Approved Patient Information Leaflet for Medicines for Human Use:
ERYKO-250

SCHEDULING STATUS: S4

ERYKO-250, 250 mg tablets

Erythromycin

Contains sugar (lactose monohydrate): each ERYKO-250 film-coated tablet contains 15 mg lactose monohydrate

Read all of this leaflet carefully before you start taking ERYKO-250

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ERYKO-250 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ERYKO-250 is and what it is used for
2. What you need to know before you take ERYKO-250
3. How to take ERYKO-250
4. Possible side effects
5. How to store ERYKO-250
6. Contents of the pack and other information

1. What ERYKO-250 is and what it is used for

The active ingredient of ERYKO-250 tablets is erythromycin stearate.

Erythromycin belong to a group of medicines called macrolide antibiotics.

Antibiotics stop the growth of bacteria (bugs) which cause infections.

ERYKO-250 tablets are used to treat infections such as:

1. Chest infections such as bronchitis and pneumonia
2. Throat, sinus and ear infections
3. Skin and tissue infections including acne vulgaris and actinomycosis.
4. Infections of the genital or urinary organs.
5. Other infections including relapsing fever, lyme disease, listeriosis.

2. What you need to know before you take ERYKO-250

Do not take ERYKO-250

- If you are allergic (hypersensitive) to erythromycin or other macrolide antibiotics such as clarithromycin or azithromycin or any of the other ingredients (listed in section 6).
- If you are suffering from severe kidney problems.
- If you are taking medicines called: ergotamine or dihydroergotamine (used to treat migraines) as this may cause serious side effects while taking erythromycin.
  Terfenadine, mizolastine, ebastine or astemizole (widely taken for hay fever or allergies) or cisapride (for stomach problems) or pimozide, buspirone and triazolam (for mental health problems), carbamazepine (medicines taken for seizures), cyclosporin and tacrolimus (medicines taken by patients who received an organ transplant), colchicine (medicine for gout), halofantrine and lumefantrine (medicines used to treat malaria), theophylline (medicine to prevent wheezing or shortness of breath), tolterodine (medicine treating symptoms of overactive bladder).
  Class IA and III antiarrhythmics i.e., disopyramide (medicine treating irregular heartbeat), arsenic trioxide (cancer medicine), methadone (pain medicine), budipine (medicine used to treat Parkinson's disease), certain fluoroquinolones (medicine used to treat certain bacterial infections), imidazole-antimycotics (medicine used to treat certain fungal infections), domperidone (medicine treating nausea and vomiting).

Combining these medicines can sometimes cause serious disturbances in heart rhythm.

- If you have abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia).
- 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”.
- If you are taking medicines such as simvastatin or lovastatin (used to lower cholesterol and triglycerides (types of fat)) in the blood.
- If you are pregnant or breastfeeding.
- If you suffer from porphyria (a group of disorders that cause nerve and skin problems).

Warnings and precautions

Take special care with ERYKO-250

- If you have previously experienced any skin rash, itchy skin or any type of allergic reaction after taking certain antibiotic medicines
- If you have any liver problems
- If you have any kidney problems
- If you have an irregular heart rhythm
- If you are pregnant as this medicine may cause an increased risk of liver problems
- If you start developing stomach problems i.e., diarrhoea, vomiting, nausea (even after treatment was stopped)
- If you are suffering from asthma and use medicine called theophylline to open your lungs
- If you suffer from a condition called myasthenia gravis as muscle weakness may be aggravated
- If you are using “statins” to lower your blood cholesterol and triglycerides

- If you are suffering from certain genetic eye disorders such as Leber's hereditary optic neuropathy (LHON) and autosomal dominant optic atrophy (ADOA), you may risk developing visual impairment
- If you have contracted a respiratory (lung) infection called pneumonia, skin infections or require medicine to prevent rheumatic fever.
- If you are taking contraceptives with ERYKO-250 the birth prevention control action may be impaired and additional preventative measures may be required
- If you have to take certain urine tests the results may be altered.

Children

ERYKO-250 tablets are not to be crushed and should be swallowed whole. Therefore ERYKO-250 should not be given to children who are not able to swallow a tablet.

