Public Assessment Report

Erythromycin 250mg Enteric Coated Tablets

PL 08553/0081
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The Medicines and Healthcare products Regulatory Agency (MHRA) has granted Dr Reddy’s Laboratories (UK) Limited a Marketing Authorisation (licence) for the medicinal product Erythromycin 250mg Enteric Coated Tablets (PL 08553/0081). This is a prescription only medicine [POM] for preventing and treating infections caused by organisms sensitive to erythromycin.

Erythromycin 250mg Enteric Coated Tablets contain the active ingredient erythromycin, which is an antibiotic.

This application is a duplicate of a previously granted licence for Retcin/Erythromycin 250mg Tablets (PL 00225/5106R).

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Erythromycin 250mg Enteric Coated Tablets outweigh the risks, hence a Marketing Authorisation has been granted.
ERYTHROMYCIN 250MG ENTERIC COATED TABLETS

PL 08553/0081

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Erythromycin 250mg Enteric Coated Tablets (PL 08553/0081) to Dr Reddy’s Laboratories (UK) Limited on 14 March 2006. The product is a prescription only medicine [POM].

This application was submitted as a simple abridged application according to Article 10.1(a)i of Directive 2001/83/EC, cross-referring to Retcin/Erythromycin 250mg Tablets (PL 00225/5106R, approved on 10 January 1991).

No new data were submitted for this simple application, nor were any necessary, as the data are identical to that of the previously granted cross-referenced product. As the cross-referenced product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

Erythromycin 250mg Enteric Coated Tablets is used for the prophylaxis and treatment of the following infections caused by erythromycin-sensitive organisms: upper and lower respiratory tract infections, soft tissue and skin infections, bone infections, oral and dental infection, gastro-intestinal infections, eye infections and sexually transmitted diseases.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 08553/0081
PROPRIETARY NAME: Erythromycin 250 mg Enteric Coated Tablets
ACTIVE(S): Erythromycin
COMPANY NAME: Dr Reddy’s Laboratories (UK) Limited
E.C. ARTICLE: Article 10.1(a)(i)
LEGAL STATUS: POM

INTRODUCTION AND BACKGROUND

This is a national ‘informed consent’ application (Article 10.1(a)(i) Directive 2001/83/EC) for tablets containing 250mg of erythromycin.

These applications make reference to marketing authorisations held by DDSA Pharmaceuticals Ltd (PL 00225/5106R) and a suitable letter of access to the data has been provided by the company (letter dated 31/03/2003). No variations to the reference product were pending.

The applicant has confirmed that they have access to data in support of the application and that they are in possession of sufficient Part II documentation to support the application.

COMPOSITION

<table>
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<tr>
<th>Name of active substances</th>
<th>Quantity</th>
<th>Unit</th>
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<tbody>
<tr>
<td>Erythromycin</td>
<td>274.000</td>
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Name of excipients

1. Lactose
2. Maize Starch
3. Potato Starch
4. Sodium Starch Glycollate
5. Magnesium Stearate (vegetable based)
6. Purified Water
7. Cellacephate
8. Diethyl Phathalate
9. Aluminium Lake E124

Solvents and excipients not detectable in final product: Acetone, Methanol, Dichloromethane, Carnauba Wax and Beeswax Yellow.

METHOD OF PREPARATION

GMP certificates have been supplied, naming the site(s) of manufacture and assembly. A copy of the manufacturing licence (ML/8553/1) has been provided. A flow chart indicating the different sites involved in the manufacturing process has been provided. The QC site, finished product manufacturer, batch release and active manufacturer are identical to those of the reference product.
CONTROL OF STARTING MATERIALS

Active substances

The active ingredient manufacturer has a Ph.Eur. Certificate of Suitability, and this has been provided.

Other ingredients

Assurance has been provided that the excipients meet the requirements of the Ph.Eur.

Lactose is sourced from healthy animals in the same conditions as milk collected for human consumption. No other ruminant materials, with the exception of the calf rennet, are used in the preparation of such derivatives (Guideline 410/01).

Packaging material (immediate packaging)

No comments.

CONTROL TESTS ON INTERMEDIATE PRODUCTS/FINISHED MEDICINAL PRODUCT AND STABILITY

The original pharmaceutical expert report shows that quality control and finished product testing will be carried out using the same validated analytical methods already used to control the DDSA product.

With regard to the stability data, no specific data has been supplied, although the current shelf-life is 3 years.

EXPERT REPORT

The pharmaceutical expert report states that the proposed product is identical to the Retcin/Erythromycin 250mg Tablets (PL 00225/5106R) licensed to DDSA Pharmaceuticals Limited.

