

Patient Information Leaflet for Medicines for Human Use:**NUCOTRIM TABLETS****SCHEDULING STATUS:** S4**NUCOTRIM 80 mg/400 mg, tablets****Trimethoprim and sulfamethoxazole****Sugar free****Read all of this leaflet carefully before you start taking NUCOTRIM**

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

1. What NUCOTRIM is and what it is used for

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

It is used for:

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

NUCOTRIM can be used in children (from 12 to 18 years old) and adults (from 18 years old).

2. What you need to know before you take NUCOTRIM**Do not take NUCOTRIM**

- If you are hypersensitive (allergic) to sulfamethoxazole, trimethoprim, sulfonamides or any of the other ingredients of NUCOTRIM (listed in section 6)
- If you have been told that you have a rare blood problem called porphyria, which can affect the skin or nervous system
- If you have severe liver or severe kidney problems
- If you have been told that you have an anaemia due to not having enough folic acid

- If you are pregnant or breastfeeding
- If you do not have enough vitamin B12 or folic acid
- If you have ever had a problem with your blood causing bruises or bleeding (thrombocytopenia)
- NUCOTRIM should not be given to infants during the first 6 weeks of life.

Warnings and precautions

Take special care with NUCOTRIM

- 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.
- If you have skin rashes, often accompanied by flu-like symptoms after taking NUCOTRIM. The rash may progress to widespread blistering or peeling of the skin. This can be a serious skin reaction to NUCOTRIM. Stop taking NUCOTRIM and seek urgent advice from your doctor.
- If you have a condition called haemophagocytic lymphohistiocytosis caused by excessive immune reactions due to a dysregulated activation of white blood cells resulting in inflammations. This can be life-threatening if not diagnosed and treated early. If you experience multiple symptoms such as fever, swollen glands, feeling weak, lightheaded, shortness of breath, bruising, or skin rash simultaneously or with a slight delay, contact your doctor immediately.
- If you develop an unexpected worsening of cough and shortness of breath, inform your doctor immediately.
- If you are elderly, you may have more severe side effects, e.g., a problem with your blood causing bruises or bleeding (thrombocytopenia). This can happen more frequently if you are also taking water tablets, e.g., thiazides.

- If you have kidney problems, your doctor might reduce the NUCOTRIM dosage (see section 3). You should take enough fluids, especially if you are on high dosages of NUCOTRIM.
- If you are underweight or have an imbalance between the nutrients your body needs to function and the nutrients it gets (malnourished).
- If you don't have enough folic acid (a vitamin) in your body, which can make your skin pale and make you feel tired, weak and breathless. This is known as anaemia. Your doctor might prescribe additional folic acid with your NUCOTRIM treatment.
- If you are allergic to sulfonamides. Examples include sulfonylurea (such as gliclazide and glibenclamide) or acetazolamide and thiazide diuretics (water tablets). You might be allergic to NUCOTRIM as well.
- If you have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- If you have severe allergy or bronchial asthma.
- If you have a problem with your metabolism called phenylketonuria and are not on a special diet to help their condition.
- If you have been told that you have a lot of potassium in your blood. Concomitant administration of co-trimoxazole as in NUCOTRIM with certain medicines, potassium supplements and food rich in potassium may lead to severe hyperkalaemia (increased potassium blood level). The symptoms of severe hyperkalaemia might include muscle cramps, irregular heart rhythm, diarrhoea, nausea, dizziness or headache.
- If you develop a condition called metabolic acidosis in which acids build up in your body. Symptoms include an accelerated heartbeat, confusion, dizziness, feeling very tired and weak, rapid breathing or long, deep breathing, nausea and vomiting or breath that smells sweet or fruity. If you experience these symptoms, contact your doctor immediately. Severe cases of metabolic acidosis can cause death. Your

doctor may do a physical examination on you, order blood and urine tests to help diagnose it and recommend an appropriate treatment plan.

- When your treatment is over a long period, your doctor may monitor your blood more regularly.
- If you have a severe blood disorder, such as a low number of red blood cells (anaemia), a low number of white blood cells (leukopenia) or a low number of platelets, which may cause bleeding and bruising (thrombocytopenia).

