Read all of this leaflet carefully before you start taking this medicine. Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is this leaflet

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, eye infections
- Oral infections
- Skin and soft tissue infections
- Gastrointestinal infections
- Prophylaxis pre- and post-operative trauma, burns, rheumatic fever
- Other infections: osteomyelitis, urthritis, gonorrhoea, syphilis, lymphogranuloma venereum, diphtheria, prostatitis, scarlet fever

2. What you need to know 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’s)
- Currently taking a medicine called
  - ergotamine or dihydroergotamine (used to treat migraines) while taking erythromycin as this may cause serious side effects.
  - terfenadine or astemizole or mizolastine (widely taken for hayfever or allergies), domperidone (for nausea (feeling sick) and vomiting (being sick)), cisapride (for stomach disorders) or pimozide or amisulpride (for psychiatric conditions) while receiving erythromycin, as combining these drugs may cause serious side effects.
- suffering from a condition called myasthenia gravis, which causes muscle weakness, consult your doctor before receiving erythromycin
- irregular heart rhythm
- a condition called porphyria
- have previously experienced diarrhoea following the use of antibiotics
- are treating a young child with antibiotics and they are irritable or vomit when fed, you should contact your physician immediately.
- are pregnant and have been told that your have a sexually transmitted disease called syphilis.

In this case erythromycin may not be effective for preventing the transfer of this infection to your body. Consult your doctor before receiving erythromycin. Alternatively if you were treated for early stages of syphilis during your pregnancy, and an child is under 1 year and is prescribed erythromycin, consult your doctor before giving erythromycin to you child.

- are taking erythromycin with ‘statins’ such as simvastatin or lovastatin (used to lower cholesterol) as serious side effects can occur. If any of these apply to you, or if you are not sure, tell your doctor.

Effect on urine test

If you are having urine test, let the doctor or nurse know that you are taking erythromycin. This is because erythromycin can affect the results of these tests.

Other medicines and Erythromycin Tablets

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

- warfarin (thins the blood)
- cisapride (used for stomach disorders)
- pimozide (used in the treatment of psychiatric disorders)
- clarithromycin or other antibiotics (used to treat certain infections)
- ergotamine or dihydroergotamine ( for migraine)
- theophylline (helps breathing)
- ciclosporin (for blood circulation problems)
- rifabutin (for tuberculosis)
- sildenafil (for erectile dysfunction)
- vinblastine (for cancer)
- antifungals e.g. fluconazole, ketoconazole and itraconazole
- colchicine (for gout)
- protease inhibitors (used to treat viral infections e.g. saquinavir)
- cilomside and omeprazole (used to treat acid reflux and other related conditions)
- methylprednisolone (used to help suppress the body’s immune system this is useful in treating a wide range of conditions)
- St John’s Wort (a herbal medicine used to treat depression)
- Verapamil (used to treat high blood pressure and chest pain)
- Any contraceptive pills
- Other drug interactions include: bromocriptine (used to treat Parkinson’s disease), digoxin or disopyramide or quinidine (all heart drugs), hexobarbital, midazolam (used as a sedative), cyclosporin or tacrolimus (used following organ transplants), atenolol, zopiclone or triazolam (induces sleep) Phenytoin or carbamazepine, valproate (drugs for epilepsy), lovastatin (a cholesterol lowering agent), your doctor should monitor you appropriately and may adjust your dosage of erythromycin as necessary.

Do not take simvastatin, tolterodine, mizolastine, amisulpride, terfenadine, domperidone, astemizole (for the treatment of hayfever and other allergies) if you have been prescribed Erythromycin ethylsuccinate granules for oral suspension.

If you or your child goes for any medical tests, tell your doctor that you are taking this medicine, as this may interfere with some test results.

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 or pharmacist for advice before taking any medicine.
If you are pregnant and treated with an oral erythromycin tablets for early syphilis, please consult your doctor as 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 these tablets exactly as advised by your doctor. You should check with your doctor or pharmacist if you are not sure.
- The dosage and duration of treatment will depend on the type and severity of the infection.
- Swallow the tablets whole with a glass of water.

The usual dose of Erythromycin 250mg tablets for adults and children over 8 years is: 1-2g daily in divided doses i.e. four to eight 250mg tablets daily taken just before or with meals or food. If you have a bad infection you may be told to take up to 4g daily.

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 tablets remaining with you, if possible. Symptoms of overdose include nausea, vomiting and diarrhoea and loss of hearing.

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 dose).

If you stop taking Erythromycin tablets
Continue to take this medicine until the course is completed or until your doctor tells you to stop; do not stop taking your medicine, even if you feel better. If you stop the treatment too early your problem could come back.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Erythromycin may sometimes cause side effects, although not everybody gets them.

STOP taking this medicine and seek medical help IMMEDIATELY if you experience any of the following reactions:
- difficulty breathing
- fainting
- swelling of the face, lips or throat
- skin rashes
- severe skin reactions including large fluid-filled blisters, sores and ulcers
- ulcers in the mouth and throat as these may be signs of an allergic reaction.

Other side effects which may occur are:
- diarrhoea which may be severe or prolonged and may contain blood or mucus
- feeling sick or being sick
- increases in a particular type of white blood cells (eosinophilia)
- stomach pains; these may be a symptom of an inflamed pancreas (pancreatitis)
- ringing in the ears (tinnitus)
- reversible loss of hearing (usually associated with high doses in patients with kidney problems)
- various liver or gall-bladder problems, which can cause yellowing of the skin and/or eyes (jaundice) or pale stools with dark urine
- chest pains
- abnormal heart rhythms (including palpitations)
- fever
- anorexia
- confusion
- fits (seizures)
- vertigo (problems with balance that can result in feelings of dizziness or sickness - particularly on standing)
- hallucinations (seeing or hearing things that aren’t there)
- feeling generally unwell (malaise)
- inflammation of the kidneys (a condition known as interstitial nephritis)
- low blood pressure
- serious skin rashes that may involve blistering and can cover large areas of the torso, face and limbs (conditions known as Stevens-Jonson syndrome, toxic epidermal necrolysis and erythema multiforme)
- vomiting and infections in young children between the age of 1 month and 12 months
- visual impairment/blurred vision (Mitochondrial optic neuropathy).

Reporting side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Google App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ERYTHROMYCIN TABLETS

Keep this medicine out of the sight and reach of children.
Do not store above 25°C. Store in the original package and keep container tightly closed.
Do not use the tablets after the expiry date 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.

6. CONTENTS OF THE PACK AND OTHER 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 looks 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 21, 100, 250, 500 and 1000 tablets as well as in blisters of 28, 56, 84, and 100 tablets. In addition bags of 5,000 and 10,000 tablets are also available(Not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Milpharm Limited
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Manufacturers: Milpharm Limited
Ares, Odyssey Business Park, West End Road, South Ruislip, HA4 6QD, United Kingdom, APL Swift Services (Malta) Ltd., HF26, Hal Far Industrial Estate, Hal Far, Birzebbuga B8030
This leaflet was last revised in 09/2017