

Approved Patient Information Leaflet for Medicines for Human Use:

ILVITRIM SUSPENSION

SCHEDULING STATUS: S4

ILVITRIM SUSPENSION 40 mg/200 mg per 5 mL suspension

Trimethoprim and sulphamethoxazole

Each 5 mL contains 0,3 % *m/v* nipastat (preservative).

Each 5 mL contains 0,44 % *v/v* ethanol 96 %.

Each 5 mL contains sugar: sucrose 2 500 mg/5 mL.

Each 5 mL contains sweetener: sodium saccharin 20 mg/5 mL.

Read all of this leaflet carefully before you start taking/giving ILVITRIM 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.
- ILVITRIM 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 ILVITRIM SUSPENSION is and what it is used for
2. What you need to know before you take/give ILVITRIM SUSPENSION
3. How to take/give ILVITRIM SUSPENSION
4. Possible side effects
5. How to store ILVITRIM SUSPENSION
6. Contents of the pack and other information

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

ILVITRIM SUSPENSION contains the active substance called trimethoprim 40 mg and sulphamethoxazole 200 mg per 5 mL suspension which belongs to the group of medicines called antibacterials for systemic use.

ILVITRIM SUSPENSION works by killing bacteria.

ILVITRIM SUSPENSION is used to treat:

- 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 with bacteria sensitive to ILVITRIM SUSPENSION.

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

Do not take/give ILVITRIM SUSPENSION

- if you or your child are hypersensitive (allergic) to sulphamethoxazole, sulphonamide or trimethoprim or any of the other ingredients of ILVITRIM SUSPENSION (listed in section 6).
- if you/your child have been told that you have or are at risk for a rare blood disorder called porphyria.
- 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 or vitamin B₁₂.
- if you are pregnant or breastfeeding.
- ILVITRIM SUSPENSION should not be given to infants during the first 6 weeks of life.

Warnings and precautions

Take special care with ILVITRIM SUSPENSION

- If you/your child has skin rashes, often accompanied by flu-like symptoms after taking ILVITRIM

SUSPENSION. The rash may progress to widespread blistering or peeling of the skin. This can be a serious skin reaction to ILVITRIM SUSPENSION. Stop taking ILVITRIM SUSPENSION and seek urgent advice from your doctor.

- There have been very rare reports about excessive immune reactions due to a dysregulated activation of white blood cells resulting in inflammations (haemophagocytic lymphohistiocytosis), which 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. 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. You/your child should take enough fluids, especially if you are underweight or malnourished.
- If you/your child 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 ILVITRIM SUSPENSION treatment.
- If they have a disease called glucose-6-phosphate dehydrogenase deficiency, which can cause jaundice or spontaneous destruction of red blood cells.
- If they have severe allergies or asthma.
- If they have a problem with their metabolism called phenylketonuria and are not on a special diet to help their condition.
- If you have been told by your child's doctor that your child has a lot of potassium in their blood. Concomitant administration of ILVITRIM 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 your child has a severe blood disorder, such as a low number of red blood cells (anaemia), a low number of white blood cells (leucopenia) or a low number of platelets, which may cause bleeding and bruising (thrombocytopenia).
- If you/your child 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/your child are allergic to sulfonamides. Examples include sulfonylurea (such as gliclazide and glibenclamide) or acetazolamide and thiazide diuretics (water tablets). You might be allergic to ILVITRIM SUSPENSION as well.

Children

Do not give ILVITRIM SUSPENSION to premature or new-born infants during the first 6 weeks of life.

Other medicines and ILVITRIM SUSPENSION

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

ILVITRIM SUSPENSION can change the results of some laboratory tests.