Other medicines and NUCOTRIM

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

- NUCOTRIM can interact with the following medicines to make their effect and risk of adverse effects stronger. If you are taking any of the following, your doctor might monitor you more closely:
 - Lamivudine, used to treat Human Immunodeficiency Virus (HIV), as there can be an increase in side effects related to blood disorders
 - Medicines to treat problems with the way the heart beats such as digoxin or procainamide, your doctor might change your treatment
 - Amantadine, used to treat Parkinson's disease, multiple sclerosis, flu or shingles
 - Water tablets such as hydrochlorothiazide and indapamide (called thiazide diuretics) as the risk of low blood platelet count (thrombocytopenia) with or without purplish spots and patches on the skin (purpura) is increased, especially if you are elderly

- Pyrimethamine used to treat and prevent malaria, and to treat diarrhoea, as you can develop side effects, e.g., deficiency in the number of red blood cells (anaemia)
- Warfarin or other medicines to thin your blood
- Phenytoin, used to treat epilepsy (fits)
- Methotrexate, used to treat certain cancers or certain diseases affecting your immune system
- Medicines used to treat diabetes, such as glibenclamide, gliclazide, tolbutamide, glimepiride (called sulfonylureas) and repaglinide, your doctor might change your treatment
- Ciclosporin, used in e.g., kidney transplant, as it increases the risk of kidney damage and your kidneys to work less effective
- Medicines that can increase the amount of potassium in your blood, such as some diuretics (water tablets, which help increase the amount of urine you produce, such as spironolactone), or some medicines used to treat high blood pressure or some heart problems called ACE inhibitors (e.g., enalapril, perindopril) or angiotensin receptor blockers (e.g., candesartan, losartan, valsartan etc). These medicines can increase the amount of potassium to dangerously high levels in your blood and you may feel abnormal heart beats (palpitations), shortness of breath, chest pain, nausea, or vomiting. Sudden or severe hyperkalaemia is a life-threatening condition and you will require immediate medical care
- Azathioprine used in patients following organ transplant or to treat immune system disorders or inflammatory bowel disease, as this can cause serious blood disorders. Your doctor might monitor your blood cells more closely.
- NUCOTRIM can change the results of some laboratory tests.

- NUCOTRIM can interact with the following medicines to make their effect weaker:
 - Contraceptives can become less effective when taken with NUCOTRIM. You should use additional protection while on NUCOTRIM treatment.
- Some medicines can interact with NUCOTRIM to make its effect and risk of adverse effects stronger. If you are taking the following, your doctor might monitor you more closely:
 - Zidovudine used in the treatment of HIV, as it can increase your risk of developing blood disorders.
- Some medicines can interact with NUCOTRIM to make its effect weaker and interfere with its ability to defend your body against disease causing microbes and therefore NUCOTRIM should not be taken together with:
 - Rifampicin, an antibiotic used in the treatment of Tuberculosis (TB)
 - Folinic acid, a health supplement
 - Para-aminobenzoic acid (PABA), also known as vitamin B 10, a health supplement, which assists with the production of folate (vitamin B9) and benefits skin and hair growth
 - Local anaesthetics (procaine, lidocaine, prilocaine, tetracaine) used for nerve blockage and epidural anaesthesia
 - Paraldehyde, used in the treatment of anxiety, sleeplessness and epilepsy (fits) as it can increase your risk of side effects, e.g., crystals forming in your urine.

NUCOTRIM with food and drink

The tablets should be swallowed with a glass of water and food. Drink plenty of fluid such as water while you are taking NUCOTRIM.

Pregnancy and breastfeeding

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.

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

Driving and using machines

It is not always possible to predict to what extent NUCOTRIM may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g., driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which NUCOTRIM affects you.

NUCOTRIM contains Nipastat

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

3. How to take NUCOTRIM

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

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

The dosage and length of NUCOTRIM treatment will depend on your needs and the infection being treated.

Adults and children over 12 years

The usual dose is two NUCOTRIM tablets every 12 hours after meals. The maximum dose (for particularly severe cases) is three NUCOTRIM tablets every 12 hours. The minimum dosage for long term treatment is one NUCOTRIM tablet every 12 hours.

