DOCTRIM SUSPENSION

SCHEDULING STATUS: S4

DOCTRIM SUSPENSION, 40 mg/200 mg, suspension
Trimethoprim and sulfamethoxazole
Contains sugar as sucrose 2 500 mg/5 mL
Contains sweetener as sodium saccharin 20 mg/5 mL

Read all of this leaflet carefully before you start taking/giving DOCTRIM 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.
- DOCTRIM SUSPENSION has been prescribed for you/your child personally and you should not share your/your child's medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

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

DOCTRIM SUSPENSION contains two different antibiotics called sulfamethoxazole and trimethoprim, which is used to treat infections caused by certain bacteria. As DOCTRIM SUSPENSION 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 DOCTRIM SUSPENSION works against.

DOCTRIM SUSPENSION can be used in adults and children over 12 years with difficulties swallowing tablets and in infants and children (from 6 weeks to 12 years old).

2. What you need to know before you take/give DOCTRIM SUSPENSION

Do not take/give DOCTRIM SUSPENSION

- If you/your child are hypersensitive (allergic) to sulfamethoxazole, trimethoprim, sulfonamides or any of the other ingredients of DOCTRIM SUSPENSION (listed in section 6)
- If you/your child have been told that you/your child have a rare blood problem called porphyria, which can affect the skin or nervous system
- If you/your child have severe liver or severe kidney problems
- If you/your child have been told that you have an anaemia due to not having enough folic acid
- If you are pregnant or breastfeeding
- If you/your child do not have enough vitamin B12 or folic acid
- If you/your child have ever had a problem with your/their blood causing bruises or bleeding (thrombocytopenia)
- DOCTRIM SUSPENSION should not be given to infants during the first 6 weeks of life.

Warnings and precautions

Take special care with DOCTRIM SUSPENSION

- If you/your child are suffering from AIDS or are having special treatment that lowers your/their immune system, e.g., after an organ transplant. You/your child can experience more severe side effects.
- If you/your child have skin rashes, often accompanied by flu-like symptoms after taking DOCTRIM SUSPENSION. The rash may progress to widespread blistering or peeling of the skin. This can be a serious skin reaction to DOCTRIM SUSPENSION. Stop taking/giving DOCTRIM SUSPENSION and seek urgent advice from your doctor.

- If you/your child 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/your child 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/your child 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/your child have kidney problems, your doctor might reduce the DOCTRIM SUSPENSION dosage (see section 3). You/your child should take enough fluids, especially if you/your child are on high dosages of DOCTRIM SUSPENSION.
- If you/your child are underweight or have an imbalance between the nutrients your/their body needs to function and the nutrients it gets (malnourished).
- If you/your child don’t have enough folic acid (a vitamin) in your/their body, which can make your/their skin pale and make you feel tired, weak and breathless. This is known as anaemia. Your doctor might prescribe additional folic acid with your/their DOCTRIM SUSPENSION treatment.
- If you/your child are allergic to sulfonamides. Examples include sulfonylurea (such as gliclazide and glibenclamide) or acetazolamide and thiazide diuretics (water tablets). You/your child might be allergic to DOCTRIM SUSPENSION as well.
- If you/your child have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- If you/your child have severe allergy or bronchial asthma.
- If you/your child have a problem with your/their metabolism called phenylketonuria and are not on a special diet to help your/their condition.
- If you have been told that you/your child has a lot of potassium in your/their blood. Concomitant administration of co-trimoxazole as in DOCTRIM SUSPENSION 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/your child develop a condition called metabolic acidosis in which acids build up in your/their 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/your child experience these symptoms, contact your doctor immediately. Severe cases of metabolic acidosis can cause death. Your doctor may do a physical examination on you/your child, order blood and urine tests to help diagnose it and recommend an appropriate treatment plan.
- When you/your child's treatment is over a long period, your doctor may monitor your/their blood more regularly.
- If you/your child has a severe blood disorder, such as a low number of red blood cells (anaemia your), a low number of white blood cells (leukopenia) or a low number of platelets, which may cause bleeding and bruising (thrombocytopenia).

