Infectocure 500mg form will be marketed for more severe infections,

while Infectocure 250mg form will be promoted as a safer, lower-dose alternative for mild to moderate conditions, particularly for sensitive populations like children and the elderly.

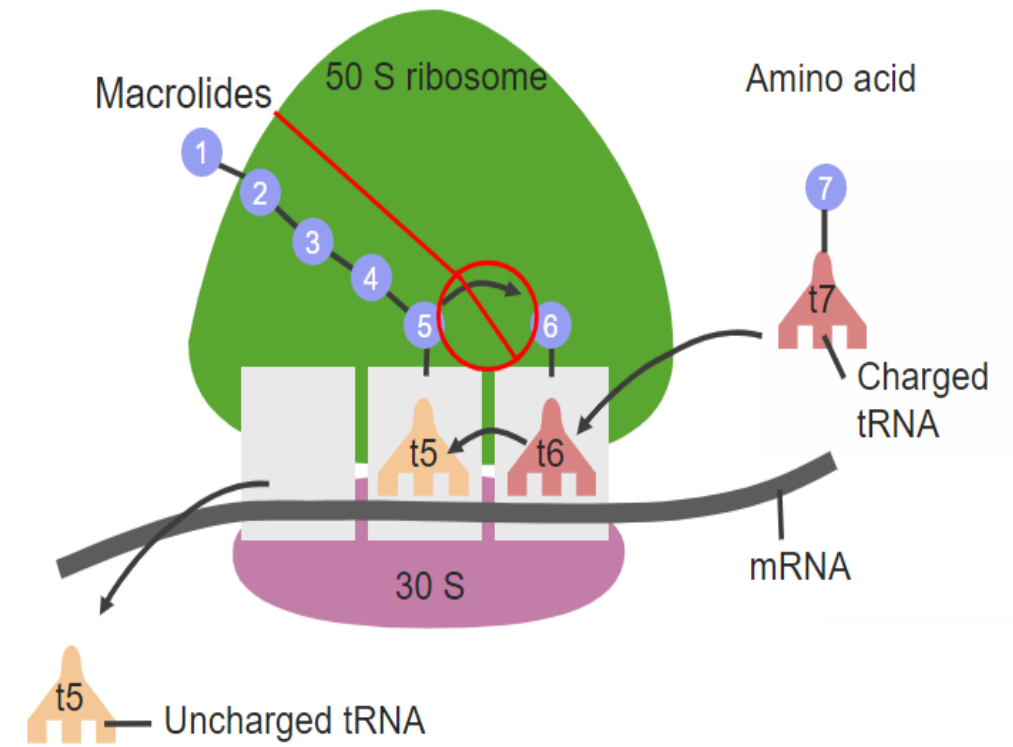


## PRODUCT KNOWLEDGE

- **Active ingredient, description & concentrations:**
- Clarithromycin: film coated tablet 250mg, 500mg
- Clarithromycin granules supplied in bottles for children: 125mg/5ml & 250mg/5ml

## MECHANISM OF ACTION:

- **Infectocure** act by binding to the large 50S subunit, **of bacterial Ribosomal, thereby inhibiting the production of protein during the stage of DNA translation.**
- **This stop bacteria from reproducing and from functioning properly** a component of the of the bacterial ribosome, thus inhibiting the translation of peptides stop the bacterial multiplication then death.
- **It has an active metabolites: The 14-hydroxy metabolite**
- **Bacteriostatic** but has bactericidal effect on some types of bacteria



## PHARMACODYNAMICS:

- **Infectocure** is bacteriostatic but

bactericidal against *Streptococcus pyogenes*, *Streptococcus pneumoniae*, and 92% of all strains *H. influenzae*

Clarithromycin and its **active metabolites (14-Hydroxy Clarithromycin)** also has antimicrobial activity.

The MICs of this metabolite are equal or two-fold higher than the MICs of the parent compound

**G+ve aerobic**, e.g.  
staph aureus, strep.  
Pyogenes,  
strep.pneumonea

**G-ve aerobic** e.g.  
H.influenza,  
Parainfluenza,  
Moraxella catarrhalis

Others e.g.  
Mycoplasma (**Atypical**)