A clinical expert report has also been provided.

PRODUCT NAME AND APPEARANCE

The proprietary name is expressed in the form of the recommended International Non-proprietary Name (rINN). This is acceptable.

SUMMARY OF PRODUCT CHARACTERISTICS

Consistent with that of the reference product.

PATIENT INFORMATION LEAFLET

Satisfactory.
LABELLING

Satisfactory.

CONCLUSIONS

A marketing authorisation may be granted.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.
CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.
OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

QUALITY

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

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

This application is identical to a previously granted application for Retcin/Erythromycin 250mg Tablets.

No new or unexpected safety concerns arose from this application.

The SPC, PIL and labelling are satisfactory and consistent with those of the cross-referenced product.

RISK-BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-referenced product. Extensive clinical experience with the active ingredient erythromycin is considered to have demonstrated the therapeutic value of the compound. The risk-benefit assessment is therefore considered to be favourable.
**ERYTHROMYCIN 250MG ENTERIC COATED TABLETS**

**PL 08553/0081**

**STEPS TAKEN FOR ASSESSMENT**

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<td>1</td>
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</tr>
<tr>
<td>2</td>
<td>Following standard checks the MHRA informed the applicant that its application was considered valid on 22 July 2003.</td>
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<tr>
<td>3</td>
<td>The MHRA’s assessment of the submitted data was completed on 3 February 2004.</td>
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<td>4</td>
<td>Further information was requested from the company on 27 September 2004.</td>
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<td>5</td>
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<td>10</td>
<td>Further information and documentation were received on 13 December 2005 and 7 March 2006.</td>
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<tr>
<td>11</td>
<td>The MHRA completed its assessment of the application on 7 March 2006.</td>
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<tr>
<td>12</td>
<td>The application was determined on 14 March 2006.</td>
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ERYTHROMYCIN 250MG ENTERIC COATED TABLETS

PL 08553/0081

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

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SUMMARY OF PRODUCT CHARACTERISTICS

1. **NAME OF THE MEDICINAL PRODUCT**

Erythromycin 250mg Enteric Coated Tablets

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

Erythromycin Ph. Eur. 274.00 mg
See 6.1 for excipients

3. **PHARMACEUTICAL FORM**

Enteric-coated tablet

4. **CLINICAL PARTICULARS**

4.1 **Therapeutic indications**

For the prophylaxis and treatment of infections caused by Erythromycin-sensitive organisms.

1. Upper and lower respiratory tract infections.
2. Soft tissue and skin infections.
4. Oral and dental infection.
5. Gastro-intestinal infections.
6. Eye infections.
7. Sexually transmitted diseases.
8. Prophylaxis
9. Microbiological indications. Erythromycin is active against Staphylococci, Streptococci, Haemophilus influenzae, L-forms, Mycoplasma pneumoniae, Legionella pneumophila, Branhamella catarrhalis, Bordetella pertussis, Corynebacterium diphtheriae, Neisseria, Treponema pallidum, Chlamydia trachomatis, Clostridia, Ureaplasma urealytica, Campylobacter. In the case of Corynebacterium diphtheriae it should be used as an adjunct to antitoxin.

4.2 **Posology and method of administration**

*Adults and children over 8 years*: 1-2 g daily in divided doses for mild to moderate infection. This dosage may be increased to 4 g daily in divided doses. Tablets should be taken before or with meals.

*Elderly*: No special dosage recommendations.
Period of dosing with regard to indications:

*Upper respiratory tract infections*: 5 to 10 days

*Lower respiratory tract infections*: 7 to 14 days or until the signs and symptoms indicate that the condition is cured. Legionnaire's Disease requires prolonged treatment. It is recommended that initially Erythromycin lactobionate intravenously should be administered.

*Skin and soft tissue infections*: 5 to 10 days. Acne may require prolonged treatment.

*Sexually transmitted diseases - NGU and syphilis*: 10 to 21 days. Some conditions may require prolonged treatment.

*Oral and dental infections*: at least 5 days.

*Eye infections - Chlamydia inclusion conjunctivitis*: 3 weeks.

*Gastro-intestinal infections - Campylobacter*: a minimum of 5 days.

Erythromycin is taken by mouth.

### 4.3 Contraindications

Erythromycin 250mg Enteric Coated Tablets are contraindicated in patients who are sensitive to Erythromycin. Do not use Erythromycin in conjunction with other anti-infective agents except when especially warranted. Erythromycin is contraindicated with either Astemizole or Terfenadine and is also contra-indicated with ergotamine and dihydroergotamine.