Other medicines and ERYKO-250

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Medicines that affect ERYKO-250 (medicines that may cause ERYKO-250 to become either ineffective or ERYKO-250 reaching too high levels in your blood)*:*

- rifampicin (type of antibacterial medicine)
- phenytoin, carbamazepine, phenobarbital (medicines used for seizures)
- St John's Wort (herbal medicine used to treat depression)
- protease inhibitors (certain antiviral medications)
- cimetidine (medicine used for stomach acid)

Medicines which ERYKO-250 may influence (medicine that may become ineffective or unsafe or you may need to have regular tests performed):

- terfenadine, erbastine, fexofenadine or astemizole (widely taken for hay fever or allergies)
- digoxin, quinidine or disopyramide (for heart problems)
- warfarin, acenocoumarol or cilostazol (for thinning the blood)
- ergotamine or dihydroergotamine (for migraines)
- carbamazepine, valproate, hexobarbital or phenytoin (for epilepsy)
- caffeine, aminophylline, theophylline (used in patients with breathing difficulties such as asthma)
- triazolam, alprazolam or midazolam or buspirone (sedatives)
- ciclosporin and tacrolimus (immune suppressants)
- cisapride (for reflux) or omeprazole (stomach acid)
- chloramphenicol, penicillin, cephalosporin, clindamycin, lincomycin, streptomycin, tetracyclines, rifabutin (antibiotic/antibacterial medicine)
- zopiclone or zolpidem (used for insomnia/sleeplessness)
- simvastatin, lovastatin and pravastatin (medicines used for high cholesterol and triglycerides treatment)
- contraceptive pills (decrease the effect of contraception)
- alfentanil (pain medicine)
- bromocriptine (Parkinson's disease treatment)
- corticosteroids i.e., methylprednisolone (medicine used to reduce inflammation or allergic reactions)
- vinblastine or tyrosine-kinase inhibitors (cancer treatment)
- sildenafil or vardenafil (medicines used for erectile disfunction)
- fluconazole, ketoconazole and itraconazole (antifungal medicine)
- colchicine (medicine for gout)
- verapamil (blood pressure medicine)
- halofantrine and lumefantrine (medicine used for malaria treatment)

- digoxin (medicine used to control the rate and/or rhythm of the heartbeat)
- tolterodine or darifenacin (medicines used to treat certain urinary bladder conditions)
- domperidone (treat nausea and vomiting)
- clozapine (medicines used to treat certain mental health conditions)

Laboratory test results

ERYKO-250 may cause that some urine test results may be altered.

ERYKO-250 with food and drink

No interactions are reported, however, for more information see section 3 below on how to take ERYKO-250.

Pregnancy and breastfeeding

ERYKO-250 is not recommended for use during pregnancy and breastfeeding.

ERYKO-250 crosses the placenta and is found in the unborn baby's blood. If you are using ~~it~~ ERYKO-250 to treat syphilis, erythromycin medicines such as ERYKO-250 may cause some serious side effects to your unborn baby and this treatment may not prevent syphilis in your unborn baby.~~-~~Your baby will need antibiotic treatment once it is born.
ERYKO-250 is also found in your breastmilk.
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ERYKO-250.

Driving and using machines

ERYKO-250 may make you feel drowsy, dizziness, headache, or cause some eye disorders (visual impairments). If you feel drowsy, can't see, or are affected in any way, avoid driving or using machines.

It is not always possible to predict to what extent ERYKO-250 may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ERYKO-250 affects them.

ERYKO-250 contains lactose monohydrate

ERYKO-250 contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ERYKO-250.

3. How to take ERYKO-250

Do not share medicines prescribed for you with any other person.

Always take ERYKO-250 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dose

Adults

For infections, the usual dose unless otherwise recommended by your doctor is one tablet 4 times a day or two tablets 3 times a day. The dosage may be increased in severe or resistant infections to up to four tablets 3 or 4 times daily. Your doctor will indicate the duration of treatment, which is usually up to 10 days.

For syphillis, your doctor will prescribe an appropriate dose over a course of 20 to 30 days.

Children

The dose for children is dependent on the child’s body weight. Your doctor will advise accordingly.

Duration of administration

Your doctor will tell you how long your treatment with ERYKO-250 will last. Do not stop treatment early because the infection may not have cleared. If you have the impression that the effect of ERYKO-250 is too strong or too weak, tell your doctor or pharmacist.

Method of administration

Oral use.

Take ERYKO-250 tablets on an empty stomach at least 30 minutes before or 2 hours after a meal. ERYKO-250 tablets must be swallowed whole and not chewed.

