PROFESSIONAL INFORMATION

SCHEDULING STATUS:

S4

1. NAME OF THE MEDICINE

CEROXIM 250 Tablets

CEROXIM 500 Tablets

CEROXIM Suspension

CEROXIM Forte Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

CEROXIM 250 Tablets

Each tablet contains:

Cefuroxime axetil equivalent to cefuroxime 250 mg

Sugar free

CEROXIM 500 Tablets

Each tablet contains:

Cefuroxime axetil equivalent to cefuroxime 500 mg

Sugar free

CEROXIM Suspension

Each 5 ml of constituted suspension contains:

Cefuroxime axetil equivalent to cefuroxime 125 mg

Contains sugar: Sucrose 2,8 g and mannitol 1 g.

Contains sweetener: Aspartame 8 mg

Preservative: Sodium benzoate *0,2 % m/v*

CEROXIM Forte Suspension

Each 5 ml of constituted suspension contains:

Cefuroxime axetil equivalent to cefuroxime 250 mg

Contains sugar: Sucrose 2,5 g and mannitol 1 g.

Contains sweetener: Aspartame 8 mg

Preservative: Sodium benzoate *0,2 % m/v*

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

CEROXIM 250 Tablets: White to off white film coated modified capsule shaped tablets debossed with '250' on one side and plain on other.

CEROXIM 500 Tablets: White to off white film coated modified capsule shaped tablets debossed with '500' on one side and plain on other.

CEROXIM Suspension and CEROXIM Forte Suspension: White to cream-colored granular powder forming white to cream coloured suspension on constitution with water. The resulting suspension has a sweet taste and fruity flavor.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CEROXIM is indicated for the treatment of infections caused by susceptible organisms in the following infections:

- Pharyngitis and tonsillitis caused by *Streptococcus pyogenes*. Penicillin is the usual medicine of choice in the treatment and prevention of streptococcal infections including the prophylaxis of rheumatic fever. CEROXIM is generally effective in the eradication of streptococci from the oral pharynx. CEROXIM is not indicated for the prophylaxis of subsequent rheumatic fever due to insufficient data available to support such use.
- Otitis media caused by *Streptococcus pneumoniae, Haemophilus influenzae* (methicillin-sensitive strains)*, Moraxella (Branhamella) catarrhalis, and Streptococcus pyogenes*.

- Sinusitis caused by *Streptococcus pneumoniae* and *Haemophilus influenzae*.
- Bronchitis caused by *Streptococcus pneumoniae*, *Haemophilus influenzae* (methicillin-sensitive strains) and *Haemophilus parainfluenzae* (ampicillin-sensitive strains).
- Acute uncomplicated cystitis caused by *Escherichia coli* and *Klebsiella pneumoniae*.

Lyme disease caused by *Borrelia burgdorferi.* CEROXIM is indicated for the treatment of early Lyme disease and subsequent prevention of late Lyme disease in adults and children over the age of 12 years.

4.2 Posology and method of administration

Posology

Adults

Pharyngitis and tonsillitis: 250 mg twice daily for seven days (range 5-10 days).

Otitis media: 500 mg twice daily for seven days (range 5-10 days).

Sinusitis and bronchitis: 250 mg twice daily for seven days (range 5-10 days).

Acute, uncomplicated cystitis: 250 mg twice daily for seven days (range 5-10 days).

Lyme disease: Adults and children over 12 years of age: 500 mg twice daily for 14 days (range 10-21 days).

Children

Usual dose: 125 mg twice daily for 7 days (range 5-10 days).

There is no experience with CEROXIM in children under 3 months of age.

Pharyngitis and tonsillitis: 10 mg/kg twice daily to a maximum of 125 mg twice daily for seven days (range 5-10 days).

For otitis media in children 3 months to 2 years of age the usual dose is: 10 mg/kg twice daily to a maximum of 125 mg twice daily (range 5-10 days).

For otitis media in children over 2 years of age the usual dose is: 15 mg/kg twice daily to a maximum of 250 mg twice daily for seven days (range 5-10 days).

Sinusitis and bronchitis: 10 mg/kg twice daily to a maximum of 125 mg twice daily for seven days (range 5-10 days).

Acute, uncomplicated cystitis: 15 mg/kg twice daily to a maximum of 250 mg twice daily for seven days (range 5-10 days).

