PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PURMYCIN – 125 mg suspension
Erythromycin as erythromycin estolate
Preservatives: Methylparaben 0,030 % m/v, Propylparaben 0,015 % m/v, Butylparaben 0,015 % m/v
Contains sugar: Sucrose 1,5 g and sorbitol 1,303 g
Contains sweetener: Sodium cyclamate 20,00 mg

PURMYCIN – 250 mg suspension
Erythromycin as erythromycin estolate
Preservatives: Methylparaben 0,09 % m/v,
Propylparaben 0,01 % m/v
Contains sugar: Sucrose 1,5 g

Read all of this leaflet carefully before you start taking PURMYCIN SUSPENSION

- 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.
- PURMYCIN SUSPENSION 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 PURMYCIN SUSPENSION is and what it is used for
2. What you need to know before you take/use PURMYCIN SUSPENSION
3. How to take/give PURMYCIN SUSPENSION
4. Possible side effects
5. How to store PURMYCIN SUSPENSION
6. Contents of the pack and other information

PATIENT INFORMATION LEAFLET

1. What PURMYCIN SUSPENSION is and what it is used for

PURMYCIN SUSPENSION contains the active substance erythromycin as erythromycin estolate.

PURMYCIN SUSPENSION belongs to a group of medicines called antibiotics and is used for the treatment of bacterial infections including:

- Respiratory tract infections (lung, nose, throat and ears infections);
- urinary tract infections (bladder, kidneys, ureters, and urethral infections);
- gastrointestinal infections (stomach flu causing nausea and vomiting);
- skin and soft tissue infections (bacterial skin infections of the upper dermal layer or folds of the skin, acne, painful skin lesions with pus);
- other infections (scarlet fever, tetanus, syphilis (in patients who are allergic to penicillin), joint infection, meningitis, bloodstream infection);
- preventative treatment of inflammatory diseases that can involve the heart, joints, skin, and brain.

2. What you need to know before you take or give PURMYCIN SUSPENSION

Do not take or give PURMYCIN SUSPENSION:

- If you or your child are hypersensitive (allergic) to erythromycin, or to any of the other ingredients of PURMYCIN SUSPENSION (listed in section 6).
- If you or your child have liver function problems.
- If you or your child have developed jaundice (yellowing of the skin and eyes) during previous treatment with erythromycin.

- If you or your child are taking the following medicines:

- simvastatin (used to lower cholesterol and triglycerides (types of fat) in the blood),
- tolterodine (used for treating overactive bladder with symptoms of urinary frequency, urgency, and leakage),
- mizolastine, astemizole, terfenadine (used for hayfever and allergies),
- amisulpride, pimozide (used for psychiatric conditions),
- domperidone (used for nausea and vomiting),
- cisapride (used for stomach disorders).

- If you or your child have a history of heart rhythm disorder (ventricular cardiac arrhythmia or torsades de pointes) called “long QT syndrome”.
- If you or your child have abnormally low levels of potassium or magnesium in your blood (hypomagnesaemia or hypokalaemia).

- If you or your child are taking medicines called ergotamine and dihydroergotamine (used to treat migraines).

Warnings and precautions

Take special care with PURMYCIN SUSPENSION:

- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).
- if you have heart problems.
- if you are taking other medicines which are known to cause serious disturbances in heart rhythm.
- if you have previously experienced diarrhoea following the use of antibiotics.
- as rare serious allergic reactions, including acute generalised exanthematous pustulosis (AGEP) have been reported. If an allergic reaction occurs, stop using PURMYCIN SUSENSION and tell your health care provider (see section 4 POSSIBLE SIDE EFFECTS).
- If you are pregnant and have been told that you have a sexually transmitted disease called syphilis. In this case erythromycin, as contained in PURMYCIN SUSPENSION, may not be effective for preventing the transfer of this infection to your baby. Consult your doctor before receiving PURMYCIN SUSPENSION.
- If you have a condition called myasthenia gravis (a condition causing abnormal weakness of the muscles).
- if you or your child go for any medical or urine tests, tell your doctor that you are taking PURMYCIN SUSPENSION, as this may interfere with some test results.
- if a high dose of PURMYCIN SUSPENSION is prescribed, reversible deafness may occur.
- As a condition called rhabdomyolysis (a breakdown of muscle tissue that releases a damaging protein into the blood) has been reported in seriously ill patients receiving erythromycin as contained in PURMYCIN SUSPENSION together with statins (e.g. simvastatin).
- If your young child treated with PURMYCIN SUSPENSION becomes irritable or vomits when fed, you should contact your health care provider immediately.