Duration of administration

Your doctor will tell you how long your treatment with NUCOTRIM will last. Do not stop treatment early because the infection can start again. Make sure that you finish the course of NUCOTRIM which the doctor has prescribed.

You must see a doctor if your symptoms worsen or do not improve after 7 days of taking NUCOTRIM.

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

Method of administration

NUCOTRIM tablets must be taken by mouth after food with a drink of water to minimise the possibility of disturbances of the digestive tract such as nausea.

If you take NUCOTRIM for a long time your doctor may

- Take blood to test whether the medicine is working properly.
- Prescribe folic acid (a vitamin) for you to take at the same time as NUCOTRIM.

If you take more NUCOTRIM than you should

When more NUCOTRIM was taken than you should take, you may feel nauseous and/or experience vomiting, dizziness and confusion.

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of NUCOTRIM

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

4. Possible side effects

NUCOTRIM can have side effects.

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

If any of the following happens, stop taking/giving NUCOTRIM 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, chest pain, red patches on the skin. This can be an allergic reaction to NUCOTRIM

- Severe and serious skin reactions which can include:
 - Toxic epidermal necrolysis (Lyell's syndrome) and Steven-Johnson syndrome (SJS) – life threatening diseases that begin with a fever and flu-like symptoms and then within a few days the skin begins to blister and peel, forming very painful raw areas, called erosions that resemble severe hot-water burns, usually starting on the face and chest before spreading to other parts of the body
 - Sweets syndrome which includes plum-coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever
 - Drug reaction with eosinophilia and systemic symptoms (DRESS) in which you may develop fever, skin rash, and abnormalities in blood and liver function tests (these may be signs of a multi-organ sensitivity disorder)
 - Fixed drug eruption (FDE) is a well-defined, circular, darker red patches that always recurs as one or a few lesions in fixed locations (commonly on the genitals, lips, trunk, and hands) upon ingestion of a specific medicine and can be severe and life-threatening when widespread fluid-filled blistering occurs
 - Sudden allergic skin eruption that appears on average five days after the medicine is started and forms skin areas studded with pinhead-sized small white or red elevations that contain pus. This eruption typically, starts on the face or in the armpits and groin and then becomes more widespread with skin folds being more affected (acute generalised exanthematous pustulosis (AGEP))
 - Systemic lupus erythematosus (SLE) is a condition in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs. It can affect the joints, skin, brain, lungs, kidneys, and blood vessels and can be life-threatening in severe cases (see also section 2)
- Unexpected worsening of cough and shortness of breath

- Inflammation of the liver sometimes with jaundice (liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine)
- Sudden headache or stiffness of your neck, accompanied by fever. This can be aseptic meningitis
- Severe and persistent allergic reactions, rash, high fever, liver problems, low white blood cell counts, low blood platelet counts, muscle pains, weakness, dark urine, vomiting and confusion – these are effects that you may experience if you have HIV and the doctor has prescribed NUCOTRIM to prevent or treat a serious fungal lung infection called *Pneumocystis jirovecii* Pneumonitis (PJP). Your doctor will likely stop your treatment with NUCOTRIM.

These are very serious side effects. If you have them, you may have had a serious reaction to NUCOTRIM. 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:

- Infection of the colon resulting in watery and sometimes bloody stools (pseudomembranous colitis)
- Changes in the blood cells (e.g., reduction in white and red blood cells), resulting in feeling weak, tired or listless, pale skin, and experiencing more frequent and recurrent infections such as fever or sore throat
- Prolonged or excessive bleeding which can include nosebleeds, bleeding gums, bruising due to low levels of platelets in your blood (thrombocytopenia) which in severe cases can cause dangerous internal bleeding