### 4.4 Special warnings and precautions for use

Caution should be exercised when administering Erythromycin to patients with impaired hepatic function as the drug is principally excreted by the liver. Super infection caused by non-susceptible bacteria or fungi may occur during prolonged or repeated therapy and this is more likely when other anti-bacterial agents are simultaneously employed.

Hepatic dysfunction including increased liver enzymes and/or cholestatic hepatitis, with or without jaundice, has been infrequently reported with Erythromycin.

Erythromycin contains lactose and is unsuitable for people with lactase insufficiency, galactosaemia or glucose/galactose malabsorption syndrome. The product also contains ponceau 4R (E124), which may cause allergic-type reactions including asthma. Allergy is more common in those people who are allergic to aspirin.
4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of Erythromycin with terfenadine or astemizole is likely to result in an enhanced risk of cardiotoxicity with these drugs. The concomitant use of Erythromycin with either astemizole or terfenadine is therefore contraindicated.

Concurrent use of Erythromycin with ergotamine or dihydroergotamine has been associated in some patients with acute ergotoxicity with the rapid development of severe peripheral vasospasm and dysesthesia. With the following drugs an increase in serum concentration may occur when they are administered concurrently with Erythromycin: digoxin, warfarin, carbamazepine, phenytoin, theophylline, cyclosporin, bromocriptine, cisapride, pimozide, disopyramide, alfentanil, triazolam and the statins. Monitoring should be undertaken and dosage adjusted accordingly.

Concurrent administration of theophylline with oral Erythromycin produces a significant decrease in Erythromycin serum concentration, which could result in subtherapeutic concentrations of Erythromycin.

4.6 Pregnancy and lactation

Erythromycin should not be used in pregnancy or breastfeeding unless there are compelling reasons to do so.

4.7 Effects on ability to drive and use machines

Not applicable

4.8 Undesirable effects

Allergic reactions are rare and mild but anaphylaxis has occurred. Skin reactions ranging from mild eruptions to erythema multiforme, Stevens-Johnson Syndrome and toxic epidermal necrolysis have rarely been reported. Occasionally nausea, abdominal discomfort and vomiting which subside after a few days without having to discontinue treatment.

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

Reversible hearing loss associated with doses of Erythromycin usually greater then 4 g per day has been reported.

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

Gastric lavage and supportive measures.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The action of Erythromycin is bacteriostatic or bactericidal, depending on the organism and the concentration achieved. The effects of Erythromycin in combination with other antibiotics are unpredictable. The synthesis of penicillinase is variably affected, resulting in synergy where antagonism with susceptible beta-lactams. The listericidal effects of penicillins, rifampicin and gentamycin are antagonised. Erythromycin is synergistic with sulphonamides against \textit{H. influenzae}.

5.2 Pharmacokinetic properties

Erythromycin binding to plasma is 73\% for the base. The drug is distributed within an apparent volume of 0.75 L/kg, and eliminated with a half-time of 1 to 1.5 hours. Erythromycin is inactivated by N-demethylation in the liver, but the concentration of active drug in the bile is high and there is evidence of entero-hepatic circulation.

The drug passes the placental barrier to reach concentrations in foetal plasma of 5-20\% of those in the maternal circulation.

Erythromycin is distributed to most sites, except brain and CSF.

Erythromycin base is concentrated within alveolar macrophages by active transport to a concentration of 20-30 times that in the plasma. The drug is also concentrated in polymorphonuclear leucocytes.

Erythromycin is inactivated by N-demethylation in the liver. From 5 to 10\% of the dose is excreted unchanged in the urine.

5.3 Preclinical safety data

Not applicable
6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Maize Starch
Potato Starch
Sodium Starch Glycollate
Magnesium Stearate (veg. based)
Purified Water
Cellacephate
Diethyl Phthalate
Ponceau 4R, E124 (Aluminium Lake) – approx 20% dye content
Acetone
Methanol
Dichloromethane
Carnauba Wax
Beeswax Yellow

6.2 Incompatibilities

None known

6.3 Shelf life

3 years (36 months)

6.4 Special precautions for storage

Do not store above 25° C. Store in a dry place, protected from light. Keep container tightly closed.

6.5 Nature and contents of container

High density polystyrene or polypropylene containers with polythene or polypropylene lids and polyurethane/polythene inserts. Pack sizes: 28, 30, 50, 56, 60, 84, 100, 250, 500 & 1000.

