

ERYTHROMED GRANULES 400

(Erythromycin 400mg/5ml Granules for Oral Suspension)

Erythromycin Ethylsuccinate equivalent to Erythromycin (400mg/5ml)

What is in this leaflet

1. What ERYTHROMED is used for
2. How ERYTHROMED works
3. Before you use ERYTHROMED
4. How to use ERYTHROMED
5. While you are using ERYTHROMED
6. Side effects
7. Storage and disposal
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial number

What ERYTHROMED is used for

ERYTHROMED is indicated in the treatment of infections caused by susceptible organisms in the diseases listed below: upper and lower respiratory tract infections, pertussis (whooping cough), skin and soft tissue infections, otitis media, erythrasma (skin disease), listeriosis (infection due to contaminated food), diphtheria (infection that affects your nose and throat), primary syphilis (sexually transmitted infection) and prophylaxis of infection of the heart.

How ERYTHROMED works

ERYTHROMED contains erythromycin ethylsuccinate, which is an antibiotic (macrolide group). These medicines work by killing or stopping the growth of bacteria, which cause infections.

Before you use ERYTHROMED

-When you must not use it

Do not take ERYTHROMED if you are:

- allergic to erythromycin or to other antibiotics from the macrolide family.
- individual with impaired hepatic function.
- or someone in your family has a history of heart rhythm disorders (ventricular cardiac arrhythmia or torsades de pointes) or an abnormality of the electrocardiogram (electrical recording of the heart) called "long QT syndrome".
- suffer from rhabdomyolysis (muscle injury)

- having hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
- having abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia)

-Pregnancy and breastfeeding

Tell your doctor or pharmacist if you are pregnant, planning to get pregnant or are breastfeeding. There are no sufficient studies among pregnant women on the use of erythromycin.

Erythromycin can be excreted into breast milk and medical advice from doctor is highly advisable prior to the consumption.

-Before you start to use it

Please consult your doctor before start to use ERYTHROMED.

-Taking other medicines

Inform your doctor or pharmacist before taking this medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop as it may interact with ERYTHROMED.

Some medicines may interfere with ERYTHROMED. These include:

- valproate, carbamazepine or phenytoin (used to control epilepsy)
- fluconazole, ketoconazole and itraconazole (medicines used to treat fungal infections)
- digoxin, quinidine or disopyramide (used to treat heart problems)
- cilostazol (a medicine used to treat peripheral circulation problems)
- hexobarbitone, phenobarbital or midazolam (used as sedatives)
- bromocriptine (used to treat Parkinson's disease)
- alfentanil (a medicine used to provide pain relief)
- 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)
- sildenafil (used to treat erectile dysfunction).
- clarithromycin, rifabutin, or rifampicin (medicines used to treat different types of bacterial infections)
- statins (used to help lower cholesterol levels e.g. lovastatin and simvastatin)
- oral contraceptives.
- astemizole, terfenadine or mizolastine (used to treat allergies such as hayfever)
- penicillin, cephalosporin (bacterial antibiotics)
- protease inhibitors (used to treat viral infections e.g. saquinavir)
- Anticoagulants e.g. warfarin, acenocoumarol and rivaroxaban (used to thin the blood)
- zopiclone or triazolam/alprazolam (used to help you sleep or relieve states of anxiety)
- ergotamine or dihydroergotamine (for migraine)
- cisapride (for stomach disorders)
- pimozide (used to treat mental problems)
- theophylline (used to treat asthma and other breathing problems)
- colchicine (used to treat gout and arthritis)
- verapamil (used to treat high blood pressure and chest pain)
- cimetidine and omeprazole (used to treat acid reflux and other related conditions)

How to use ERYTHROMED

-How much to use

Always use ERYTHROMED exactly as your doctor has prescribed. You should check with your doctor or pharmacist if

For oral administration only.

Adults: 400mg (5ml), 6 hourly or 800mg (10ml), 12 hourly.

Dosage may be increased up to 4g per day according to the severity of the infection.

ERYTHROMED GRANULES 400

(Erythromycin 400mg/5ml Granules for Oral Suspension)

Erythromycin Ethylsuccinate equivalent to Erythromycin (400mg/5ml)

Children 30-50mg/kg daily in divided doses; double in severe infections.

