Erythromycin 250 mg Gastro-resistant Tablets

PL 25298/0036

UKPAR

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Erythromycin 250 mg Gastro-resistant Tablets

PL 25298/0036

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Brown & Burk UK Limited a Marketing Authorisation (licence) for the medicinal product, Erythromycin 250 mg Gastro-resistant Tablets (PL 25298/0036), on 9th November 2010. This is a prescription-only medicine (POM).

Erythromycin is an antibiotic used for the treatment and prevention of infections caused by erythromycin-sensitive organisms, such as:

- Upper and lower respiratory tract infections
- Eye, ear infections
- Oral infections
- Skin and soft tissue infections
- Gastrointestinal infections
- Prophylaxis pre- and post-operative trauma, burns, rheumatic fever
- Other infections – osteomyelitis, urethritis, gonorrhoea, syphilis, lymphogranuloma venerum, diphtheria, prostatitis, scarlet fever

This application is considered to be identical to a previously granted licence for Erythromycin Tablets BP 250mg (PL 16363/0019), authorised to Milpharm Limited on 9th April 2002. The proposed and reference products are identical.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of Erythromycin 250 mg Gastro-resistant Tablets outweigh the risk; hence a Marketing Authorisation has been granted.
Erythromycin 250 mg Gastro-resistant Tablets

PL 25298/0036

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Brown & Burk UK Limited a Marketing Authorisation for the medicinal product, Erythromycin 250 mg Gastro-resistant Tablets (PL 25298/0036), on 9th November 2010. The product is a prescription-only medicine (POM).

This is a simple, abridged, ‘informed consent’ application submitted according to Article 10(c) of EC Directive 2001/83 (as amended), cross-referencing the Marketing Authorisation for Erythromycin Tablets BP 250mg (PL 16363/0019), licensed to Milpharm Limited on 9th April 2002.

Erythromycin 250 mg Gastro-resistant Tablets are indicated for the prophylaxis and treatment of infections caused by erythromycin-sensitive organisms. Erythromycin is highly effective in the treatment of a great variety of clinical infections such as:

- Upper respiratory tract infections: Tonsillitis, peritonsillar abscess, pharyngitis, laryngitis, sinusitis, secondary infections in influenza and common colds
- Lower respiratory tract infections: Tracheitis, acute and chronic bronchitis, pneumonia (lobar pneumonia, bronchopneumonia, primary atypical pneumonia), bronchiectasis, Legionnaire's disease
- Ear infections: Otitis media and otitis externa, mastoiditis
- Eye infections: Blepharitis
- Oral infections: Gingivitis, Vincent's angina
- Skin and soft tissue infections: Boils and carbuncles, paronychia, abscesses, pustular acne, impetigo, cellulitis, erysipelas
- Gastro-intestinal infections: cholecystitis, staphylococcal enterocolitis
- Prophylaxis: pre- and post-operative trauma, burns, rheumatic fever
- Other infections: osteomyelitis, urethritis, gonorrhoea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever

Erythromycin has also proved to be of value in endocarditis and septicaemia, but in these conditions initial administration of erythromycin lactobionate by the intravenous route is advisable.

Erythromycin belongs to the pharmacotherapeutic group, macrolides (ATC Code - J01F A01) and exerts its anti-microbial action by binding to the 50S ribosomal sub-unit of susceptible microorganisms and suppressing protein synthesis

The pharmacovigilance system as described by the Marketing Authorisation Holder (MAH) fulfils the requirements and provides adequate evidence that the MAH has the services of a Qualified Person (QP) responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.
The MAH has provided adequate justification for not submitting a Risk Management Plan (RMP). As the application is for a product that is identical to the reference product, for which safety concerns requiring additional risk minimisation have not been identified, a risk minimisation system is not considered necessary. The reference product has been in use for many years and the safety profile of the active is well established.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environmental Risk Assessment (ERA). It is not considered that this medicinal product represents any risk to the environment. There is no reason to conclude that marketing of this product will change the overall use pattern of the existing market. The availability of this medicinal product, which is identical to the cited reference product, will not lead to any increase in environmental exposure concentrations of the active ingredient, erythromycin.