In particular tell your child's doctor or pharmacist if you or your child are taking any of the following medicines:

- Zidovudine used in the treatment of HIV, as it can increase your risk of developing less blood cells.
- Ciclosporin, used after organ transplant surgeries
- Rifampicin (an antibiotic)
- Pyrimethamine, used to treat and prevent malaria, and to treat diarrhoea, as you can develop side effects, e.g. anaemia
- If you/your child is taking any of the following, as the effect of these medicines can become

stronger, and your doctor might monitor you more closely:

- Blood thinners such as warfarin.
- Phenytoin, used to treat epilepsy (fits)
- Methotrexate, a medicine used to treat certain cancers or certain diseases affecting the immune system
- Medicines to treat problems with the way the heart beats such as digoxin or procainamide
- Medicines used to treat diabetes, such as glibenclamide, glipizide or tolbutamide (sulphonylureas) and repaglinide.
- Lamivudine used in the treatment of HIV (Human Immunodeficiency Virus), as ILVITRIM SUSPENSION at high dosages can increase the effect of lamivudine.
- Medicines that can increase the amount of potassium in the blood, such as diuretics (water tablets, which help increase the amount of urine produced, such as spironolactone), steroids (like prednisolone) and digoxin or ACE inhibitors (may be used to treat high blood pressure or some heart problems). These medicines can increase the amount of potassium to dangerously high levels in your blood.
- Folinic acid, a supplement can lower the effect of ILVITRIM SUSPENSION
- Contraceptives can become less effective when taking with ILVITRIM SUSPENSION. You should use additional protection while on ILVITRIM SUSPENSION treatment.
- Azathioprine may be 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.
- Amantadine, used to treat Parkinson's disease, multiple sclerosis, flu or shingles.

ILVITRIM SUSPENSION with food and drink

Your child should take ILVITRIM SUSPENSION with some food or drink.

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

Driving and using machines

It is not always possible to predict to what extent ILVITRIM SUSPENSION may interfere with your/your child's 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 ILVITRIM SUSPENSION affects you/your child.

ILVITRIM SUSPENSION contains nipastat

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

ILVITRIM SUSPENSION contains alcohol

ILVITRIM SUSPENSION contains 17,6 mg of alcohol (ethanol) in each 5 mL which is equivalent to 0,352 g/100 mL (0,352 % w/v).

The amount in 5 mL of ILVITRIM SUSPENSION is equivalent to less than 1,8 mL beer or 0,7 mL wine.

The small amount of alcohol in ILVITRIM SUSPENSION will not have any noticeable effects.

ILVITRIM SUSPENSION contains sucrose

ILVITRIM SUSPENSION contains 2 500 mg of sucrose per 5 mL. This should be taken into account in if you/your child has diabetes mellitus.

ILVITRIM SUSPENSION contains sodium saccharin (sweetener)

ILVITRIM SUSPENSION contains less than 1 mmol sodium saccharin (sweetener) (23 mg) per 5 mL, that

is to say essentially 'sodium-free'.

3. How to take or give ILVITRIM SUSPENSION

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

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

The usual dose is:

Infants:

6 weeks to 5 months: Half a medicine measure (2,5 mL) every 12 hours.

Children:

6 months to 5 years: One medicine measure (5 mL) every 12 hours.

6 years to 12 years: Two medicine measures (10 mL) every 12 hours.

Duration of administration

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

Method of administration

- ILVITRIM SUSPENSION is for oral use.
- ILVITRIM SUSPENSION must be given/taken by mouth, after food.
- Shake the bottle well before use.

If you take/give more ILVITRIM SUSPENSION than you should

When more ILVITRIM SUSPENSION is taken/given than you/they should, you/your child may feel

nausea, vomit, dizzy and confused.

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

If you forget to take/give ILVITRIM 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 forgotten individual doses.

4. Possible side effects

ILVITRIM SUSPENSION can have side effects.

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

If any of the following happens, stop taking/giving ILVITRIM 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
- a type of allergic reaction to a medicine causing skin lesions (fixed drug eruption)
- severe blistering of the skin. These serious skin reactions include toxic epidermal necrolysis (Lyell's syndrome), Steven-Johnson syndrome (SJS), systemic lupus erythematosus to name a few (see also section 2)
- unexpected worsening of cough and shortness of breath
- increase in liver enzymes (blood tests) and 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 meningitis aseptic.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- a fungal infection called thrush or candidiasis which can affect your child's mouth or vagina
- high levels of potassium in your blood, which can cause abnormal heart beats (palpitations)
- headache
- feeling sick (nausea)
- diarrhoea
- skin rashes.