Directions for use of the CEROXIM and CEROXIM Forte Suspensions:

1. Shake the bottle to loosen the granules and remove the cap.

Use the measure cup to add water to the bottle (23 or 22 mL water for the 50 mL pack of CEROXIM Suspension or CEROXIM Forte Suspension respectively; and 44 or 43 ml water for the 100 mL pack of CEROXIM Suspension or CEROXIM Forte Suspension respectively) and replace the cap.

Directions for use of the CEROXIM and CEROXIM Forte Suspensions:

1. Shake the bottle to loosen the granules and remove the cap.
2. Use the measure cup to add water to the bottle (23 or 22 mL water for the 50 mL pack of CEROXIM Suspension or CEROXIM Forte Suspension respectively; and 44 or 43 mL water for the 100 mL pack of CEROXIM Suspension or CEROXIM Forte Suspension respectively) and replace the cap.
3. Invert and shake the bottle vigorously until the sound of granules in the bottle disappear.
4. Turn the bottle into an upright position and shake vigorously.
5. Patient Instructions:

   SHAKE THE BOTTLE BEFORE USE.

Method of administration

Oral use.

Because of the bitter taste of cefuroxime axetil, tablets should not be crushed. CEROXIM should be taken half an hour after food for optimum absorption.

4.3 Contraindications

- Hypersensitivity to cephalosporin antibiotics, cefuroxime or to any of excipients listed in section 6.1.
- Hypersensitivity to penicillin and other beta-lactam antibiotics.
- Pregnancy and breastfeeding (see section 4.6)

4.4 Special warnings and precautions for use

CEROXIM should be used with caution in patients with:

- a history of gastro-intestinal disease, especially ulcerative colitis, regional enteritis or pseudomembranous colitis.
- renal function impairment a reduced dose may be required.
- porphyria, as safety has not been established.

Hypersensitivity reactions

Special care is indicated in patients who have experienced an allergic reaction to penicillins or other beta-lactam antibiotics because there is a risk of cross-sensitivity. As with all beta-lactam antibacterial medicines, serious and occasionally fatal hypersensitivity reactions have been reported. In case of severe hypersensitivity reactions, treatment with cefuroxime must be discontinued immediately and adequate emergency measures must be initiated.

Before beginning treatment, it should be established whether the patient has a history of severe hypersensitivity reactions to cefuroxime, to other cephalosporins or to any other type of beta-lactam medicine. Caution should be used if cefuroxime is given to patients with a history of non-severe hypersensitivity to other beta-lactam medicines.

Jarisch-Herxheimer reaction

The Jarisch-Herxheimer reaction has been seen following cefuroxime axetil treatment of Lyme disease. It results directly from the bactericidal activity of cefuroxime axetil on the causative bacteria of Lyme disease, the spirochaete Borrelia burgdorferi. Patients should be reassured that this is a common and usually self-limiting consequence of antibiotic treatment of Lyme disease (see section 4.8).

Overgrowth of non-susceptible microorganisms

As with other antibiotics, use of cefuroxime axetil may result in the overgrowth of Candida. Prolonged use may also result in the overgrowth of other non-susceptible microorganisms (e.g. *enterococci* and *Clostridium difficile*), which may require interruption of treatment (see section 4.8).

Antibacterial medicine–associated pseudomembranous colitis have been reported with nearly all antibacterial medicines, including cefuroxime and may range in severity from mild to life threatening. This diagnosis should be considered in patients with diarrhoea during or subsequent to the administration of cefuroxime (see section 4.8).

Discontinuation of therapy with cefuroxime and the administration of specific treatment for *Clostridium difficile* should be considered. Medicines that inhibit peristalsis should not be given (see section 4.8). Pseudomembranous colitis may occur. Patients who develop abdominal or stomach cramps, abdominal tenderness, severe and watery diarrhoea (which may be bloody) and fever should be investigated for this diagnosis. If the diagnosis of pseudomembranous colitis is suspected, CEROXIM should be stopped immediately and appropriate therapy initiated.

Interactions with Laboratory Tests
It is recommended that either glucose oxidase or hexokinase methods be used to determine blood/plasma glucose levels in patients receiving CEROXIM. CEROXIM may give false-negative test results with ferricyanide blood glucose test. CEROXIM does not interfere in the alkaline picrate assay for creatinine. A false-positive Coombs reaction may appear in patients who receive large doses of CEROXIM (see Section 4.8)

Excipients

CEROXIM Suspension contains 2,8 g of sucrose per 5 mL and CEROXIM Forte Suspension contains 2,5 g of sucrose per 5 mL. The sucrose content of CEROXIM should be taken into account when treating diabetic patients. Appropriate advice should be provided. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase isomaltase insufficiency should not take CEROXIM.