No new data were submitted, nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report (PAR) was generated for it.
1. INTRODUCTION

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Erythromycin 250 mg Gastro-resistant Tablets. The proposed Marketing Authorisation Holder (MAH) is Brown & Burk UK Limited.

The reference product is Erythromycin Tablets BP 250mg (PL 16363/0019), authorised to Milpharm Limited on 9th April 2002. The proposed and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The approved name of the product is Erythromycin 250 mg Gastro-resistant Tablets. The product has been named in line with current requirements and the product name is acceptable.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Each Erythromycin 250 mg Gastro-resistant Tablet contains 250 mg of the active ingredient, erythromycin. The tablets are made gastro-resistant with an enteric coating. The tablets are licensed for marketing in the following containers (full details are provided in the SmPC):

   i) Polypropylene tamper-evident tablet container with polyethylene cap - pack size: 500 tablets
   ii) polyvinylchloride (PVC) / aluminium foil blister strips, packed into cardboard outer cartons - pack size: 28 tablets

The approved shelf-life (24 months) and storage conditions (‘Do not store above 25°C. Keep the container tightly closed. Store in the original container’ for the polypropylene / polyethylene container, and ‘Do not store above 25°C. Store in the original package’) are satisfactory.

2.3 Legal status

POM - The product is available by supply through pharmacies, subject to a medical prescription.
2.4 Marketing Authorisation Holder / Contact Persons / Company

The proposed Marketing Authorisation Holder is ‘Brown & Burk UK Limited, 5 Marryat Close, Hounslow West, Middlesex TW4 5DQ, United Kingdom’.

The Qualified Person (QP) responsible for pharmacovigilance was stated and their CV included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is identical with the details registered for the cross-reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product / shelf-life specification

The proposed finished product specification is consistent with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

There are no materials of human or animal origin contained in, or used in the manufacturing process for, the proposed product. None of the excipients are sourced from genetically modified organisms.

3. EXPERT REPORT

A satisfactory quality overall summary has been prepared by an appropriately qualified expert. The CV of the expert was provided.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product (reddish-orange coloured, round, biconvex tablets, plain on both sides) is identical to that of the cross-reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The approved SmPC is consistent with the details registered for the cross-reference product.
6. PATIENT INFORMATION LEAFLET (PIL) / LABELLING

PIL
The approved PIL is satisfactory and in line with the approved SmPC. It is consistent with the details registered for the cross-reference product.

PIL user testing has been accepted, based on a bridging statement provided by the applicant making reference to the successful user-testing of the PIL for the reference product, Erythromycin Tablets BP 250mg (PL 16363/0019). The text, content and layout of the proposed PIL are essentially identical to the approved PIL for the reference product. The bridging is accepted.

Labelling
Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements. In line with current legislation the applicant has included the name of the products in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The grounds for this application are considered adequate. A Marketing Authorisation was, therefore, granted.
NON-CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10(c) of EC Directive 2001/83 (as amended).

No new non-clinical data have been supplied with this application and none are required for an application of this type. A non-clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the non-clinical expert has been supplied.

The Marketing Authorisation Holder has provided adequate justification for not submitting an Environmental Risk Assessment (ERA).
CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10(c) of EC Directive 2001/83 (as amended), cross-referring to the Marketing Authorisation for Erythromycin Tablets BP 250mg (PL 16363/0019).

No new clinical data have been supplied with the application, and none are required for applications of this type. A clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the clinical expert has been supplied.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
The data for this application are consistent with those previously assessed for the cross-reference product and as such have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

EFFICACY
This application is considered identical to the previously granted licence for Erythromycin Tablets BP 250mg (PL 16363/0019, Milpharm Limited).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The approved SmPC is satisfactory and consistent with the details registered for the cross-reference product.

PIL user testing has been accepted, based on a bridging statement provided by the applicant making reference to the successful user-testing of the PIL for the reference product, Erythromycin Tablets BP 250mg (PL 16363/0019). The bridging is accepted.