Less frequent side effects:

- pseudomembranous colitis (infection of the colon resulting in watery and sometimes bloody stools)
- changes in the blood cells, resulting in feeling weak, tired or listless, pale skin, and more frequent infections
- cyanosis (bluish or greyish colour of the skin, nails, lips or around the eyes)
- hypothyroidism 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.
- low blood sugar
- low sodium concentration in your blood
- decreased appetite

- build-up of acid in your body (metabolic acidosis)
- depression
- seeing strange or unusual sights (hallucination)
- fits (convulsions or seizures)
- tingling or numbness in your hands and feet
- loss of balance and coordination (ataxia)
- dizziness
- feeling tired
- difficulty to sleep
- 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
- inflammation of blood vessels
- vomiting
- swollen and inflamed tongue
- inflammation of the pancreas with severe upper stomach pain, often with nausea and vomiting (pancreatitis)
- the appearance of a rash or sunburn when your child has been outside (even on a cloudy day)
- arthralgia (pains in the joints)
- myalgia (pains in the muscles)
- problems with your urine, difficulty passing urine, passing more or less urine than usual
- blood or cloudiness in your urine
- kidney problems
- muscle pain and/or muscle weakness in HIV patients
- problems controlling movements.

Side effects with frequency unknown:

- psychotic disorder (a mental state in which you may lose touch with reality)(changes in behaviour)
- plum coloured, raised, painful sores on the limbs and sometimes on the face and neck with a fever (Sweets syndrome)
- drug reaction with eosinophilia and systemic symptoms (an allergic type of reaction 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).

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 or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ILVITRIM SUSPENSION.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@shanur.co.za.

5. How to store ILVITRIM SUSPENSION

Store all medicines out of reach of children.

Store in a cool place, at or below 25 °C.

Protect from heat and light.

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 ILVITRIM SUSPENSION contains

- The active substance is trimethoprim and sulphamethoxazole.
- The other ingredients are sodium carboxymethylcellulose, polysorbate 80, sodium citrate, sucrose, sodium saccharin, nipastat (a mixture of methyl, ethyl, propyl and butyl esters of p-hydroxybenzoic acid), ethanol 96 % v/v, aluminium magnesium silicate, aniseed oil and potable water.

ILVITRIM SUSPENSION 40 mg/200 mg per 5 mL suspension

Each 5 ml of suspension contains: trimethoprim 40 mg and sulphamethoxazole 200 mg.

Each 5 mL contains 0,3 % *m/v* nipastat (preservative).

Each 5 mL contains 0,44 % *v/v* ethanol 96 %.

Each 5 mL contains: sucrose 2 500 mg/5 mL.

Each 5 mL contains sweetener: sodium saccharin 20 mg/5 mL.

What ILVITRIM SUSPENSION looks like and contents of the pack

ILVITRIM SUSPENSION 40 mg/200 mg per 5 mL suspension

A white opaque viscous suspension.

ILVITRIM SUSPENSION is packed in one is supplied in either one of the following:

50 mL: white or amber PVC bottles, amber glass bottles or white HDPE bottles

100 mL: white or amber PVC bottles, amber glass bottles or white HDPE bottles

500 mL: white or amber PVC bottles.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Shanur Healthcare (Pty) Ltd, 28/20.2/0417, Ilvitrim suspension, Trimethoprim 40 mg; Sulphamethoxazole 200 mg / 5 mL, suspension

Shanur Healthcare (Pty) Ltd

Loch House Unit 3

3A Eton Road

Parktown

Johannesburg, 2193

Tel: +27 87 405 9660

This leaflet was last revised in

13 February 2026

Registration number

ILVITRIM SUSPENSION 40 mg/200 mg per 5 mL suspension: 28/20.2/0417

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL: <https://shanur.co.za/product-info/>

Shanur Healthcare (Pty) Ltd

Tel: +27 87 405 9660