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

Approved Professional Information for Medicines for Human Use:

ILVITRIM SUSPENSION

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

ILVITRIM SUSPENSION 40 mg/200 mg per 5 mL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ILVITRIM SUSPENSION 40 mg/200 mg per 5 mL

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 sugar: sucrose 2 500 mg/5 mL.

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A white opaque viscous suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Infections caused by sensitive organisms of the upper and lower respiratory tract, the urinary tract and the alimentary and genital tract in both sexes, and skin infections.

4.2 Posology and method of administration

Posology

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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 measure (10 mL) every 12 hours.

In the treatment of acute infections ILVITRIM SUSPENSION should be administered for at least 5 days or for at least 2 days after the symptoms have disappeared. If clinical improvement is not evident after 7 days therapy, the patient should be reassessed.

Special populations

Renal impairment

If ILVITRIM SUSPENSION is indicated for patients with renal impairment, the following dosage scheme, based on creatinine clearance is suggested:

Above 25 mL/min: Standard dosage

15 - 25 mL/min: Standard dosage for a maximum of 3 days followed by half the standard daily dosage.

Below 15 mL/min: Not to be administered unless haemodialysis facilities are available when half the standard daily dosage may be given.

Measurements of plasma concentrations of sulfamethoxazole at intervals of 2 days are recommended in samples obtained 12 hours after administration of ILVITRIM SUSPENSION. If the concentration of total sulfamethoxazole exceeds 150 ug/mL then treatment should be interrupted until the value falls below 120 ug/mL.

No Information is available for children with renal failure.

Method of administration

ILVITRIM SUSPENSION is for oral administration.

ILVITRIM SUSPENSION must be taken by mouth, after food.

Shake bottle well before use.

4.3 Contraindications

- Hypersensitivity to sulphamethoxazole, sulphonamide or trimethoprim or to any of the excipients listed in section 6.1.
- Patients suffering from porphyria.
- Liver parenchymal damage.
- Megaloblastic anaemia due to vitamin B_{12} and folic acid deficiency or blood dyscrasia.
- Patients receiving anticonvulsant medicines.
- Severe renal insufficiency.
- ILVITRIM SUSPENSION should not be used during pregnancy, in women prior to delivery or by breastfeeding woman.
- In premature or new-born infants during the first 6 weeks of life.

4.4 Special warnings and precautions for use

Life-threatening adverse reactions

- Erythema multiforme, toxic dermal necrolysis or allergic vasculitis may occur. Treatment should be discontinued immediately when a rash appears because of the danger of severe allergic reactions.
- Fatalities, although very rare, have occurred due to severe reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anaemia, other blood dyscrasias and hypersensitivity of the respiratory tract.
- Life-threatening cutaneous reactions Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported.
- Patients should be advised of the signs and symptoms and monitored closely for skin reactions.

The highest risk for occurrence of SJS or TEN is within the first weeks of treatment.

- If symptoms or signs of SJS, TEN (e.g. progressive skin rash often with blisters or mucosal lesions) or DRESS (e.g. fever, eosinophilia) are present, treatment should be discontinued (see section 4.8).
- The best results in managing SJS, TEN and DRESS come from early diagnosis and immediate discontinuation of any suspect medicine. Early withdrawal is associated with a better prognosis.
- If the patient has developed SJS, TEN and DRESS with the use of this medicine, treatment with this medicine must not be re-started in this patient at any time.
- At the start of treatment, the occurrence of a generalised febrile erythema associated with pustules, should raise the suspicion of acute generalised exanthematous pustulosis (AGEP) (see section 4.8); it requires cessation of treatment and contraindicates any new administration of ILVITRIM SUSPENSION alone or in combination with other medicines.
- Direct exposure to sunlight should be avoided as it facilitates development of sensitisation dermatitis.

Haemophagocytic lymphohistiocytosis (HLH)

Cases of HLH have been reported very rarely in patients treated with this medicine. HLH is a life-threatening syndrome of pathologic immune activation characterised by clinical signs and symptoms of an excessive systemic inflammation (e.g. fever, hepatosplenomegaly, hypertriglyceridaemia, hypofibrinogenaemia, high serum ferritin, cytopenias and haemophagocytosis). Patients who develop early manifestations of pathologic immune activation should be evaluated immediately. If diagnosis of HLH is established, treatment should be discontinued.

Respiratory toxicity

Very rare, severe cases of respiratory toxicity, sometimes progressing to Acute Respiratory Distress Syndrome (ARDS) have been reported during treatment. The onset of pulmonary signs such as cough, fever, and dyspnoea in association with radiological signs of pulmonary infiltrates, and deterioration in

pulmonary function may be preliminary signs of ARDS. In such circumstances, ILVITRIM should be discontinued, and appropriate treatment given.