Colour mock-ups of the labelling have been provided and are satisfactory. The approved labelling artwork complies with statutory requirements.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. The benefit: risk ratio is considered to be positive.
Erythromycin 250 mg Gastro-resistant Tablets

PL 25298/0036

STEPS TAKEN FOR ASSESSMENT

1. The MHRA received the Marketing Authorisation application on 15th March 2010

2. Following standard checks and communication with the applicant the MHRA considered the application valid on 18th March 2010

3. Following assessment of the application the MHRA requested further information relating to the quality dossier on 8th July 2010

4. The applicant responded to the MHRA’s requests, providing further information for the quality sections on 7th October 2010

5. The application was determined on 9th November 2010
Erythromycin 250 mg Gastro-resistant Tablets

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STEPS TAKEN AFTER AUTHORISATION

Not applicable
SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SmPC) for Erythromycin 250 mg Gastro-resistant Tablets (PL 25298/0036) is as follows:

1 NAME OF THE MEDICINAL PRODUCT
   Erythromycin 250 mg Gastro-resistant Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
   Erythromycin 250mg

   For excipients see 6.1.

3 PHARMACEUTICAL FORM
   Gastro-resistant tablet

   Reddish orange coloured round biconvex tablets, plain on both sides. They are made gastro-resistant by enteric coating.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
   For the prophylaxis and treatment of infections caused by Erythromycin-sensitive organisms. Erythromycin is highly effective in the treatment of a great variety of clinical infections such as:

   2. Lower respiratory tract infections: Tracheitis, acute and chronic bronchitis, pneumonia (lobar pneumonia, bronchopneumonia, primary atypical pneumonia), bronchiectasis, Legionnaire's disease
   3. Ear infections: Otitis media and otitis externa, mastoiditis.
   4. Eye infections: Blepharitis
   5. Oral infections: Gingivitis, Vincent's angina
   6. Skin and soft tissue infections: Boils and carbuncles, paronychia, abscesses, pustular acne, impetigo, cellulitis, erysipelas
   7. Gastro-intestinal infections: cholecystitis, staphylococcal enterocolitis
   8. Prophylaxis: pre- and post-operative trauma, burns, rheumatic fever
   9. Other infections: osteomyelitis, urethritis, gonorrhoea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever

   Note: Erythromycin has also proved to be of value in endocarditis and septicaemia, but in these conditions initial administration of erythromycin lactobionate by the intravenous route is advisable.

4.2 Posology and method of administration
   Oral use

   Swallow whole with a glass of water. Do not crush or chew.

   Adults and older children: Usual dosage is 250mg every four to six hours. This may be increased to 4g per day in unusually severe infection.
4.3 Contraindications

Known hypersensitivity to erythromycin.

Erythromycin is contraindicated in patients taking simvastatin, tolterodine, mizolastine, amisulpride, astemizole, terfenadine, and cisapride or pimozide.

Erythromycin is contraindicated with ergotamine and dihydroergotamine.

4.4 Special warnings and precautions for use

Erythromycin is excreted principally by the liver, so caution should be exercised in administering the antibiotic to patients with impaired hepatic function or concomitantly receiving potentially hepatotoxic agents. Hepatic dysfunction including increased liver enzymes and/or cholestatic hepatitis, with or without jaundice, has been infrequently reported with erythromycin.

There have been reports suggesting erythromycin does not reach the foetus in adequate concentrations to prevent congenital syphilis. Infants born to women treated during pregnancy with oral erythromycin for early syphilis should be treated with an appropriate penicillin regimen.

There have been reports that erythromycin may aggravate the weakness of patients with myasthenia gravis.

Erythromycin interferes with the fluorometric determination of urinary catecholamines.

As with other broad-spectrum antibiotics, pseudomembranous colitis has been reported rarely with erythromycin.