CEROXIM suspension and CEROXIM Forte suspensions contain aspartame, which is a source of phenylalanine and should be used with caution in patients with phenylketonuria.
CEROXIM suspension and CEROXIM Forte suspensions contain mannitol which may have a mild laxative effect.

4.5 Interaction with other medicines and other forms of interaction

Concurrent administration of probenecid increases the area under the mean serum concentration time-curve by 50 %. Concomitant use of CEROXIM and furosemide should be avoided when possible, due to enhanced nephrotoxicity. The combined use of cephalosporins and aminoglycosides should be undertaken with caution, due to nephrotoxicity. The efficacy of combined oral contraceptives may be decreased by concomitant use with CEROXIM.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety and efficacy in pregnancy has not been established (see section 4.3).
Studies in animals have shown no harmful effects on pregnancy, embryonal or foetal development, parturition or postnatal development.

Breastfeeding

Safety and efficacy in lactation has not been established (see section 4.3). CEROXIM is excreted in human milk in small quantities. Adverse effects at therapeutic doses are not expected, although a risk of diarrhoea and fungus infection of the mucous membranes cannot be excluded. Breastfeeding might have to be discontinued due to these effects. The possibility of sensitisation should be taken into account.

Fertility

There are no data on the effects of cefuroxime axetil on fertility in humans. Reproductive studies in animals have shown no effects on fertility.

4.7 Effects on ability to drive and use machines

As CEROXIM may cause dizziness, patients should be warned to be cautious when driving or operating machinery.

4.8 Undesirable effects

Tabulated list of adverse reactions

MedDRA System organ class	**Frequency**	**Adverse reactions**
Infections and infestations	*Frequent*	Candida overgrowth, oral thrush, vaginitis.
	Frequency unknown	*Clostridium difficile* overgrowth
Blood and lymphatic system disorders	*Frequent*	Eosinophilia
	Less frequent	Thrombocytopenia, leukopenia (sometimes profound), neutropenia,
	Frequency unknown	haemolytic anaemia
Immune system disorders	*Less frequent*	Hypersensitivity reactions including, cutaneous vasculitis, bronchospasm, drug fever, serum sickness and anaphylaxis, Jarisch-Hexheimer reaction
Nervous system disorders	*Frequency unknown*	convulsions.
	Frequent	Headache, dizziness
Ear and labyrinth disorders	*Less frequent*	Hearing loss in children with meningitis.
Gastrointestinal disorders	*Frequent*	Nausea, diarrhoea, abdominal pain.
	Less frequent	A particular form of enterocolitis (pseudomembranous colitis) (see section 4.4
	Frequency unknown	Vomiting, diarrhoea accompanied by blood in the stools which may be a

		symptom of enterocolitis.
Hepatobiliary disorders	*Frequency unknown*	Transient increases in hepatic enzyme levels, alanine aminotransferase (serum glutamic pyruvic acid transaminase), aspartate aminotransferase (serum glutamic oxaloacetic transaminase), LDH (lactate dehydrogenase) levels, cholestatic jaundice, hepatitis, rise in bilirubin.
Skin and subcutaneous tissue disorders	*Less frequent*	porphyria, skin rashes.
	Frequency unknown	Urticarial, pruritus, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (exanthematic ncerolysis) (see *Immune system disorders*), angioneurotic oedema
Renal and urinary disorders	*Less frequent*	Acute interstitial nephritis, nephrotoxicity when CEROXIM is used in combination with aminoglycosides or furosemide.
Reproductive system and breast disorders	Frequency unknown	Vaginal candidiasis.
Investigations	Frequency unknown	Positive antiglobulin (Coombs') test.

Description of selected adverse reactions

Cephalosporins as a class tend to be absorbed onto the surface of red cells membranes and react with antibodies directed against the medicine to produce a positive Coombs test (which can interfere

with cross-matching of blood) and very rarely haemolytic anaemia. Transient rises in serum liver enzymes have been observed which are usually reversible.

Paediatric population

The safety profile for cefuroxime axetil in children is consistent with the profile in adults.

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. Health care providers are requested 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 Holder of certificate of registration viaemail or telephonically: pharmacovigilance.africasme@sunpharma.com or tel: +27 (0) 12 643 2000

4.9 Overdose

See section 4.8.

Symptoms of overdose

Seizures have been reported.

Overdose can lead to neurological sequelae including encephalopathy, convulsions and coma. Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment (see sections 4.2 and 4.4).