Other medicines and DOCTRIM SUSPENSION

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

- DOCTRIM SUSPENSION can interact with the following medicines to make their effect and risk of adverse effects stronger. If you/your child are taking any of the following, your doctor might monitor you/your child 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/your child's 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/your child can develop side effects, e.g., deficiency in the number of red blood cells (anaemia)
    - Warfarin or other medicines to thin your/your child's blood
    - Phenytoin, used to treat epilepsy (fits)

- Methotrexate, used to treat certain cancers or certain diseases affecting your/your child's immune system
- Medicines used to treat diabetes, such as glibenclamide, gliclazide, tolbutamide, glimepiride (called sulfonylureas) and repaglinide, your doctor might change your/your child's treatment
- Ciclosporin, used in e.g., kidney transplant, as it increases the risk of kidney damage and causes your/your child's kidneys to work less effective
- Medicines that can increase the amount of potassium in your/your child's blood, such as some diuretics (water tablets, which help increase the amount of urine you/your child 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//your child's 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/your child 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//your child's blood cells more closely.

- DOCTRIM SUSPENSION can change the results of some laboratory tests.

- DOCTRIM SUSPENSION can interact with the following medicines to make their effect weaker:
  - Contraceptives can become less effective when taken with DOCTRIM SUSPENSION. You should use additional protection while on DOCTRIM SUSPENSION treatment.

- Some medicines can interact with DOCTRIM SUSPENSION to make its effect and risk of adverse effects stronger. If you/your child are taking the following, your doctor might monitor you more closely:
  - Zidovudine used in the treatment of HIV, as it can increase your/your child's risk of developing blood disorders.

- Some medicines can interact with DOCTRIM SUSPENSION to make its effect weaker and interfere with its ability to defend your//your child's body against disease causing microbes and therefore DOCTRIM SUSPENSION 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/your child's risk of side effects, e.g., crystals forming in your urine.

DOCTRIM SUSPENSION with food and drink

The suspension should be taken/given by mouth after food or drink.
Drink/give plenty of fluid such as water while you/your child are taking DOCTRIM SUSPENSION.

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 DOCTRIM SUSPENSION while you are pregnant or breastfeeding your baby.

Driving and using machines

It is not always possible to predict to what extent DOCTRIM SUSPENSION may interfere with your/your child's daily activities. You should ensure that you/your child 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 DOCTRIM SUSPENSION affects you/your child.

DOCTRIM SUSPENSION contains Nipastat

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

DOCTRIM SUSPENSION contains alcohol and sucrose
DOCTRIM SUSPENSION contains alcohol 0,025 mg of alcohol (ethanol) in each 5 mL which is equivalent to 0,5 % *v/v* alcohol (ethanol). The amount in 5 mL of this medicine is equivalent to 0,5 mL of beer and less than 0,5 mL of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

DOCTRIM SUSPENSION contains 2 500 mg per 5 mL sucrose. This should be taken into account in if you/your child have diabetes mellitus.
If you have been told by your doctor that you/your child have an intolerance to some sugars, contact your doctor before taking or giving this DOCTRIM SUSPENSION.

Sodium
DOCTRIM SUSPENSION contains less than 1 mmol sodium (23 mg) per 5 mL, i.e., essentially ‘sodium free’.

3. How to take/give DOCTRIM SUSPENSION
Do not share medicines prescribed for you or your child with any other person.
Always take/give DOCTRIM SUSPENSION exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dosage and length of DOCTRIM SUSPENSION treatment will depend on your/your child’s needs and the infection being treated.

Adults and children over 12 years with difficulties swallowing tablets
DOCTRIM SUSPENSION is recommended in adults and children above 12 years only if there are difficulties in swallowing tablets.
20 mL (four medicine measures) DOCTRIM SUSPENSION every 12 hours (i.e. morning and evening).

Infants and children
6 weeks to 5 months: Half (2,5 mL) a medicine measure twice daily.
6 months to 5 years: One (5 mL) medicine measure twice daily.