Rhabdomyolysis with or without renal impairment has been reported in seriously ill patients receiving erythromycin concomitantly with lovastatin.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of erythromycin with simvastatin, tolterodine, mizolastine, amisulpride, terfenadine or astemizole is likely to result in an enhanced risk of cardio toxicity with these drugs. The concomitant use of erythromycin with either simvastatin, tolterodine, mizolastine, amisulpride, astemizole or terfenadine is therefore contra-indicated.

The metabolism of terfenadine and astemizole is significantly altered when either are taken concomitantly with erythromycin. Rare cases of serious cardio-vascular events have been observed, including torsades de pointes, other ventricular arrhythmias and cardiac arrest. Death has been reported with the terfenadine/erythromycin combination.

Elevated cisapride levels have been reported in patients receiving erythromycin and cisapride concomitantly. This may result in QT prolongation and cardiac arrhythmias including ventricular tachycardia, ventricular fibrillation and torsades de pointes.

Similar effects have been observed with concomitant administration of pimozide and clarithromycin, another macrolide antibiotic.

Concurrent use of erythromycin and ergotamine or dihydroergotamine has been associated in some patients with acute ergot toxicity, characterised by the rapid development of severe peripheral vasospasm and dysaesthesia.

Increases in serum concentrations of the following drugs metabolised by the cytochrome P450 system may occur when administered concurrently with erythromycin: alfentanil, astemizole, bromocriptine, carbamazepine, cyclosporin, digoxin, dihydroergotamine, disopyramide, ergotamine, hexobarbitalone, midazolam, phenytoin, quinidine, tacrolimus, terfenadine, theophylline, triazolam, valproate, and warfarin. Appropriate monitoring should be undertaken and dosage should be adjusted as necessary.
Erythromycin has been reported to decrease the clearance of zopiclone and thus may increase the pharmacodynamic effects of this drug.

When oral erythromycin is given concurrently with theophylline, there is also a significant decrease in erythromycin serum concentrations. The decrease could result in subtherapeutic concentrations of erythromycin.

4.6 Pregnancy and lactation
Erythromycin has been in widespread use for a number of years without apparent ill consequence. Animal studies have shown no hazard.

Erythromycin has been reported to cross the placental barrier in humans, but foetal plasma levels are generally low.

Erythromycin is excreted in breast milk, therefore, caution should be exercised when erythromycin is administered to a nursing mother.

4.7 Effects on ability to drive and use machines
None stated

4.8 Undesirable effects
Occasional side effects such as nausea, abdominal discomfort, vomiting and diarrhoea may be experienced. Reversible hearing loss associated with doses of erythromycin usually greater than 4g per day has been reported. Allergic reactions are rare and mild, although anaphylaxis has occurred. Skin reactions ranging from mild eruptions to erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis have rarely been reported. There are no reports implicating erythromycin products with abnormal tooth development, and only rare reports of damage to the blood, kidneys or central nervous system.

Cardiac arrhythmias have been very rarely reported in patients receiving erythromycin therapy. There have been isolated reports of chest pain, dizziness and palpitations; however, a cause and effect relationship has not been established.

Symptoms of hepatitis, hepatic dysfunction and/or abnormal liver function test results may occur.

4.9 Overdose
Symptoms: hearing loss, severe nausea, vomiting and diarrhoea.

Treatment: gastric lavage, general supportive measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Pharmacotherapeutic Group: Macrolides- ATC Code: J01FA01

Erythromycin exerts its antimicrobial action by binding to the 50S ribosomal sub-unit of susceptible microorganisms and suppresses protein synthesis. Erythromycin is usually active against most strains of the following organisms both in vitro and in clinical infections:

Gram-positive bacteria - *Listeria monocytogenes*, *Corynebacterium diphtheriae* (as an adjunct to antitoxin), *Staphylococci spp*, *Streptococci spp* (including *Enterococci*).

Mycoplasma - *Mycoplasma pneumoniae, Ureaplasma urealyticum*

*Other organisms* - *Treponema pallidum, Chlamydia spp, Clostridia spp, L-forms, the agents causing trachoma and lymphogranuloma venereum*

Note: The majority of strains of *Haemophilus influenzae* are susceptible to the concentrations reached after ordinary doses.