Treatment of overdose

Treatment is symptomatic and supportive. Serum levels of CEROXIM can be reduced by haemodialysis or peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 20.1.1 Broad and medium spectrum antibiotics

Pharmacotherapeutic group: antibacterials for systemic use, second-generation cephalosporins, ATC code: J01DC02

Cefuroxime is a bactericidal second-generation cephalosporin. The antibacterial action of cefuroxime results from inhibition of bacterial cell wall synthesis by binding to essential target proteins in bacterial cytoplasmic membranes. Cefuroxime has bactericidal activity against a wide range of bacterial organisms, including beta-lactamase producing strains.

Mechanism of resistance

Bacterial resistance to cefuroxime may be due to one or more of the following mechanisms:

- hydrolysis by beta-lactamases; including (but not limited to) by extended-spectrum beta-lactamases (ESBLs), and AmpC enzymes that may be induced or stably derepressed in certain aerobic Gram-negative bacteria species;
- reduced affinity of penicillin-binding proteins for cefuroxime;
- outer membrane impermeability, which restricts access of cefuroxime to penicillin binding proteins in Gram-negative bacteria;
- bacterial efflux pumps.

Organisms that have acquired resistance to other injectable cephalosporins are expected to be resistant to cefuroxime.

Depending on the mechanism of resistance, organisms with acquired resistance to penicillins may demonstrate reduced susceptibility or resistance to cefuroxime.

Cefuroxime axetil breakpoints

Minimum inhibitory concentration (MIC) breakpoints established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) are as follows:

Microoganism	**Breakpoints (mg/L)**	
	S	R
Enterobacteriaceae [1, 2]	≤ 8	>8
Staphylococcus spp.	Note[3]	Note[3]

Streptococcus A, B, C and G	Note[4]	Note[4]
Streptococcus pneumoniae	≤ 0,25	> 0,5
Moraxella catarrhalis	≤ 0,125	> 4
Haemophilus influenzae	≤ 0,125	> 1
Non-species related breakpoints[1]	IE[5]	IE[5]

[1] The cephalosporin breakpoints for Enterobacteriaceae will detect all clinically important resistance mechanisms (including ESBL and plasmid mediated AmpC). Some strains that produce beta-lactamases are susceptible or intermediate to 3rd or 4th generation cephalosporins with these breakpoints and should be reported as found, i.e. the presence or absence of an ESBL does not in itself influence the categorization of susceptibility. In many areas, ESBL detection and characterization is recommended or mandatory for infection control purposes.

[2] Uncomplicated UTI (cystitis) only (see section 4.1).

[3] Susceptibility of staphylococci to cephalosporins is inferred from the methicillin susceptibility except for ceftazidme and cefixime and ceftibuten, which do not have breakpoints and should not be used for staphylococcal infections.

[4] The beta-lactam susceptability of beta-haemolytic streptococci groups A, B, C and G is inferred from the penicillin susceptibility.

[5] insufficient evidence that the species in question is a good target for therapy with the drug. An MIC with a comment but without an accompanying S or R-categorization may be reported.

S=susceptible, R=resistant

Microbiological susceptibility:

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is such that the utility of cefuroxime axetil in at least some types of infections is questionable.

Microorganisms for which acquired resistance may be a problem

Gram-positive aerobes:

Streptococcus pneumonia

Gram-negative aerobes:

Citrobacter freundii

Enterobacter aerogenes

Enterobacter cloacae

Escherichia coli

Klebsiella pneumoniae

Proteus mirabilis

Proteus spp. (other than P. vulgaris)

Providencia spp.

Gram-positive anaerobes:

Peptostreptococcus spp.

Propionibacterium spp.

Gram-negative anaerobes:

Fusobacterium spp.

Bacteroides spp.

Inherently resistant microorganisms

Gram-positive aerobes:

Enterococcus faecalis

Enterococcus faecium

Gram-negative aerobes:

Acinetobacter spp.

Campylobacter spp.

Morganella morganii

Proteus vulgaris

Pseudomonas aeruginosa

Serratia marcescens

Gram-negative anaerobes:

Bacteroides fragilis

Others:

Chlamydia spp.

Mycoplasma spp.

Legionella spp.

* All methicillin-resistant *S. aureus* are resistant to cefuroxime.

5.2 Pharmacokinetic properties

Absorption

Cefuroxime axetil is an oral prodrug of cefuroxime. After oral absorption, cefuroxime axetil is hydrolysed in the intestinal mucosa and blood to release cefuroxime into the plasma. Oral absorption is optimal when administered with food.

