

Package leaflet: Information for the user

Primacine 250 mg /5 ml Granules for Oral Suspension

erythromycin ethylsuccinate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 in this leaflet:

1. What Primacine is and what it is used for
2. What you need to know before you take Primacine
3. How to take Primacine
4. Possible side effects
5. How to store Primacine
6. Contents of the pack and other information

1. What Primacine is and what it is used for

Primacine contains the active substance erythromycin as erythromycin ethylsuccinate. They belong to a group of drugs called antibiotics and are used in adults and children to treat infections caused by bacteria.

2. What you need to know before you take Primacine

Do not take Primacine:

- if you are allergic to erythromycin or any of the other ingredients of this medicine (*listed in section 6*)
- if you are 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 (widely taken for hayfever and allergies), cisapride (for stomach disorders) or pimozide (for psychiatric conditions) while receiving erythromycin, as combining these drugs can sometimes cause serious disturbance in heart rhythm. Consult your doctor for advice on alternative medicine you can take instead
 - domperidone (used to treat nausea (feeling sick) and vomiting (being sick))
 - lovastatin or simvastatin (used to lower cholesterol levels) as abnormal muscle breakdown leading to kidney problems (rhabdomyolysis) can occur
 - lomitapide (used to lower increased blood fats such as cholesterol and triglycerides). Taking this medicine at the same time as erythromycin may lead to a rise in enzymes produced by liver cells (transaminases), which indicates that the liver is under stress and may lead to liver problems
- if you have hereditary fructose intolerance or an intolerance to some sugars
- if you have abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia).

- if you 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”.

Warnings and precautions

Talk to your doctor or pharmacist before taking Primacine:

- if you have any liver problems or have been told that any drugs you are taking can cause liver problems
- if you have previously experienced diarrhoea following the use of antibiotics
- if you are pregnant and have been told that you have a sexually transmitted disease called syphilis. In this case erythromycin may not be effective for preventing the transfer of this infection to your baby. Alternatively if you were treated for early stages of syphilis during your pregnancy, and your child is under 1 year and is prescribed erythromycin, consult your doctor before giving erythromycin to your child
- if you are treating a young child with antibiotics and they are irritable or vomit when fed
- if you suffer from a condition called myasthenia gravis, which causes muscle weakness
- if you are using erythromycin for a long period of time
- if you suffer from a genetic problem that interferes with the metabolism of mitochondria (Leber’s hereditary optic neuropathy or autosomal dominant optic atrophy)
- if you have heart problems such as an abnormal ECG heart tracing (prolonged QT interval) or a slow heart beat (bradycardia)
- if you are receiving drugs to treat heart problems
- if you have uncorrected hypokalaemia or hypomagnesaemia (low blood levels of potassium or magnesium, which can cause muscle weakness, twitching or abnormal heart rhythm)
- if you are elderly
- if you are about to undergo laboratory tests for signs of pheochromocytoma (a rare tumour of the adrenal glands) as erythromycin may interfere with the test results
- if you are taking other medicines which are known to cause serious disturbances in heart rhythm.

Other medicines and Primacine

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

This is especially important if you are taking the following medicines or medicines from the following families:

- astemizole, terfenadine or mizolastine (used to treat allergies such as hayfever)
- domperidone (used to treat nausea (feeling sick) and vomiting (being sick))
- pimozide (used to treat mental problems)
- ergotamine or dihydroergotamine (used to relieve migraines)
- cisapride (used to treat stomach disorders)
- statins (used to help lower cholesterol levels e.g. lovastatin and simvastatin)
- beta-lactam antibiotics (used to treat bacterial infections, e.g. penicillin and cephalosporin)
- protease inhibitors (used to treat viral infections e.g. saquinavir)

- oral contraceptives.

This is also important if you are taking medicines called:

- colchicine (used to treat gout and arthritis)
- cimetidine and omeprazole (used to treat acid reflux and other related conditions)
- clindamycin, lincomycin, chloramphenicol, streptomycin, tetracyclines, colistin, rifabutin, or rifampicin (used to treat different types of bacterial infections)
- fluconazole, ketoconazole and itraconazole (used to treat fungal infections)
- digoxin, quinidine or disopyramide (used to treat heart problems)
- cilostazol (used to treat peripheral circulation problems)
- hexobarbitone, phenobarbital or midazolam (used as sedatives)
- zopiclone or triazolam/alprazolam (used to help you sleep or relieve states of anxiety)
- Anticoagulants e.g. warfarin, acenocoumarol and rivaroxaban (used to thin the blood)
- valproate, carbamazepine or phenytoin (used to control epilepsy)
- theophylline (used to treat asthma and other breathing problems)
- ciclosporin or tacrolimus (used following organ transplants)
- bromocriptine (used to treat Parkinson's disease)
- alfentanil (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)
- verapamil (used to treat high blood pressure and chest pain)
- vinblastine (used to treat certain types of cancer)
- sildenafil (used to treat erectile dysfunction)
- corticosteroids, given by mouth, by injection or inhaled (used to suppress the body's immune system – this is useful in treating a wide range of conditions)
- hydroxychloroquine or chloroquine (used to treat conditions including rheumatoid arthritis, or to treat or prevent malaria). Taking these medicines at the same time as erythromycin may increase the chance of getting abnormal heart rhythms and other serious side effects that affect your heart.