5.2 **Pharmacokinetic properties**

Absorption and Fate: Erythromycin is adversely affected by gastric acid. For this reason erythromycin tablets are enteric coated.

It is absorbed from the small intestine. It is widely distributed throughout body tissues. Little metabolism occurs and only about 5% is eliminated in the urine. It is excreted principally by the liver.

5.3 **Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**

Maize Starch  
Croscarmellose Sodium Type A  
Povidone  
Talc  
Magnesium Stearate (E572)

*Sub coat*:  
Hypromellose (E464)  
Macrogol 6000  
Erythrosine (E127)  
Talc

*Enteric coat*:  
Methacrylic Acid ethylacrylate Copolymer (1:1) dispersion 30%  
Macrogol 6000  
Talc  
Polysorbate 80 (E433)  
Erythrosine (E127)

6.2 **Incompatibilities**

Not applicable.

6.3 **Shelf life**

24 months

6.4 **Special precautions for storage**

Do not store above 25°C.

(a) Tablet container: Keep the container tightly closed. Store in the original container.

(b) Blister: Store in the original package.
6.5 Nature and contents of container

Tablet container
Nature: Polypropylene tamper evident tablet container with polyethylene cap.
Contents: 500 tablets

Blister:
Nature: 250 µm PVC/20 µm aluminium blister packs
Contents: 28 tablets.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Brown & Burk UK Limited
5 Marryat Close
Hounslow West
Middlesex
TW4 5DQ
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 25298/0036

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/11/2010

10 DATE OF REVISION OF THE TEXT

09/11/2010
PATIENT INFORMATION LEAFLET

UKPAR Erythromycin 250 mg Gastro-resistant Tablets

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PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Erythromycin 250 mg Gastro-resistant Tablets

1. WHAT ERYTHROMYCIN TABLETS ARE AND WHAT THEY ARE USED FOR

Erythromycin is an antibiotic for the treatment and prevention of infections caused by erythromycin-sensitive organisms, such as:
- Upper and lower respiratory tract infections
- Ear, nose, throat infections
- Oral infections
- Skin and soft tissue infections
- Gastrointestinal infections.
- Prophylaxis pre- and post-operative trauma, burns, rheumatic fever
- Other infections: osteomyelitis, urethritis, gonorrhoea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever

2. BEFORE YOU TAKE ERYTHROMYCIN TABLETS

DO NOT take Erythromycin Tablets if you are:
- Allergic (hypersensitive) to erythromycin or any of the other ingredients in the product (see Section 6 "What Erythromycin Tablets contain")

Take special care with Erythromycin Tablets:
- Speak to your doctor if you have:
  - Kidney problems
  - Liver disease
  - Myasthenia gravis (a muscle disorder)

Taking other medicines
Please inform your doctor if you are taking or have recently taken any other medicines, including those obtained without a prescription, particularly:
- Warfarin (thins the blood)
- Cisapride (used in stomach disorders)
- Pimozide (used in the treatment of psychiatric disorders)
- Clarithromycin (antibiotic used to treat certain infections)
- Ergotamine or dihydroergotamine (for migraine)
- Zopiclone (induces sleep)
- Theophylline (helps breathing)
- Lovastatin (blood cholesterol lowering drug)

Other drug interactions include: amlodipine, bromocriptine, carbamazepine, cyclosporin, digoxin, disopyramide, haloperidol, midazolam, phenytoin, quinidine, tacrolimus, triazolam, valproate. Your doctor should monitor you appropriately and may adjust your dosage of erythromycin as necessary.

DO NOT TAKE simvastatin, tolterodine, mizolastine, amisulpiride, terfenadine or astemizole if you have been prescribed erythromycin.

If you are asked to provide a urine test, tell your doctor that you are taking Erythromycin as it may interfere with some tests.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant or planning to become pregnant.
Erythromycin has been reported to cross the placental barrier.
Erythromycin passes into breast milk.

Ask your doctor for advice before taking any medicine.