If you take more ERYKO-250 than you should

An overdose is likely to cause nausea, vomiting, diarrhoea and drowsiness.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you stop taking ERYKO-250

Do not stop taking ERYKO-250 tablets, even if you feel better. It is important to take the tablets for as long as the doctor has told you to, otherwise the problem might come back.

If you forget to take ERYKO-250

Do not take a double dose to make up for forgotten individual doses.

Take it as soon as you remember. Do not take more tablets in one day than your doctor has told you to.

4. Possible side effects

ERYKO-250 can have side effects.

Not all side effects reported for ERYKO-250 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ERYKO-250, please consult your health care provider for advice.

If any of the following happens, stop taking ERYKO-250 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- a red, scaly rash with bumps under the skin and blisters (exanthematous pustulosis)
- severe or prolonged diarrhoea, which may have blood or mucus in it
- a rash, difficulty breathing, swelling of the face and throat. This is a sign that you may have developed an allergic reaction
- yellowing of the skin (jaundice), skin irritation, pale stools, dark urine, tender abdomen or loss of appetite. These are signs that your liver may not be working properly
- severe skin reactions such as blistering of the skin, mouth, lips, eyes and genitals (symptoms of a rare allergic reaction called Stevens-Johnson syndrome/toxic epidermal necrolysis)
- chest pain and heart palpitations or changes in heartbeat
- fever, chills, weakness, sore throat, sores in the mouth or throat, bleeding gums, bone pain, low blood pressure, fast heartbeat, and trouble breathing due to agranulocytosis (blood disorder)

These are very serious side effects. If you have them, you may have had a serious reaction to ERYKO-250. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- stomach problems such as feeling sick, vomiting, stomach pain, indigestion, diarrhoea

Less frequent side effects

- swelling, redness or itchiness of the skin

- inflammation of the pancreas
- ringing in the ears or hearing loss
- vertigo (feels like your head is spinning)
- muscle pain or loss of muscle tissue. If you suffer from myasthenia gravis (a condition in which the muscles become weak and tire easily) ERYKO-250 may worsen these symptoms
- oral thrush
- chest pain or changes in heart rhythm such as palpitations
- a change in the levels of products made by the liver, inflammation of the liver or an inability of the liver to function properly (you may notice yellowing of the skin, dark urine, pale stools or itchiness of the skin).
- seizures
- vaginal thrush

Side effects with frequency unknown:

- confusion, loss of bearings, hallucinations (seeing things), abnormal dreams or nightmares
- weight loss, fevers, night sweats, fatigue, cough, chest pain, swelling, stomach ache, rash, pain, weakness, confusion, and coma due to blood disorder called eosinophilia
- dizziness, headache, sleeplessness
- visual impairment
- low blood pressure and swelling or redness of arm or leg
- fever, painful urination, and pain in the lower back or side

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ERYKO-250**.**

5. How to store ERYKO-250

Store all medicines out of reach of children.

Store in a cool, dry place at or below 25 ˚C. Keep out of direct sunlight.

Do not remove the blister pack from the carton until required for use.

Do not store in bathrooms.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What ERYKO-250 contains

- The active ingredient is erythromycin stearate equivalent to 250 mg erythromycin activity.
- The other ingredients are maize starch, calcium hydrogen phosphate, sodium starch glycollate (Type A), sodium citrate, povidone (PVP K-30), magnesium stearate, purified talc, magnesium hydroxide, polacrillin potassium (Indion 294), hydroxypropylmethylcellulose, propylene glycol, titanium dioxide (CI No. 77891), erythrosine lake (CI No. 45430)

What ERYKO-250 looks like and contents of the pack

ERYKO-250 tablets are pink, ovaloid, slightly biconvex, approximately 21,5 x 8,7 mm (length and width respectively) film-coated tablets.

ERYKO-250 is supplied in cartons containing 10 blister packs (composed of colorless PVC and silver colored aluminum foil) of 10 tablets each. i.e. 100 tablets, or 2 x 10's i.e. 20 tablets, or 7 x 8's i.e. 56 tablets.

White polyethylene polymer plastic Patient Ready Packs containing 20, 40 or 56 tablets.

Colorless, transparent polypropylene polymer plastic packs packed in opaque white HDPE containers containing 100 or 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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