## MAIN INDICATIONS:

Infection	Causal bacterial
<b>Lower respiratory tract infections:</b>	
Community-acquired pneumonia	-streptococcus pneumonia, H. influenzae, staphylococcus aureus, chlamydia pneumonia
Acute exacerbations of chronic bronchitis	streptococcus pneumonia, H. influenzae, staphylococcus aureus,
<b>Upper respiratory tract infections</b>	
Pharyngitis (strep throat)	Streptococcus pyogenes, Chlamydia pneumonia ,mycoplasma pneumonia
Acute maxillary sinusitis	mycoplasma pneumonia, H. influenzae, staphylococcus aureus,
Skin and soft tissue infections	staphylococcus aureus, staphylococcus pyogene
<b>H pylori eradication and prevention of duodenal ulcer recurrence</b>	

## PHARMACOKINETICS:

- ***Absorption:***

- Clarithromycin is rapidly and well absorbed from the **gastrointestinal tract** .
- Clarithromycin. is quite resistant to **degradation by stomach acid**

- ***Distribution:***

Clarithromycin gives good penetration into different compartments.

Increased levels have been found in both tonsillar and lung tissue.

Clarithromycin also penetrates the gastric mucus.

Clarithromycin is 80% bound to plasma proteins at therapeutic levels.

## PHARMACOKINETICS:

- **Serum half-life:**
- The serum half-life of the active 14-(R)-hydroxy metabolite ranges between **5 to 6 hours**.

- **Metabolism:**

cytochrome P450 enzyme system

- **Elimination:**

After oral administration of clarithromycin

70 - 80% was found in the feces. Approximately 20 -30% of clarithromycin is collected as the unchanged in the urine

- **Method of administration:**

Infectocure can be given irrespective of food intake.

## USES OF INFECTOCURE IN PREGNANCY AND LACTATION:

- **Pregnancy:**
- Clarithromycin should be used during pregnancy after a careful benefit/risk assessment.
- **Lactation:**
- Clarithromycin and its active metabolite are excreted in breast milk,  
So nursing might have to be discontinued.

# USES OF INFECTOCURE IN SPECIAL POPULATION

- **Dosage in renal functional impairment:**
  - At creatinine clearance rate of less than 30 ml/min,
  - the dosage should be halved to 250 mg daily or in the most severe infections to 250 mg twice daily. The duration of treatment should not exceed 14 days in these patients.
- **In elderly patients:**
  - No dose adjustment required
- **People with hepatic impairment:**
  - No dose adjustment required,
  - But in people with impairment liver function, should be used with caution.

## CONTRAINDICATIONS:

- **Infectocure is contraindicated in patients who:**
  - with hypersensitivity to clarithromycin.
  - Patients who have changes in their heart rhythm (QT prolongation) or ventricular cardiac arrhythmia, and not used with medication may cause QT prolongation eg: astemizole & cisapride)
- **Infectocure** should not be given with certain medications, Ergot medications (ergotamine: used to treat migraines)
- The statins lovastatin & simvastatin.

## ADVERSE EFFECTS:

- May affect gastrointestinal system, with some symptoms like:
- Diarrhea, vomiting & abdominal pain.
- Other adverse effect, 1-10%:
  - Headache
  - Skin rash
  - Insomnia.

## INFECTOCURE COMPETITIVE EDGE:

### **Clarithromycin edges over azithromycin**

- 1-azithromycin has a drug food interaction, so, it should be taken 1 hours before food or 2 hours after it
- 2- azithromycin developed higher resistance than clarithromycin. Specially clarithromycin is mainly Rx product so has a minimal abuse.

### **Clarithromycin over amoxicillin/clavulanic**

Amox/Clav. Has a role in otitis media but also has a higher resistance than clarithromycin due to the misuse, it has significant side effect:

1-GIT disturbance (including Diarrhea)

2-According to Wilson book the dose has been raised from 45mg to 90mg in AOM due to the resistance

## MAIN SELLING POINTS:

- second-generation macrolides
- Resistant to degradation by stomach acid
- active against Both aerobic , anaerobic gram +positive and gram -negative organism & atypical
- Bioequivalent to Klacid.**
- High quality of production in EGPI factory.