If you are pregnant and treated orally with Erythromycin Tablets for early syphilis, please consult your doctor since erythromycin may not be effective in preventing infection to the baby.

Driving and using machines
Erythromycin Tablets are not expected to affect your ability to drive or operate machinery.

3. HOW TO TAKE ERYTHROMYCIN TABLETS

Always take Erythromycin Tablets exactly as your doctor has told you. The pharmacist’s label should tell you how much to take and how often.

For oral use. Swallow whole with a glass of water. Do not crush or chew.
**UKPAR Erythromycin 250 mg Gastro-resistant Tablets**

**PL 25298/0036**

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**Adults and older children:** The usual dosage is one 250mg tablet every four to six hours. This may be increased to 4g per day if your infection is very severe.

It is important that you complete your full course of antibiotics; do not stop taking the tablets early if you feel better.

**If you take more Erythromycin Tablets than you should:**

If you or a child accidentally takes too much medicine, contact your doctor or nearest hospital emergency department immediately. Take this leaflet, the box and any remaining tablets with you, if possible. Symptoms of overdose include nausea, vomiting, diarrhoea and hearing loss.

**If you forget to take Erythromycin Tablets:**

If you miss a dose, take the tablets as soon as you remember and carry on as before. If it is almost time for your next dose, skip the missed dose and continue as usual (do not take a double dose to make up for the forgotten one).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Erythromycin Tablets can cause side effects, although not everyone gets them.

**If you develop an allergic reaction, this may result in swelling of certain parts of your body, including the face and neck, accompanied by difficulty in breathing. If this happens to you, stop taking the tablets and seek urgent medical help.**

The following have also been reported:

- Nausea, vomiting and diarrhoea
- Hearing loss
- Liver problems, accompanied with or without jaundice (yellowing of the skin and whites of eyes)
- Abdominal discomfort
- Anaphylaxis (sudden, severe allergic reaction)
- Erythema multiforme (a red rash caused by hypersensitivity to a drug or disease or other allergen)
  - Stevens-Johnson syndrome (a severe inflammatory eruption of the skin and mucous membranes)
  - Damage to the blood, kidneys or central nervous system
  - Cardiac arrhythmia (an abnormal rate of muscle contractions in the heart)

- Toxic epidermal necrolysis (large proportion of the skin becomes intensely red and peels off)
- Chest pain, dizziness and palpitations (irregular, hard or rapid heartbeat)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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**5. HOW TO STORE ERYTHROMYCIN TABLETS**

Keep out of the reach and sight of children.

Do not store Erythromycin Tablets above 25°C. Store in the original package and keep the container tightly closed.

Do not use these tablets after the expiry date which is stated on the package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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**6. FURTHER INFORMATION**

**What Erythromycin Tablets contain**

The active substance is erythromycin, 250mg per tablet.

The other ingredients are Maize starch, Croscarmellose sodium Type A, Povidone, Talc, Magnesium stearate (E572), Hypromellose (E464), Macrogol 6000, Erythrosine (E127), Methacrylic acid ethylacrylate copolymer (1:1) and Polysorbate 80 (E433).

**What Erythromycin Tablets look like and contents of the pack**

The tablets are reddish orange coloured, biconvex enteric film-coated and round in shape. They are available in containers of 500 tablets, and also in blister packs of 29 tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Brown & Burk UK Ltd
5 Marryat Close, Hounslow West, Middlesex TW4 5DQ, UK.

**Manufacturer**

Miphar Limited
Ares, Odyssey Business Park, West End Road, South Ruislip, HA4 6QD United Kingdom

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This leaflet was last approved on
Container label

Also includes E127.
Read the package leaflet before use.
Oral use. Swallow whole with a glass of water.
Do not crush or chew.
Keep out of the reach and sight of children.
Do not store above 25°C.
Keep the container tightly closed. Store in the original container.
Use as directed by a physician.

PL 25298/0036
Brown & Burk UK Ltd.
5 Maryat Close, Hounslow West,
Middlesex, TW4 5DQ, United Kingdom

Erythromycin #250 mg
Gastro-resistant Tablets

Braille