6 years to 12 years: Two (10 mL) medicine measures twice daily.

Duration of administration

Your doctor will tell you how long your/your child's treatment with DOCTRIM SUSPENSION will last. Do not stop treatment early because the infection can start again. Make sure that you/your child finishes the course of DOCTRIM SUSPENSION which the doctor has prescribed.

You must see a doctor if your/your child's symptoms worsen or do not improve after 7 days of taking DOCTRIM SUSPENSION.

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

Method of administration

Use a medicine measure or measuring spoon graduated 2,5 mL, and 5mL. This spoon can also be used to measure 2,5 mL (one half of a spoon). Rinse the medicine measure or measuring spoon after each use.

Shake the bottle before giving/taking the medicine.

DOCTRIM SUSPENSION must be taken by mouth after food or drink to minimise the possibility of disturbances of the digestive tract such as nausea.

If you/your child take DOCTRIM SUSPENSION for a long time your/their doctor may

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

If you/your child take more DOCTRIM SUSPENSION than you/they should

When more DOCTRIM SUSPENSION was taken than you/your child should take, you/your child 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/give a dose of DOCTRIM SUSPENSION

If you forget to take/give a dose, take/give it as soon as you remember it. Do not take/give a

double dose to make up for the forgotten dose.

4. Possible side effects

DOCTRIM SUSPENSION can have side effects.

Not all side effects reported for DOCTRIM SUSPENSION are included in this leaflet. Should your/your child's general health worsen or if you/your child experience any untoward effects while taking/receiving DOCTRIM SUSPENSION, please consult your health care provider for advice.

If any of the following happens, stop taking/giving DOCTRIM 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, chest pain, red patches on the skin. This can be an allergic reaction to DOCTRIM SUSPENSION
- Severe and serious skin reactions which can include:
    - Toxic epidermal necrolysis (Lyell's syndrome) and Steven-Johnson syndrome (SJS) – these are 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/your child 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/your child's 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 your child may experience if you/your child have HIV and the doctor has prescribed DOCTRIM SUSPENSION to prevent or treat a serious fungal lung infection called *Pneumocystis jirovecii* Pneumonitis (PJP). Your doctor will likely stop your treatment with DOCTRIM SUSPENSION.

These are very serious side effects. If you/your child have them, you/your child may have had a serious reaction to DOCTRIM SUSPENSION. You/your child 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/your child's blood (thrombocytopenia) which in severe cases can cause dangerous internal bleeding
- High levels of potassium in your/your child's 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/your child's 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/your child's 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/your child's flank, lower back, feet and ankles, blood or cloudiness in your urine, problems with your /your child's urine, difficulty passing urine, passing more or less urine than usual.

These are all serious side effects. You/your child 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/your child's hands and feet (peripheral neuritis)
- Vision disorders, seeing flickering or flashing lights
- Sort-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/your child's 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/your child's 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/your child's bloodstream. This makes you/your child feel tired, gain weight and unable to tolerate cold temperatures
- Psychotic disorder, a mental state in which you/your child 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/your child 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 DOCTRIM SUSPENSION.

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

5. How to store DOCTRIM SUSPENSION

Store all medicines out of reach of children.

- Store at or below 25 °C in a cool, dry place.
- Protect from light and moisture.
- 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 DOCTRIM SUSPENSION contains

- The active substances are trimethoprim and sulfamethoxazole. The combination of

these two antibiotics is also called co-trimoxazole.

- The other ingredients are:
  Aluminium magnesium silicate
  Aniseed oil
  Ethanol
  Nipastat (as preservative)
  Polysorbate 80
  Purified water
  Sodium carboxymethylcellulose
  Sodium citrate
  Sodium saccharin
  Sucrose.

What DOCTRIM SUSPENSION looks like and contents of the pack

A smooth, white suspension with a characteristic aniseed odour.
DOCTRIM SUSPENSION is supplied in round amber HDPE bottles of 50 mL or 100 mL with a white LDPE snap-on cap.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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