PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

XEROPRIM, tablets

80 mg Trimethoprim and 400 mg Sulphamethoxazole

Sugar free

Read all of this leaflet carefully before you start taking XEROPRIM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist or other health care provider.
- XEROPRIM 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 XEROPRIM is and what it is used for

2. What you need to know before you take XEROPRIM

3. How to take XEROPRIM

4. Possible side effects

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1. What XEROPRIM is and what it is used for

XEROPRIM contains two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by certain bacteria. As XEROPRIM only works against some types of bacteria, it is only suitable for treating some types of infections.

It is used for:

- Upper and lower lung infections
- Urinary bladder or urinary tract infections
- Gastrointestinal tract (your mouth, oesophagus (gullet), stomach and intestines) infections
- Genital tract (reproductive track including sexually transferred diseases) infections
- Skin infections
- Other infections caused by bacteria that XEROPRIM works against.

2. What you need to know before you take XEROPRIM

Do not take XEROPRIM:

- If you are allergic to to sulfamethoxazole, trimethoprim, sulphonamides or any of the other ingredients of XEROPRIM (listed in section 6).
- If you suffer from porphyria.
- If you have severe liver problems.
- If you have severe kidney problems.
- If you are pregnant or breastfeeding.
- XEROPRIM should not be given to infants during the first 6 weeks of life.
- If you suffer from blood disorders or anaemia due to abnormally large red blood cells.
- If you have been diagnosed with vitamin b12 and folic acid deficiency.

Warnings and precautions

Take special care with XEROPRIM:

- You may break out in a severe skin rash after you take XEROPRIM. You should stop using XEROPRIM at the first appearance of a skin rash or any other sign of allergy.
- If you are suffering from AIDS or are having special treatment that lowers your immune system, e.g. after an organ transplant. You can experience more severe side effects.
- Tell your doctor if you have been diagnosed with anaemia due to deficiency of a vitamin called folic acid as XEROPRIM will not be prescribed to you if you have folic acid deficiency.
- If you are elderly you may have more severe side effects, e.g. problem with your blood causing bruises or bleeding (thrombocytopenia). This can happen more frequently if you are also taking water tablets, e.g. thiazides.
- When your treatment is over a long period, your doctor may monitor your blood more regularly.
- If you have kidney problems, your doctor might reduce the XEROPRIM dosage (see section 3). You should take enough fluids, especially if you are on high dosages of XEROPRIM.
- If you are allergic to sulphonamides. Examples include sulfonylurea (such as gliclazide and glibenclamide) or acetazolamide and thiazide diuretics (water tablets). You might be allergic to XEROPRIM as well.
- XEROPRIM may make you more sensitive to the sun. Limit your time in the sun. Avoid tanning booths and sunlamps. Use sunscreen and wear protective clothing when outdoors. Get medical help right away if you get sunburned or have skin blisters/redness.Tell your doctor if you have any allergies or suffer from asthma.
- Tell your doctor if you have a thyroid disorder. You doctor may perform a thyroid test.
- XEROPRIM should not be given to children under 12 years of age.

Other medicines and XEROPRIM

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, as the effect of these medicines can become stronger and your doctor might monitor you more closely:

- Warfarin or other medicines to thin your blood.
- Methotrexate, used to treat certain cancers or certain diseases affecting your immune system.
- Sulfonylurea compounds, used to treat diabetes, can become stronger when using XEROPRIM.
- Para-aminobenzoic acid (PABA) is a supplement and can increase your risk of side effects, e.g. crystals forming in your urine.
- Phenytoin, used to treat epilepsy.
- XEROPRIM can change the results of some laboratory tests.

Tell your doctor if you are taking any of the following, as the effect of these medicines can become stronger and your doctor might change your treatment:

- Diuretics (water tablets) especially if you are elderly with heart problems.
- Digoxin or procainamide to treat problems with the way your heart beats.
- Tolbutamide and repaglinide used to treat diabetes.
- Ciclosporin, used in e.g. kidney transplant, as it can cause your kidneys to work less effective.
- Pyrimethamine used to treat and prevent malaria, and to treat diarrhoea, as you can develop side effects, e.g. anaemia.

- Zidovudine used in the treatment of HIV, as it can increase your risk of developing less blood cells.
- Lamivudine used in the treatment of HIV, as XEROPRIM at high dosages can increase the effect of lamivudine.
- Medicines that can increase the amount of potassium in your blood such as ACE inhibitors (e.g. lisinopril, quinapril), ARB inhibitors (e.g. irbesartan, valsartan, losartan and candesartan) (used to treat high blood pressure or some heart problems), diuretics (water tablets such as spironolactone), steroids (like prednisolone), digoxin. These medicines can increase the amount of potassium to dangerously high levels in your blood.
- Folinic acid, a supplement can lower the effect of XEROPRIM.
- Contraceptives can become less effective when taking with XEROPRIM. You should use additional protection while on XEROPRIM treatment.
- Azathioprine used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease. Your doctor might monitor your blood cells more closely.