- High levels of potassium in your blood, (hyperkalaemia) which can cause abnormal heart beats (palpitations), shortness of breath, chest pain, nausea, or vomiting. This can be a life-threatening condition if it is severe and occurs suddenly
- Low sodium concentration in your blood that can cause neurologic symptoms ranging from confusion, irritability, disorientation in mild cases to seizures (fits), brain swelling and coma in serious cases which can be life-threatening
- Build-up of acid in your body (metabolic acidosis) which include symptoms such as an accelerated heartbeat, confusion, dizziness, feeling very tired and weak, rapid breathing or long, deep breathing. Severe cases of metabolic acidosis can cause death (see section 2)
- Fits (convulsions or seizures)
- Bluish or greyish colour of the skin, nails, lips or around the eyes (cyanosis) which is due to a lack of oxygen in the blood
- Inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (pancreatitis)
- A severe skin condition that causes redness and peeling over most of the body surface (exfoliative dermatitis)
- Red or purple, warm, painful, tender bumps most commonly located in the shins (front of the lower leg) and accompanied by fever and joint pain (erythema nodosum)
- An itchy and painful skin rash, appearing as red to purple patches, pimple-like blisters, or round marks on the skin that resemble a bull's eye, but can also affect the mucous membranes in the mouth, eyes, and genitals (erythema multiforme)
- Kidney problems which can include pain and swelling in your flank, lower back, feet and ankles, blood or cloudiness in your urine, problems with your urine, difficulty passing urine, passing more or less urine than usual.

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

Tell your doctor if you notice any of the following:

Sulfamethoxazole

Frequent side effects

- A fungal infection called thrush or candidiasis which can affect the mouth or vagina
- Headache
- Nausea
- Diarrhoea
- Rash.

Less frequent side effects

- Fever (high temperature)
- Low blood sugar (hypoglycaemia) that can include symptoms like excessive sweating, tiredness, light-headedness, feeling dizzy, weak, irritable or nervous, increased heart rate, blurred vision, confusion
- Decreased appetite
- Depression, a mood disorder that causes a persistent feeling of sadness and loss of interest
- Seeing strange or unusual sights (hallucination)
- Loss of balance and coordination (ataxia)
- Dizziness
- Feeling tired
- Difficulty to sleep
- Tingling or numbness in your hands and feet (peripheral neuritis)
- Vision disorders, seeing flickering or flashing lights
- Short-sighted for a short period

- Inflammation of the eye which causes pain and redness (uveitis)
- Feeling unsteady or giddy (vertigo)
- Ringing or other unusual sounds in your ears (tinnitus)
- Vomiting
- Inflamed tongue which may cause the tongue to become sensitive, painful, red and swollen (glossitis)
- Inflamed and sore mouth (stomatitis)
- An increase in liver enzymes (to be shown by blood tests)
- Red, itchy patches on your skin when you have been outside (even on a cloudy day) due to skin's overreaction to sunlight (photosensitivity reaction)
- Pains in the joints (arthralgia) or in the muscles (myalgia).

Side effects occurring with frequency unknown

- Hypothyroidism, a condition where the thyroid doesn't create and release enough thyroid hormone into your bloodstream. This makes you feel tired, gain weight and unable to tolerate cold temperatures
- Psychotic disorder, a mental state in which you may lose touch with reality.

Trimethoprim

Frequent side effects

- Headache.

Less frequent side effects

- Itchy skin
- Rash
- Fever

- Nausea
- Vomiting
- Sore mouth.

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 NUCOTRIM.

Alternately you can contact Gulf Drug Company (Pty) Ltd at +27 31 538 8700 or per info@gulfdrug.co.za.

5. How to store NUCOTRIM

Store all medicines out of reach of children.

- Store at or below 25 °C in a cool, dry place.
- Protect from light and moisture.
- Keep HDPE containers tightly closed.
- Do not remove tablets from blister until required for use.
- 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 NUCOTRIM contains

- The active substances are trimethoprim and sulfamethoxazole. The combination of these two antibiotics is also called co-trimoxazole.
- The other ingredients are:
 - Magnesium stearate
 - Maize starch
 - Microcrystalline cellulose
 - Nipastat (as preservative)
 - Pregelatinised starch
 - Purified water.

What NUCOTRIM looks like and contents of the pack

White, round flat tablet bisected on one side.

The bisection line is only to facilitate breaking for ease of swallowing and not to divide the tablet into equal doses.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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