Ministry of Health and Population  
 Affairs  
 Registration  
 Committee for  
 Availability &  
 Studies



Code No. FM-RBC-09

وزارة الصحة و السكان  
 الإدارة المركزية لشؤون الصيدية  
 الإدارة العامة للتسجيل  
 اللجنة العلمية المتخصصة لتقييم دراسات  
 التوافر و التكافؤ الحيوى

Serial: 00048 / 2017

السيد الدكتور / زفين مجلس ادارة شركة EGPI  
 تحية طيبة وبعد،،،

تحيط سيادتكم علماً أنه تم عرض دراسة التكافؤ الحيوى الخاصة بالمستحضر التالى:

- **Product Name:** Infectiome 500mg film coated tablets
- **Dosage Form:** Film Coated Tablet
- **Active Ingredient:** Clarithromycin 500mg
- **Company:** Egyptian Group For Pharmaceutical Industries (EGPI)

التي تم إجراؤها بمركز : Advanced Research Center  
 مكرمةً بالمستحضر التالى:

- **Product Name:** Klacid 500mg film coated tablets
- **Dosage Form:** Film Coated Tablet
- **Active Ingredient:** Clarithromycin 500mg
- **Company:** Manufactured By: Kahira Pharmaceuticals & Chemical Industries Company - Egypt  
 Under License of: Abbott Laboratories – U.K.

على اللجنة العلمية المتخصصة لتقييم دراسات التوافر والتكافؤ الحيوى بجلستها فى ٢٠١٧/٠٤/٢٠ وجاء رأى اللجنة  
 باعتماد دراسة التكافؤ الحيوى للمستحضر المذكور سابقاً.  
 بيانات إضافية يتأى ما تم تقديمه من الشركة و محضر سحب العينات الصادر من قبل مفتش الإدارة العامة للتفتيش الصيدى:

سبب إجراء الدراسة	طبقة لما هو مذكور بخطار السجل الصيدى للمستحضر.
نوع التفتيش	Pilot Batch
رقم التفتيش	P16004
بيان التركيب (مرفق)	طبقة بيان التركيب الجديد المقدم من قبل لجنة المتغيرات للمستحضرات الصيدية المسجلة بجلستها فى ٢٠١٢/١٢/٢٢ و الصادر فى ٢٠١٣/٠١/٠٢ نظراً لتغيير مواد تصنيع.
مصادر المواد الخام الفعالة	مصدر المادة الخام الفعالة هو: Ind - Swift Laboratories Limited - India ، طبقة لما تم تقديمه من قبل شركة.
موافقة خاصة باستيفاء متطلبات تسجيل المستحضر، وكذا لاستيفاء متطلبات لجنة المتغيرات للمستحضرات الصيدية المسجلة بجلستها فى ٢٠١٣/١٢/٢٢، و الصادر فى ٢٠١٣/٠١/٠٢، نظراً لتغيير مواد المواج.	

وذلك للاحاطة واتخاذ اللازم.

وتفضلوا بقبول وافر الاحترام ،،،

مدير عام الإدارة العامة  
 للتسجيل  
 د. هبة تويل محمد  
 أ.م.د/ حنان امين رزق  
 ع.ع.ع / ٥٠٧

مدير ادارة تسجيل الأدوية  
 البشرية  
 د. هبة تويل محمد

رئيس قسم التوافر و التكافؤ  
 الحيوى  
 د. احمد رضا احمد

مقرر اللجنة العلمية المتخصصة  
 لتقييم دراسات التوافر و التكافؤ  
 الحيوى  
 د. عبد الرحمن محسن عبد العزيز  
 تحريراً فى ٢٠١٧/٠٤/٢٠  
 صورة مبلغة الى مدير وحدة التطوير المؤسسى

الإدارة المركزية لشؤون الصيدية  
 الإدارة العامة للتسجيل  
 لجنة التكافؤ الحيوى  
 صادر برقم :  
 ٥٧ / ٤٢٥٦

صورة مبلغة الى مدير ادارة استنقبال الأدوية البشرية

# COMPETITORS

## Clarithromycin 500 mg

Product Name	Company	Pack	Price
Klacid	Abbott	14 tab	257
Klacid xl	Abbott	14 tab	299
Clarithro	Pharco	14 tab	125
Klarimix	October Pharma	14 tab	82
Clarikan sr	MARCYRL	14 TAB	108
Infectocure	EGPI	14 tab	108

## Clarithromycin 250 mg

Product Name	Company	Pack	Price
Klacid	Abbott	14 tab	146
Clarithro	Pharco	14 tab	72
Klarimix	October Pharma	14 tab	60
Infectocure	EGPI	14 tab	62

# ***INFECTOURE***

Clarithromycin 250, 500 mg Tab.  
125, 250 mg Susp.

**Sure will be cured**



# INFECTOURE

Clarithromycin 250, 500 mg Tab.  
125, 250 mg Susp.