Elderly patients

Particular care is always advisable when treating older patients because, as a group, they are more susceptible to adverse reactions and more likely to suffer serious effects as a result particularly when complicating conditions exist, e.g. impaired kidney and/or liver function and/or concomitant use of other medicines.

Renal impairment

ILVITRIM SUSPENSION should be used cautiously and in reduced dosage in patients with impaired renal function (see section 4.2).

Because of the risk of crystalluria, an adequate fluid intake should be maintained, and the administration of alkalis may be necessary if very large doses are used.

Urinary output

An adequate urinary output should be maintained at all times. Evidence of crystalluria *in vivo* is rare, although sulphonamide crystals have been noted in cooled urine from treated patients. In patients suffering from malnutrition the risk may be increased.

Folate

Regular monthly blood counts are advisable when ILVITRIM SUSPENSION is given for long periods, or to folate deficient patients or to older patients, since there exists a possibility of asymptomatic changes in haematological laboratory indices due to lack of available folate. Supplementation with folinic acid may be considered during treatment but this should be initiated with caution due to possible interference with antimicrobial efficacy (see section 4.5).

Patients with glucose-6-phosphate dehydrogenase deficiency

In glucose-6-phosphate dehydrogenase (G-6-PD) deficient patients, haemolysis may occur.

Patients with severe atopy or bronchial asthma

ILVITRIM SUSPENSION should be used with caution in patients with severe atopy or bronchial asthma.

Treatment of streptococcal pharyngitis due to Group A beta-haemolytic streptococci

ILVITRIM SUSPENSION should not be used in the treatment of streptococcal pharyngitis due to Group A beta-haemolytic streptococci; eradication of these organisms from the oropharynx is less effective than with penicillin.

Phenylalanine metabolism

Trimethoprim has been noted to impair phenylalanine metabolism, but this is of no significance in phenylketonuric patients on appropriate dietary restriction.

Patients with or at risk of porphyria

The administration of ILVITRIM SUSPENSION to patients known or suspected to be at risk of porphyria should be avoided (see section 4.3). Both trimethoprim and sulphonamides (although not specifically sulfamethoxazole) have been associated with clinical exacerbation of porphyria.

Patients with hyperkalaemia and hyponatraemia

Close monitoring of serum potassium and sodium is warranted in patients at risk of hyperkalaemia and hyponatraemia.

Metabolic acidosis

Treatment has been associated with metabolic acidosis when other possible underlying causes have

been excluded. Close monitoring is always advisable when metabolic acidosis is suspected.

Patients with serious haematological disorders

Except under careful supervision ILVITRIM SUSPENSION should not be given to patients with serious haematological disorders (see section 4.8). ILVITRIM SUSPENSION has been given to patients receiving cytotoxic therapy with little or no additional effect on the bone marrow or peripheral blood. The combination of antibiotics in ILVITRIM SUSPENSION should only be used where, in the judgement of the health care provider, the benefits of treatment outweigh any possible risks; consideration should be given to the use of a single effective antibacterial agent.

Immunocompromised patients

A high incidence of side-effects occurs in immunocompromised patients such as those suffering from AIDS or patients receiving immunosuppressive therapy. The adverse effects include skin rash, recurrent fever, neutropenia, thrombocytopenia and raised liver enzyme values.

Cross-sensitivity

Cross-sensitivity has been observed between sulfamethoxazole as in ILVITRIM SUSPENSION and chemically related compounds such as some diuretics, particularly acetazolamide and thiazides, and the sulfonylurea hypoglycaemic medicines.

Excipient sucrose

This medicine contains sucrose: patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. The sucrose content of 2 500 mg per 5 mL should be taken into account in patients with diabetes mellitus.

Excipient sodium saccharin (sweetener)

This medicine contains less than 1 mmol sodium saccharin (sweetener) (23 mg) per 5 mL, that is to say essentially 'sodium-free'.

Excipient ethanol

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.

Excipient nipastat

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

4.5 Interaction with other medicines and other forms of interaction

Interaction with laboratory tests: Trimethoprim may interfere with the estimation of serum/plasma creatinine when the alkaline picrate reaction is used. This may result in overestimation of serum/plasma creatinine of the order of 10 %. The creatinine clearance is reduced: the renal tubular secretion of creatinine is decreased from 23 % to 9 % whilst the glomerular filtration remains unchanged.