6.6 Special precautions for disposal

Not applicable
7. MARKETING AUTHORISATION HOLDER

Dr. Reddy’s Laboratories (UK) Ltd
6 Riverview Road
Beverley
HU17 0LD
UK

8. MARKETING AUTHORISATION NUMBER(S)

PL 08553/0081

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/03/2006

10. DATE OF REVISION OF THE TEXT

14/03/2006
ERYTHROMYCIN 250MG ENTERIC COATED TABLETS

PL 08553/0081

Component code

ERYTHROMYCIN 250mg ENTERIC COATED TABLETS

Patient Information Leaflet

Please read this leaflet carefully before you start to take your medicine. It contains all the information you should need to know. If you have any questions concerning your medicine ask your doctor or pharmacist for more information. Keep this leaflet; you may want to refer to it again.

What is your medicine?

The name of this medicine is Erythromycin 250mg Enteric Coated Tablets. Each tablet contains Erythromycin Ph. Eur equivalent to 250mg Erythromycin. Your tablets also contain lactose, maize starch, potato starch, sodium starch glycinate, magnesium stearate (E472), colloidal anhydrous magnesium silicate, sodium starch glycollate, tamarindo wax, ferric oxide yellow (E172), water and gelatine.

Erythromycin 250mg Enteric Coated Tablets are round, red, film-coated tablets, available in containers of 28, 30, 56, 60, 84, 120, 250, 500 and 1000 tablets.

The Manufacturer of Erythromycin is:

The Marketing Authorisation Holder is:

Dr. Relli’s Laboratories (UK) Limited
29-214 York Road
Birkenhead
Wirral
Beveryly, East Yorkshire
London SW11 3DD

How does Erythromycin work?

Erythromycin is an antibiotic that acts on bacteria sensitive to Erythromycin.

Why have you been prescribed Erythromycin?

Erythromycin is used for the prevention or treatment of infections caused by Erythromycin-sensitive organisms. It is used in the treatment of:

- Chlamydial infections
- Skin and soft tissue infections
- Bone infections
- Mouth and dental infections
- Stomach infections
- Eye infections
- Sexually transmitted diseases
- Legionnaire’s Disease.

Before taking Erythromycin

Before taking this medicine, tell your doctor if you have ever had any unusual or allergic reactions to Erythromycin or any of the other ingredients of Erythromycin, or any other antibiotics. This product contains lactose and is unsuitable for people with lactose intolerance, galactosemia or glucose-6-phosphate dehydrogenase deficiency. Erythromycin also contains the colour Ponceau 4R (E124) which may cause allergic-type reactions including skin rash. Allergy is more common in those people who are allergic to aspirin.

Tell your doctor or pharmacist if you are allergic to any other substances such as foods, preservatives or dyes.

The presence of other medical problems may affect the use of this medicine. Tell your doctor if you have liver problems for which you have or are receiving treatment.

Use in pregnancy and while breast-feeding

IF YOU ARE PREGNANT, PLANNING TO BECOME PREGNANT, OR ARE BREAST- FEEDING DO NOT USE THIS MEDICINE AND INFORM YOUR DOCTOR OF YOUR CONDITION.

Can you drive or operate machinery when taking Erythromycin?

Erythromycin will not affect your ability to drive or operate machinery.

Can you take Erythromycin with other medicines?

There are some medicines that can interfere with Erythromycin. It is very important to tell your doctor or pharmacist about all the medicines that you are taking, whether or not they were prescribed by your doctor or bought without a prescription from the pharmacy or elsewhere. Your doctor will be able to identify medicines you should not take with Erythromycin.

Tell your doctor if you have or have been taking a medicine known as a Tetracycline (which you may have purchased over the counter), Loxolin or Arzisticid, which are used for hay fever and relief of allergies. They should not be taken with Erythromycin as they could damage your heart.

Other medicines which interfere with Erythromycin include:

- Ergotamine and dihydroergotamine used for attacks of migraine which can lead to toxic reactions when taken with Erythromycin.
- The following medicines may affect the concentrations of Erythromycin: Digoxin used to treat heart conditions, Warfarin used to thin the blood, Carbenicillin used to treat sepsis and to prevent meningitis, Phenytoin used to treat epilepsy, Theophylline used to treat obstruction of airways including severe asthma, Cyclosporine used to treat psoriasis, Bumetamide used in the treatment of Parkinson’s Disease, Disopyramide used to treat heart conditions. Atenolol used as an anti-arrhythmic, and Trasazol, an anti-fungal medicine.

When and how to take Erythromycin tablets

Take this medicine by mouth and only in the doses prescribed by your doctor. Do not take more of it, and do not take it more often or for a longer time than your doctor ordered.

Usual dosages stated below:

The medicine is to be taken by mouth. Do not crush or bite, but swallow whole.