XEROPRIM with food and drink

Drink plenty of fluid such as water while you are taking XEROPRIM to prevent crystals forming in the urine.

Pregnancy and breastfeeding and fertility

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 healthcare professional for advice before taking this medicine.

You should not take XEROPRIM while you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent XEROPRIM 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 XEROPRIM affects them.

XEROPRIM contains

XEROPRIM contains Nipastat, a mixture of parahydroxybenzoate esters. It may cause allergic reactions (possibly delayed).

3. How to take XEROPRIM

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

Always take XEROPRIM exactly as described in this leaflet or your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure. The usual dose is:

Adults and children over 12 years:

Take 2 tablets every 12 hours for a period of 10 to 14 days.

Not recommended for children under 12 years.

Kidney disease

Your doctor will do a blood test and calculate your dosage depending on the results.

Take the tablets with a sufficient quantity of liquid (e.g. one glass of water).

Do not chew the tablets.

If you take more XEROPRIM than you should

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center.

Immediate medical advice should be sought in the event of an overdose with symptoms of nausea, vomiting, dizziness

If you forget to take XEROPRIM

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking XEROPRIM

Your doctor will tell you how long your treatment with XEROPRIM will last. Do not stop treatment early because the infection can start again. If you have the impression that the effect of XEROPRIM is too strong or too weak, tell your doctor or pharmacist.

4. Possible side effects:

XEROPRIM can have side effects.

Not all side effects reported for XEROPRIM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XEROPRIM, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking XEROPRIM 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 all over the body

These are all very serious side effects. If you have them, you may have had a serious reaction to XEROPRIM. 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: The following side effects occur frequently:

- Pseudomembranous colitis (infection of the colon resulting in watery and sometimes bloody stools)
- A severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis).
- A combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).
- Onset of rash at a fixed location on the body each time you take the same medicines (fixed drug eruption).
- Unexpected worsening of cough and shortness of breath.
- Inflammation of the liver, resulting in abdominal pain, dark urine, pale stools, weakness, fatigue.
- Less urine than is normal for you.
- Upper abdominal pain; abdominal pain that radiates to your back; tenderness when touching the abdomen; fever; rapid pulse; nausea; vomiting are symptoms of inflammation of the pancreas.
- Sudden headache or stiffness of your neck, accompanied by fever (aseptic meningitis).

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

Tell your doctor if you notice any of the following:

<u>Frequent side effects</u>

- Fungal overgrowth

- High levels of potassium in your blood, which can cause abnormal heart beats (palpitations).
- Headache
- Nausea, vomiting, diarrhoea, swollen and inflamed tongue, inflamed and sore mouth
- Rash, itchy skin
- Fever

Less frequent side effects

- Agranulocytosis (less white blood cells in the body)
- Thrombocytopenia (abnormally low blood platelets)
- Leukopenia (lower-than-normal white blood cells in the blood)
- Neutropenia (deficiency of white blood cells);
- Anaemia (lower-than-normal red bloods cells in the blood)
- Purple coloured spots or rash on the skin
- Abnormally large red blood cells
- Inflamed blood vessels
- Eosinophilia (A high level of disease-fighting white blood cells known as eosinophils in the blood.)
- Enlarged thyroid gland
- Increased acid in the blood, eating disorder, low blood sugar levels, low sodium levels
- Depression, hallucination, mental illness,
- Impaired coordination, dizziness, tiredness, difficulty sleeping, seizures, tingling or numbness in your hands and feet
- Vision disorders, seeing flickering or flashing lights, short-sighted for a short period, inflammation of the eye which causes pain and redness
- Feeling unsteady or giddy

- Ringing or other unusual sounds in your ears
- Cough, difficulty breathing, lung problems
- Cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes)
- Vomiting
- Swollen and inflamed tongue
- Inflamed and sore mouth
- Stiff joints
- Skin rash, skin inflammation
- Muscle stiffness and pain
- Kidney failure, painful urination, blood in the urine, low or no urine output

Frequency unknown

- Buildup of acid in the body
- Hypothyroidism where the thyroid does not create and release enough thyroid hormone into your bloodstream. This makes you feel tired, gain weight and unable to tolerate cold temperatures.
- Mental illness
- Cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes)

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via http:///www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store XEROPRIM

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store in a cool dry place, below 25 ºC. Protect from light and heat. Store in the original package/container.

Do not store in a bathroom.

Do not use XEROPRIM after the expiry date stated on the carton.

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 XEROPRIM contains

The active substances in each tablet are 80 mg trimethoprim and 400 mg sulphamethoxazole.

The other ingredients are: microcrystalline cellulose, pregelatinised starch, maize starch, nipastat, sodium carboxy methyl cellulose, magnesium stearate.

What XEROPRIM looks like and contents of the pack

White, round flat tablet bisected on one side.

XEROPRIM is packed in:

patient ready packs of 28, 56 and 100 tablets and bottles of 20, 100 and 500 tablets.

Name, Business Address and Telephone Number of the Holder of the Certificate of Registration

Oethmaan Biosims (Pty) Ltd

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