Zidovudine: in some situations, concomitant treatment with zidovudine may increase the risk of haematological adverse reactions to ILVITRIM SUSPENSION. If concomitant treatment is necessary, consideration should be given to monitoring of haematological parameters.

Ciclosporin: reversible deterioration in renal function has been observed in patients treated with ILVITRIM SUSPENSION and cyclosporin following renal transplantation.

Rifampicin: concurrent use of rifampicin and ILVITRIM SUSPENSION results in a shortening of the plasma half-life of trimethoprim after a period of about one week. This is not thought to be of clinical significance.

When trimethoprim is administered simultaneously with medicines that form cations at physiological pH and are also partly excreted by active renal secretion (e.g. procainamide, amantadine), there is the possibility of competitive inhibition of this process which may lead to an increase in plasma concentration of one or both of the medicines.

Diuretics (thiazides): in older patients concurrently receiving diuretics, mainly thiazides, there appears to be an increased risk of thrombocytopenia with or without purpura.

Pyrimethamine: occasional reports suggest that patients receiving pyrimethamine at doses in excess of 25 mg weekly may develop megaloblastic anaemia should ILVITRIM SUSPENSION be prescribed concurrently.

Warfarin: ILVITRIM SUSPENSION has been shown to potentiate the anticoagulant activity of warfarin via stereo-selective inhibition of its metabolism. Sulfamethoxazole may displace warfarin from plasma-albumin protein-binding sites *in vitro*. Careful control of the anticoagulant therapy during treatment with ILVITRIM SUSPENSION is advisable.

Phenytoin: ILVITRIM SUSPENSION prolongs the half-life of phenytoin and if co-administered could result in excessive phenytoin effect. Close monitoring of the patient's condition and serum phenytoin levels are advisable.

Digoxin: concomitant use of trimethoprim with digoxin has been shown to increase plasma digoxin levels in a proportion of older patients.

Methotrexate: ILVITRIM SUSPENSION may increase the free plasma levels of methotrexate. If ILVITRIM SUSPENSION is considered appropriate therapy in patients receiving other anti-folate medicines such as methotrexate, a folate supplement should be considered (see section 4.4). Trimethoprim interferes with assays for serum methotrexate when dihydrofolate reductase from *Lactobacillus casei* is used in the assay. No interference occurs if methotrexate is measured by radioimmuno assay.

Lamivudine: administration of trimethoprim/sulfamethoxazole 160 mg/800 mg (ILVITRIM SUSPENSION) causes a 40 % increase in lamivudine exposure because of the trimethoprim component. Lamivudine has no effect on the pharmacokinetics of trimethoprim or sulfamethoxazole.

Interaction with sulphonylurea hypoglycaemic agents is uncommon but potentiation has been reported.

Repaglinide: trimethoprim may increase the exposure of repaglinide which may result in hypoglycaemia.

Hyperkalaemia: caution should be exercised in patients taking any other medicines that can cause hyperkalaemia, for example ACE inhibitors, angiotensin receptor blockers and potassium-sparing diuretics such as spironolactone. Concomitant use of trimethoprim-sulfamethoxazole (ILVITRIM SUSPENSION) may result in clinically relevant hyperkalaemia.

Folinic acid: folinic acid supplementation has been shown to interfere with the antimicrobial efficacy of trimethoprim-sulfamethoxazole. This has been observed in *Pneumocystis jirovecii pneumonia* prophylaxis and treatment.

Contraceptives: oral contraceptive failures have been reported with antibiotics. The mechanism of this

effect has not been elucidated. Women on treatment with antibiotics should temporarily use a barrier method in addition to the oral contraceptive or choose another method of contraception.

Azathioprine: There are conflicting clinical reports of interactions between azathioprine and trimethoprim-sulfamethoxazole, resulting in serious haematological abnormalities.

4.6 Fertility, pregnancy and lactation

Pregnancy

Trimethoprim and sulfamethoxazole as in ILVITRIM SUSPENSION cross the placenta and their safety in pregnant women has not been established. ILVITRIM SUSPENSION should not be used during pregnancy (see section 4.3).

Breastfeeding

The components of ILVITRIM SUSPENSION (trimethoprim and sulfamethoxazole) are excreted in breast milk. Administration of ILVITRIM SUSPENSION should be avoided in late pregnancy and in breastfeeding mothers where the mother or infant has, or is at particular risk of developing, hyperbilirubinemia. ILVITRIM SUSPENSION should not be given to the new-born infant during the first weeks of life (see section 4.3)

Fertility

There is no fertility data available.