Adults and children over 8 years: 1-2 g (four to eight tablets) daily in divided doses for mild to moderate infection. This dosage may be increased to 4 g (sixteen tablets) daily in divided doses. Tablets should be taken before or with meals.

 Elderly as for adults.

Length of medication with regard to treatment of particular infections:

Upper respiratory tract infections: 3 to 10 days.
Lower-respiratory tract infections: 7 to 14 days or until the signs and symptoms indicate that the condition is cured. Legionnaire’s Disease requires prolonged treatment.

Vest and soft tissue infections: 5 to 10 days.

Some may require prolonged treatment. Sinusally transmitted infections: Gonorrhoea and syphilis: 10 to 21 days. Some conditions may require prolonged treatment.

Ophthalmic infections: at least 5 days.

Eye infections: Chlamydial inclusion conjunctivitis: 3 weeks.

Vaginal bacterial infections: Cervicovaginitis: a minimum of 5 days.

If you feel that the medicine is not working as well after you have taken it for a short time (1-2 weeks) do not increase the dose, instead check with your doctor. Your doctor will prescribe the lowest dose necessary to control your symptoms.

What to do if you missed a dose:

If you miss a dose, skip the missed dose and go back to your regular dosing schedule. Do not take two doses at once.

What side effects can Erythromycin cause?

If you start to suffer from a rash, itching or any other skin trouble whilst taking this medicine, STOP the treatment and tell your doctor immediately. These may be signs of allergy to this medicine. If you develop swelling of the face and/or throat or difficulty in breathing you may require emergency treatment and you should seek medical advice immediately.

Hepatitis and liver dysfunction may occur. This may show up as yellowing of the skin and/or whites of the eyes, abdominal discomfort and loss of appetite. If you are taking a high dose of your medicine, you may find that you lose your hearing which should only be temporary. A diarrhoeal disease (pseudomembranous colitis) may also occur. This may show as watery diarrhoea, fever and cramps.

Occasionally Erythromycin can cause a skin condition known as erythema multiforme, which is characterised by patches of red, raised skin that often look like targets, and unusual tenderness, fever and painful joints. Rarely, taking of the skin may occur due to a condition known as toxic epidermal necrolysis.

If you have these or any other ill-effects, tell your doctor.

How your medicine:

- Do not store above 25°C.
- Store in a dry place, protected from light.
- Keep container tightly closed.
- KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

If your doctor tells you to stop the treatment, return any remaining tablets to the doctor or pharmacist.

On the label you will find the words “Expire Day” followed by numbers indicating the day, month and year. This is the date when the medicine is no longer fit for use. Do not use the medicine after this date but return it to your doctor or pharmacist.

REMEMBER: medicine is for you. Never give it to someone else, even if their symptoms are the same as yours.

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

Date of preparation: 06/03/98

Erythromycin 250mg Enteric Coated Tablets, PL 08553/0081

© Dr. Reddy’s Laboratories (U.K.) Limited

Component code
Labelling
ERYTHROMYCIN 250MG ENTERIC COATED TABLETS

PL 08553/0081

Each tablet contains Erythromycin Ph. Eur equivalent to 250mg Erythromycin. Also contains Lactose, Pomeau R (E124), Magnesium stearate (E572), Beeswax Yellow (E901).

For oral use. Use as directed by the physician. Do not store above 25°C. Store in a dry place, protected from light. Keep container tightly closed.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.
ERYTHROMYCIN 250MG ENTERIC COATED TABLETS

PL 08553/0081

Each tablet contains Erythromycin Ph. Eur equivalent to 250mg Erythromycin. Also contains Lactose, Povidone 4R (E104), Magnesium Stearate (E572), Brilliant Yellow (E101). For oral use. Use as directed by the physician. Do not store above 25°C. Store in a dry place, protected from light. Keep container tightly closed.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

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MHRA: PAR – Erythromycin 250mg Enteric Coated Tablets PL 08553/0081
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For oral use. Use as directed by the physician. Do not store above 25°C. Store in a dry place, protected from light. Keep container tightly closed.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

Dr. Reddy’s Laboratories (UK) Limited
6 Riverview Road, Beverley, HU17 0LD

<table>
<thead>
<tr>
<th>Title</th>
<th>Erythromycin 250mg Tablets</th>
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<td>Dimensions</td>
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<td>Cutter set</td>
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<td>Component code</td>
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<td>IDN number</td>
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<td>Software</td>
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<td>Version number</td>
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<td>Reason for revision</td>
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MHRA: PAR – Erythromycin 250mg Enteric Coated Tablets PL 08553/0081