Other medicines and PURMYCIN SUSPENSION

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

Tell your doctor if you are taking any of the following:

- Carbamazepine: medicine used to treat epilepsy.

- Corticosteroids e.g. methylprednisolone: medicines used to reduce inflammation and suppress the immune system.
- Digoxin: medicine used to treat heart failure and to treat certain types of abnormal heart rhythms.
- Theophylline: medicine used to treat asthma.
- Warfarin, acenocoumarol and rivaroxaban: medicines used to prevent or treat blood clots.
- Chloramphenicol: antibiotic medicine used to treat bacterial infections.
- Lincomycins, clindamycin and streptomycin: used to treat severe bacterial infections in people who cannot use penicillin antibiotics.
- Domperidone (used for nausea and vomiting)
- Alfentanil: painkiller used for anaesthesia in surgery
- Bromocriptine: used to treat menstrual problems and stop milk production
- Cilostazol: used to improve blood flow through the blood vessels
- Cyclosporin: used to suppress the immune system function
- Disopyramide: used to treat heart rhythm abnormalities
- Hexobarbitone, phenobarbital, triazolam, alprazolam, midazolam and zopiclone: used to treat insomnia (inability to sleep).
- Omeprazole: used to treat heartburn and indigestion
- Phenytoin and valproate: used to treat epilepsy
- Quinidine: used to treat certain types of irregular heartbeats
- Rifabutin and rifampicin: an antibiotic used in the treatment of tuberculosis (TB)
- Sildenafil: used to treat male sexual function problems
- Tacrolimus: to prevent the body from rejecting a transplanted organ
- Vinblastine: used to treat cancer
- Antifungals e.g. fluconazole, ketoconazole and itraconazole; used to treat fungal infections.
- St John’s Wort: herbal medicine used for depression and mood disorders.
- HMG-CoA Reductase Inhibitors e.g. simvastatin and lorvastatin: used to lower cholesterol and triglycerides (types of fat) in the blood
- Contraceptives: used to prevent pregnancy.
- Mizolastine, astemizole, terfenadine: used for hayfever and allergies)
- Tetracyclines and colistin: used to treat bacterial infections
- Protease inhibitors: antiviral medicines used to treat HIV
- Ergotamine and dihydroergotamine: used to treat migraines

- Cisapride: used for stomach disorders
- Pimozide: used for psychiatric conditions
- Colchicine: used to treat gout
- Verapamil: used to treat high blood pressure
- Cimetidine: used to treat stomach ulcers

PURMYCIN SUSPENSION with food and drink

PURMYCIN SUSPENSION should be given before meals.

Pregnancy, breastfeeding and fertility

The safety of PURMYCIN SUSPENSION during pregnancy and whilst breastfeeding has not been established.

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 this medicine.

Driving and using machines

PURMYCIN SUSPENSION is not expected to influence your ability to drive, use machinery or perform any tasks that require concentration.

It is not always possible to predict to what extent PURMYCIN SUSPENSION 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 PURMYCIN SUSPENSION affects them (see section 4).

PURMYCIN SUSPENSION contains sucrose and sorbitol

PURMYCIN SUSPENSION contains sucrose and sorbitol which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PURMYCIN SUSPENSION.

3. How to take/give PURMYCIN SUSPENSION

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

Always take or give PURMYCIN SUSPENSION exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Shake the bottle before use.

The usual dose of PURMYCIN SUSPENSION is

Adults:
The usual dose is one (1) to two (2) medicine measures (5 ml to 10 ml) of PURMYCIN - 250 SUSPENSION every 6 hours before meals.
Children:
The usual dose is 30 mg/kg to 50 mg/kg body mass of PURMYCIN - 125 SUSPENSION daily in divided doses before meals.
In severe infections your doctor may double these doses.

Your doctor will tell you how long your treatment with PURMYCIN SUSPENSION will last. Do not stop treatment early. Complete the prescribed course unless otherwise directed.

If you have the impression that the effect of PURMYCIN SUSPENSION is too strong or too weak, tell your doctor or pharmacist.

If you take or give more PURMYCIN SUSPENSION than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take or give PURMYCIN SUSPENSION
Do not take or give a double dose to make up for forgotten individual doses.
If you have missed a dose of PURMYCIN SUSPENSION, take or give the dose that you have missed as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose. If you have forgotten to take or give several doses, contact your doctor without delay.