4.7 Effects on ability to drive and use machines

It is not always possible to predict to what extent ILVITRIM SUSPENSION may interfere with the daily activities of a patient. ILVITRIM SUSPENSION can cause hallucinations, headache, dizziness and vertigo (see section 4.8). Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ILVITRIM SUSPENSION affects them.

4.8 Undesirable effects

a) Tabulated list of adverse reactions

System Organ Class	**Frequency**		
	Frequent	**Less Frequent**	**Not known**
Infections and infestations	Overgrowth fungal	Pseudomembranous colitis	
Blood and lymphatic system disorders		Leukopenia, neutropenia, thrombocytopenia, agranulocytosis, anaemia megaloblastic, aplasticanaemia, haemolytic anaemia, methaemoglobinaemia (with cyanosis) or sulphaemoglobinaemia, eosinophilia, purpura, haemolysis in certain susceptible G-6-PD deficient patients	
Immune system disorders		Serum sickness, anaphylactic reaction, allergic myocarditis, hypersensitivity vasculitis resembling Henoch-Schoenlein purpura, periarteritis nodosa, systemic lupus erythematosus.	

		Severe hypersensitivity reactions associated with PJP*, rash, pyrexia, neutropenia, thrombocytopenia, hepatic enzyme increased, hyperkalaemia, hyponatraemia, rhabdomyolysis	
Endocrine disorders		hypothyroidism	
Metabolism and nutrition disorders	Hyperkalaemia	Hypoglycaemia, hyponatraemia, decreased appetite, metabolic acidosis	
Psychiatric disorders		Depression, hallucinations	Psychotic disorder
Nervous system disorders	Headache	Meningitis aseptic*, seizure, neuropathy peripheral, ataxia, dizziness, drug fever, fatigue, insomnia, nightmares, confusion	
Eye disorders		Optic neuropathy, transient myopia, uveitis	
Ear and labyrinth disorders		Vertigo, tinnitus	
Vascular disorders		Polyarteritis nodosa	
Respiratory, thoracic and mediastinal		Cough*, dyspnoea*, lung infiltration*, goitre	

disorders			
Gastrointestinal disorders	Nausea, diarrhoea, anorexia	Vomiting, glossitis, stomatitis, pancreatitis	
Hepatobiliary disorders		Jaundice cholestatic *, hepatic necrosis*, transaminases increased, blood bilirubin increased	
Skin and subcutaneous tissue disorders	Rash	Photosensitivity, dermatitis exfoliative, angioedema, fixed drug eruption, erythema multiforme, Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN)*, acute generalised exanthematous pustulosis (AGEP).	Acute febrile neutrophilic dermatosis (Sweet's syndrome), Drug reaction with eosinophilia and systemic symptoms (DRESS)*
Musculoskeletal and connective tissue disorders		Arthralgia, myalgia	
Renal and urinary disorders		Renal impairment (sometimes reported as renal failure), tubulointerstitial nephritis and uveitis syndrome, renal tubular acidosis.	

* See description of selected adverse reactions

b) Description of selected adverse reactions

Aseptic meningitis

Aseptic meningitis was rapidly reversible on withdrawal of the medicine but recurred in a number of cases on re-exposure to either co-trimoxazole or to trimethoprim alone.

Pulmonary hypersensitivity reactions

Cough, dyspnoea and lung infiltration may be early indicators of respiratory hypersensitivity which, while very rare, has been fatal.

Hepatobiliary disorders

Jaundice cholestatic and hepatic necrosis may be fatal.

Severe cutaneous adverse reactions (SCARs)

Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported to be life-threatening (see section 4.4).

As with any other medicine, allergic reactions such as an itchy rash and hives may occur in patients with hypersensitivity to the components of the medicine. Very rare cases of acute generalised exanthematous pustulosis (AGEP) have been observed (see section 4.4).

Effects associated with Pneumocystis jirovecii Pneumonitis (PJP) management

Severe hypersensitivity reactions, rash, pyrexia, neutropenia, thrombocytopenia, hepatic enzyme increased, hyperkalaemia, hyponatraemia and rhabdomyolysis.

At the high dosages used for PJP management severe hypersensitivity reactions have been reported, necessitating cessation of therapy. Severe hypersensitivity reactions have been reported in PJP patients on re-exposure to co-trimoxazole, sometimes after a dosage interval of a few days.

Rhabdomyolysis has been reported in HIV positive patients receiving co-trimoxazole for prophylaxis or treatment of PJP.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Suspected adverse reactions can also be reported directly to the HCR via medsafety@shanur.co.za.

4.9 Overdose

Signs and symptoms

Nausea, vomiting, dizziness, confusion, cyanosis, haematuria, oliguria or anuria and allergic skin reactions (skin rashes, anaphylaxis, etc.).