Children 2 to 8 years: 1g (12.5ml) daily in divided doses.

Infant and children up to 2 years: 500mg (6.25ml) daily in divided doses

Direction for mixing:

Shake bottle until all granules flows freely, add boiled and cooled water to the 50ml mark on the bottle. Shake vigorously and then make up the volume to 60ml by adding more water to suspend the granules homogenously.

Shake well before use.

-When to use it

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take ERYTHROMED before meals.

-How long to use it

Continue taking ERYTHROMED as your doctor recommended. If symptoms persist, consult your doctor.

-If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Overdosage should be handled with the prompt elimination of unabsorbed drug and all other appropriate measures should be instituted.

While you are using ERYTHROMED Things you must do

- Inform your doctor or pharmacist if symptoms persist after taking this medication.
- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking ERYTHROMED
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor.
- Do not give ERYTHROMED to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

- Prolonged or repeated use of erythromycin may result in an overgrowth of nonsusceptible bacteria or fungi.
- Be careful driving or operating machinery until you know how ERYTHROMED affects you.

Side effects

ERYTHROMED may cause severe allergy and serious skin reactions. Stop using ERYTHROMED and seek medical assistance immediately if you experience any of the following symptoms:

- skin reddening, blisters, rash, fever, sore throat or eye irritation.

If you notice that the child vomits and/or irritability with feeding occurs, contact doctor immediately as it may be due to the Infantile Hypertrophic Pyloric Stenosis (IHPS).

If you notice any of the following, contact your doctor immediately:

- increase in a particular type of white blood cells (eosinophilia), 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 or throat. These may be signs of an allergic reaction.
- hallucinations (seeing or hearing things that aren't there)
- confusion
- fits (seizures)
- vertigo (problems with balance that can result in feelings of dizziness or sickness – particularly on standing)
- visual impairment/blurred vision (Mitochondrial optic Neuropathy)
- ringing in the ears (tinnitus)
- reversible loss of hearing (usually associated with high doses or in patients with kidney problems)
- abnormal heart rhythms (including palpitations, a faster heartbeat, a life-threatening irregular heart beat called torsades de pointes or abnormal ECG heart tracing) or heart stopping (cardiac arrest)
- low blood pressure
- diarrhoea which may be severe or prolonged and may contain blood or mucus
- feeling or being sick
- stomach pains; these may be a symptom of an inflamed pancreas (pancreatitis)
- various liver or gall-bladder problems, which can cause yellowing of the skin and/or eyes (jaundice) or pale stools with dark urine
- serious skin rashes that may involve blistering and can cover large areas of the torso, face and limbs (conditions known as Stevens Johnson syndrome, toxic epidermal necrolysis and erythema multiforme)
- inflammation of the kidneys (a condition known as interstitial nephritis)
- chest pain
- fever
- loss of appetite

ERYTHROMED GRANULES 400

(Erythromycin 400mg/5ml Granules for Oral Suspension)

Erythromycin Ethylsuccinate equivalent to Erythromycin (400mg/5ml)

- feeling generally unwell (malaise)
- vomiting and irritability

Vanilin (flavor), Sodium Metabisulfite, Colloidal Anhydrous Silica and Sucrose.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my

[Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

-MAL number

Storage and disposal of ERYTHROMED

Storage

Before reconstitution, store below 30°C. Keep container tightly closed. Protect from heat and light.

After reconstitution, store below 30°C and discard any remaining suspension after 7 days.

Manufacturer and Product Registration Holder

KCK Pharmaceutical Industries Sdn. Bhd.
Plot 61, Bayan Lepas Industrial Park
Phase 4, Lintang Bayan Lepas 1,
11900 Bayan Lepas,
Pulau Pinang, Malaysia.

Date of revision

13/12/2021

Serial Number

NPRA(R2) 21/158

-Disposal

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.

Product description

-What it looks like

An almost white powder when reconstituted forms a white, vanilla flavoured, homogenous suspension.

Mode of administration

Oral

Dosage Form

Oral Solution (Granules for suspension)

Packaging

60 ml bottle.

-Ingredients

-Active ingredient

Erythromycin Ethylsuccinate equivalent to Erythromycin 400mg

-Inactive ingredients

Disodium hydrogen phosphate,
Potassium dihydrogen phosphate,