If you stop taking PURMYCIN SUSPENSION
Continue to take or give PURMYCIN SUSPENSION until the course is completed or until your doctor tells you to stop. You should not stop taking PURMYCIN SUSPENSION without talking to your health care provider first even if you feel better.

4. Possible side effects
PURMYCIN SUSPENSION can have side effects.
Not all side effects reported for PURMYCIN SUSPENSION are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking PURMYCIN SUSPENSION, please consult your health care provider for advice.

If any of the following happens, stop taking or giving PURMYCIN SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting,
- blistering of the skin, mouth, eyes and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS),
- a life-threatening skin disorder characterized by a blistering and peeling of the skin known as Toxic epidermal necrolysis (TEN),
- a skin reaction known as Erythema multiforme,
- a severe skin reaction known as Acute generalised exanthematous pustulosis (AGEP).

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Inflammation of the liver (hepatitis),
- yellowing of the skin and eyes (jaundice),
- liver failure (hepatic failure),
- inflammation of the organ lying behind the lower part of the stomach (pancreas) (pancreatitis),
- swelling of the large intestine caused by a bacteria (pseudomembranous colitis)
- a sudden, uncontrolled electrical disturbance in the brain (seizure),
- damage on the optic nerve in the eye (optic neuropathy),
- a type of abnormal fast heart rhythm (torsade de pointes/ventricular tachydysrhythmias),
- a sudden, unexpected loss of heart function, breathing and consciousness (cardiac arrest),
- a life-threatening heart rhythm that results in a fast, inadequate heartbeat (ventricular fibrillation)
- an extended interval between the heart contracting and relaxing (electrocardiogram QT prolonged)

- inflammation of the tubules of the kidneys and the surrounding tissue (tubulointerstitial nephritis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following side effects:

Less frequent:

- fever, reinfection or a second infection with a bacteria, fungus or virus (super infection),
- skin eruptions

Frequency unknown:

- a higher than normal level if disease fighting white blood cells(eosinophilia),
- reversible deafness,
- seeing or hearing things that are not real (hallucinations),
- confusion, a feeling of spinning even when you're not moving(vertigo),
- low blood pressure (hypotension),
- nausea, vomiting, diarrhoea, upper abdominal discomfort, an eating disorder (anorexia),
- a condition in which the opening between the stomach and small intestine thickens (infantile hypertrophic pyloric stenosis),
- enlarged liver (hepatomegaly),
- chest pain, a general sense of being unwell (malaise),
- increase in liver enzymes.

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, pharmacist or nurse. 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 PURMYCIN SUSPENSION

5. How to store PURMYCIN SUSPENSION

Store all medicines out of reach of children.

Store at or below 25 ºC.
Keep container tightly closed.
Protect from light.
Shake the bottle before use.
Keep in original packaging until required for use.
Do not store in a bathroom.
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 PURMYCIN SUSPENSION contains

The active substance in PURMYCIN-125 suspension is 125 mg of erythromycin as erythromycin estolate.
The other ingredients are butylparaben, citric acid monohydrate (for pH adjustment), colour spectracol sunset yellow (C.I. 15985), disodium edetate, flavour orange liquid, guar gum powder, methylparaben, polysorbate, propylparaben, purified water, simethicone, sodium chloride, sodium citrate (for pH adjustment), sodium cyclamate, sorbitol solution, sucrose, xanthan gum.

The active substance in PURMYCIN-250 suspension is 250 mg of erythromycin as erythromycin estolate.
The other ingredients are avicel, ethanol, citric acid anhydrous (for pH adjustment), flavour banana, methylparaben, polysorbate, propylparaben, purified water, sodium carboxymethyl cellulose, sucrose.

What PURMYCIN SUSPENSION looks like and contents of the pack

PURMYCIN - 125 SUSPENSION: An orange suspension of pourable consistency with an orange odour.

PURMYCIN - 250 SUSPENSION: A white suspension of pourable consistency with a banana odour.

100 ml is packed in an amber glass bottle with a white polypropylene duet screw cap.

500 ml is packed in an amber glass bottle with an aluminium screw cap.

100 ml is packed in a high density polyethylene brown bottle sealed with a low density polyethylene snap cap.

Not all packs and pack sizes are necessarily marketed

Holder of Certificate of Registration

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PURMYCIN-125 SUSPENSION: L/20.1.1/148
PURMYCIN-250 SUSPENSION: L/20.1.1/149

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Botswana:	S2
125 mg	B9322765
250 mg	B9322775

Namibia:	NS2
125 mg	90/20.1.1/001169
250 mg	90/20.1.1/001170

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