## Sure will be cured

Is second-generation macrolides, clarithromycin & 14-HC\* had bactericidal activity against  
92% of all strains of H.influenza<sup>(1)</sup>

Active against gram-positive, gram-negative & atypical pathogen.<sup>(2)</sup>

### Bacterial respiratory infection

#### Gram-positive

Streptococcus pneumoniae

Streptococcus pyogenes

Staphylococcus aureus

#### Gram-negative

Moraxella catarrhalis

Ligionella spp.

H.influenza

#### Others (Atypical)

Chlamydia pneumoniae

Mycoplasma pneumoniae

\*Active metabolite of clarithromycin, 14 hydroxy- clarithromycin (14-HC).

1-Infect Drug Resist. 2019; 12:585-595

2-Infectocure insert leaflet

# **INFECTOURE**

Clarithromycin 250, 500 mg Tab.  
125, 250 mg Susp.

## **Sure will be cured**

### **Community Aquired Pneumonia**

#### **Symptoms:**

**Increased Yellowish or  
Greenish sputum volume  
Increased sputum purulence  
Worsening tachypnea**



# **INFECTOURE**

Clarithromycin 250, 500 mg Tab.  
125, 250 mg Susp.

## **Sure will be cured**

### **Guideline**

#### **British thoracic society:**

**According to the British thoracic society clarithromycin is indicated as a first and second line 500 mg bd orally of treatment in both moderate and severe cases**

#### **American Thoracic Society:**

**in the outpatient/inpatient as empirical treatment of CAP as first line of treatment :**

# **INFECTOURE**

Clarithromycin 250, 500 mg Tab.  
125, 250 mg Susp.

## **Sure will be cured**

### **For empirical use in Patients with LRTIs\*\***

Clarithromycin concentration in respiratory tissue about 2-20 times & in the alveolar macrophage about 400 times higher than serum level  
Reach maximum Respiratory Tissue Concentration by 4 Hours  
(Including Nasal Mucosa, Tonsils & lung) and still  
Noticeable 12 hours after last Dose.

**\*\*Lower respiratory tract infections.**

3- Lung India, 2018 Mar-Apr; 35(2): 143 - 149.

4- Can J infect Dis - 1993 May - June; 4(3): 148 - 152.

# INFECTOCURE

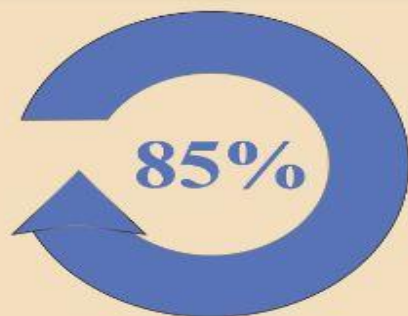
Clarithromycin 250, 500 mg Tab.  
125, 250 mg Susp.

**Sure will be cured**

**In chronic obstructive pulmonary disease (COPD) exacerbation**

**Clarithromycin**

250 mg

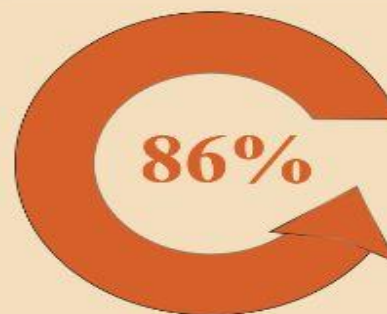


N = 223

Twice daily / 10 Days

**Levofloxacin**

500 mg



N = 211

Once daily / 7 Days

**FDA has alerted a black box warning for using levofloxacin and other fluoroquinolones due to increased risk of disabling and irreversible side effects including tendinitis and tendon rupture, peripheral neuropathy, phototoxicity and CNS and is contraindicated in children younger than 18 years**

# **INFECTOURE**

Clarithromycin 250, 500 mg Tab.  
125, 250 mg Susp.

**Sure will be cured**

- **Active against gram-positive, gram-negative & atypical pathogen**
- **The concentration in respiratory tissue higher than serum**
- **For empirical use in patients with LRTIs**

## **Therapeutic Indications, Dosage & Duration**

- **Lower respiratory tract infections :**  
Acute , Chronic Bronchitis and Community-Acquired pneumonia: From 7 - 14 days
- **Upper respiratory tract infections :**  
Acute Maxillary Sinusitis: for 14 days  
Pharyngitis, Tonsillitis: for 10 days
- **Acute Otitis Media in children**
- **Skin & soft tissue infection: From 7 - 14 days**

# INFECTOCURE

Clarithromycin 250, 500 mg Tab.  
125, 250 mg Susp.

**Sure will be cured**

## Package:

14 film coated tab.  
in 2 strips.



Package:  
Plastic Bottle of  
60ml