Pregnancy and breast-feeding

Erythromycin should be used by women during pregnancy only if clearly needed. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. The active ingredient of Primacine may cross the placenta in pregnant women and is excreted in breast milk. Information from studies regarding the risk of birth defects is inconsistent, but some studies have reported heart defects following Primacine use in early pregnancy.

Driving and using machines

Dizziness and blurred vision have been reported with erythromycin use. Do not drive or use machines unless you are sure you are not affected.

Primacine contains sodium and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Contains 2.588 g of sucrose per 5 ml dose. This should be taken into account in patients with diabetes mellitus. May be harmful to the teeth. This medicine contains 48.2 mg of sodium (main component of cooking/table salt) in

each 5 ml. This is equivalent to 2.4 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Primacine

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

Adults and children over 8 years of age:

The recommended dose is 1 – 2 g daily in divided doses. This is 500 mg two to four times a day. For severe infections up to 4 g daily in divided doses.

Children aged 2 – 8 years of age:

The recommended dose is 30 mg per kilogram of body weight daily in divided doses. For severe infections this may be increased to 50 mg per kilogram of body weight daily in divided doses.

The normal dose is 250 mg four times a day or 500 mg twice daily.

Children under 2 years of age:

The recommended dose is 125 mg four times a day or 250 mg twice daily.

If you are unsure about how your child's dose of medicine has been worked out or what your child's dose should be, consult your doctor or pharmacist.

If you forget to take Primacine

If you forget to take a dose of Primacine, take it as soon as you remember. Do not take a double dose to make up for the missed dose.

If you take more Primacine than you should

If you accidentally take more medicine in one day than your doctor has told you to, or if a child has taken some of the medicine, stop taking the medicine and seek medical advice urgently. An overdose could cause temporary hearing loss, nausea, vomiting and diarrhoea.

If you stop taking Primacine

Ask your doctor before stopping treatment with Primacine. Do not stop taking Primacine just because 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 Primacine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Primacine can cause side effects, although not everybody gets them.

Contact a doctor **immediately** if you experience a serious skin reaction: a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis).

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

Other side effects of Primacine include:

- 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)
- loss of appetite (anorexia)
- irritability and vomiting in a feeding infant
- increase in a particular type of white blood cells (eosinophilia)
- ringing in the ears (tinnitus)
- reversible loss of hearing (usually associated with high doses or in patients with kidney problems)
- disturbance in vision (double vision, blurred vision)
- liver failure and 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, a faster heartbeat, a life-threatening irregular heart beat called torsades de pointes or abnormal ECG heart tracing) or heart stopping (cardiac arrest)
- fever
- confusion
- fits (seizures)
- dizziness
- vertigo (problems with balance that can result in feelings of dizziness, a spinning sensation or sickness – particularly on standing)
- hallucinations (seeing or hearing things that aren't there)
- feeling generally unwell (malaise)
- abnormal muscle breakdown which can lead to muscle problems (rhabdomyolysis)
- inflammation of the kidneys (a condition known as interstitial nephritis)
- low blood pressure
- itching or hives
- 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).

Reporting of 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

Ireland

HPRA Pharmacovigilance Website: www.hpra.ie.

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Primacine

Keep this medicine out of the sight and reach of children.

Granules for oral suspension: Do not store above 25 °C. Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Reconstituted suspension: Once the granules are reconstituted by your doctor or pharmacist, store below 25 °C. Keep the bottle tightly closed, and use within 14 days. Do not freeze.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Primacine contains

- **the active substance** is erythromycin ethylsuccinate; each 5 ml of the oral suspension contains 250 mg erythromycin ethylsuccinate.
- **the other ingredients** are carmellose sodium, sodium citrate, banana flavour, quinoline yellow (E104), saccharin sodium, silica, colloidal anhydrous and sucrose (*see end of Section 2 'Primacine contains sodium and sucrose'*).

What Primacine looks like and contents of the pack

Primacine comes as granules for preparation by your pharmacist. Once reconstituted it is a yellow liquid with a banana flavour. It is available in 100 ml HDPE bottles with child resistant closures, and is also available in strengths of 125 mg or 500 mg per 5 ml.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

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