Bone marrow depression has been reported in acute trimethoprim overdosage.

Treatment

Treatment is supportive and symptomatic.

If vomiting has not occurred, induction of vomiting may be desirable.

Dependant on the status of renal function administration of fluids is recommended if urine output is low.

Both trimethoprim and active sulfamethoxazole are moderately dialysable by haemodialysis. Peritoneal dialysis is not effective.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A: 20.2 Antimicrobial (chemotherapeutic) agents other than antibiotics.

Pharmacotherapeutic group: Antibacterials for systemic use – Sulfonamides and trimethoprim, incl. derivatives

ATC code: J01EE01

Mechanism of action

ILVITRIM SUSPENSION is a combination of trimethoprim and sulphamethoxazole resulting in a synergistic effect causing a bactericidal action (in vitro). The action of co-trimoxazole is achieved by the sequential blocking of two enzymes essential in folinic acid synthesis in the organism.

5.2 Pharmacokinetic properties

Absorption

After oral administration trimethoprim and sulfamethoxazole are rapidly and nearly completely absorbed. The presence of food does not appear to delay absorption. Peak levels in the blood occur between one and four hours after ingestion and the level attained is dose related. Effective levels persist in the blood for up to 24 hours after a therapeutic dose. Steady state levels in adults are reached after dosing for 2 to 3 days. Neither component has an appreciable effect on the concentrations achieved in the blood by the other.

Distribution

Approximately 50 % of trimethoprim in the plasma is protein bound. Tissue levels of trimethoprim are generally higher than corresponding plasma levels, the lungs and kidneys showing especially high concentrations. Trimethoprim concentrations exceed those in plasma in the case of bile, prostatic fluid and tissue, saliva, sputum and vaginal secretions. Levels in the aqueous humour, breast milk, cerebrospinal fluid, middle ear fluid, synovial fluid and tissue (intestinal) fluid are adequate for antibacterial activity. Trimethoprim passes into amniotic fluid and foetal tissues reaching concentrations approximating those of maternal serum.

Approximately 66 % of sulfamethoxazole in the plasma is protein bound.

The concentration of active sulfamethoxazole in amniotic fluid, aqueous humour, bile, cerebrospinal fluid, middle ear fluid, sputum, synovial fluid and tissue (interstitial) fluids is of the order of 20 – 50 % of the plasma concentration.

Biotransformation

Renal excretion of intact sulfamethoxazole accounts for 15 – 30 % of the dose. This medicine is more extensively metabolised than trimethoprim, via acetylation, oxidation or glucuronidation. Over a 72-hour period, approximately 85 % of the dose can be accounted for in the urine as unchanged medicine plus

the major (N4-acetylated) metabolite.

Elimination

The half-life of trimethoprim in man is in the range 8,6 – 17 hours in the presence of normal renal function. It is increased by a factor of 1,5 to 3,0 when the creatinine clearance is less than 10 mL/minute. There appears to be no significant difference in older patients compared with young patients.

The principal route of excretion of trimethoprim is renal and approximately 50 % of the dose is excreted in the urine within 24 hours as unchanged medicine. Several metabolites have been identified in the urine. Urinary concentrations of trimethoprim vary widely.

The half-life of sulfamethoxazole in man is approximately 9 to 11 hours in the presence of normal renal function. There is no change in the half-life of active sulfamethoxazole with a reduction in renal function but there is prolongation of the half-life of the major, acetylated metabolite when the creatinine clearance is below 25 mL/minute.

The principal route of excretion of sulfamethoxazole is renal; between 15 % and 30 % of the dose recovered in the urine is in the active form. In older patients there is a reduced renal clearance of sulfamethoxazole.

Paediatric population

The pharmacokinetics in the paediatric population with normal renal function of both components of Co-Trimoxazole, MP and SMZ are age dependent. Elimination of TMP-SMZ is reduced in neonates, during the first two months of life, thereafter both TMP and SMZ show a higher elimination with a higher body clearance and a shorter elimination half-life. The differences are most prominent in young infants (> 1,7 months up to 24 months) and decrease with increasing age, as compared to young children (1 year up

to 3,6 years), children (7,5 years and < 10 years).

Elderly patients

In elderly patients, a slight reduction in renal clearance of sulfamethoxazole but not trimethoprim has been observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

Potable water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store in a cool place, at or below 25 °C. Protect from heat and light.

6.5 Nature and contents of container

ILVITRIM SUSPENSION 40 mg/200 mg per 5 mL suspension:

Packed 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.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 April 1994

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

10. DATE OF REVISION OF THE TEXT

13 February 2026