Following administration of cefuroxime axetil tablets peak serum levels (2,1 mcg/mL for a 125 mg dose, 4.1 mcg/ml for a 250 mg dose, 7,0 mcg/mL for a 500 mg dose and 13,6 mcg/ml for a 1000 mg dose) occur approximately 2 to 3 hours after dosing when taken with food.
The rate of absorption of cefuroxime from the suspension is reduced compared with the tablets, leading to later, lower peak serum levels and reduced systemic bioavailability (4 to 17% less). Cefuroxime axetil oral suspension was not bioequivalent to cefuroxime axetil tablets when tested in healthy adults and therefore is not substitutable on a milligram-per-milligram basis (see section 4.2).
The pharmacokinetics of cefuroxime is linear over the oral dosage range of 125 to 1000 mg. No accumulation of cefuroxime occurred following repeat oral doses of 250 mg to 500 mg.

Distribution

Protein binding is approximately 33 % to 50 % depending on the methodology used. Following a single dose of cefuroxime axetil 500 mg tablet to 12 healthy volunteers, the apparent volume of distribution was 50 L (CV %=28 %). Concentrations of cefuroxime in excess of the minimum inhibitory levels for common pathogens can be achieved in the tonsilla, sinus tissues, bronchial mucosa, bone, pleural fluid, joint fluid, synovial fluid, interstitial fluid, bile, sputum and aqueous humor. Cefuroxime passes the blood- brain barrier when the meninges are inflamed.

Biotransformation

Cefuroxime is not metabolised and is excreted unchanged in the urine by glomerular filtration and tubular secretion.

Elimination

The elimination half-life is between 1 and 1,5 hours after oral dosing. Cefuroxime is excreted by glomerular filtration and tubular secretion. The renal clearance is in the region of 125 to 148 mL/min/1.73 m^2 The elimination half-life is prolonged with renal impairment and in neonates. Serum levels of cefuroxime are reduced by dialysis.

Special patient populations

Gender

No differences in the pharmacokinetics of cefuroxime were observed between males and females.

Hepatic impairment

There are no data available for patients with hepatic impairment. Since cefuroxime is primarily eliminated by the kidney, the presence of hepatic dysfunction is expected to have no effect on the pharmacokinetics of cefuroxime.

Pharmacokinetic/pharmacodynamic relationship

For cephalosporins, the most important pharmacokinetic- pharmacodynamic index correlating with in vivo efficacy has been shown to be the percentage of the dosing interval (% T) that the unbound concentration remains above the minimum inhibitory concentration (MIC) of cefuroxime for individual target species (i.e.
% T>MIC).

Paediatrics

In older infants (aged >3 months) and in children, the pharmacokinetics of cefuroxime are similar to that observed in adults.

There is no clinical trial data available on the use of cefuroxime axetil in children under the age of 3 months.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development. No carcinogenicity studies have been performed; however, there is no evidence to suggest carcinogenic potential. Gamma glutamyl transpeptidase activity in rat urine is inhibited by various cephalosporins, however the level of inhibition is less with cefuroxime. This may have significance in the interference in clinical laboratory tests in humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

CEROXIM TABLETS

Hydrogenated vegetable oil

Colloidal anhydrous silica

Croscarmellose sodium

Microcrystalline cellulose (PH101)

Sodium lauryl sulphate

Compositions of the coating agent (Opadry White OY-S-58910)

Hypromellose 5Cp (E464)

Titanium dioxide (E171)

Macrogol MW 400 (E1521)

Talc (E553b)

Purified water

CEROXIM SUSPENSION AND SUSPENSION FORTE

Aspartame

Flavour peppermint

Flavour tutti frutti

Mannitol

Mono sodium citrate

Silica colloidal hydrated

Sodium benzoate

Sodium chloride

Sucrose

Xanthan gum

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

CEROXIM SUSPENSION AND SUSPENSION FORTE:

36 months

CEROXIM TABLETS:

24 months

6.4 Special precautions for storage

CEROXIM Tablets:

Store at or below 25 °C, protected from moisture.

CEROXIM and CEROXIM Forte Suspension:

The unconstituted suspension is stored at or below 25 °C, protected from moisture.

Keep the container tightly closed.

The constituted suspension is stored in a refrigerator at 2 to 8 °C for 10 days.

Discard the unused portion of reconstituted suspension after 10 days.

6.5 Nature and contents of container

CEROXIM Tablets: Cartons containing PVC/Aclar Blister strips of 10 or 5 x10 tablets.

CEROXIM Suspension and CEROXIM Forte Suspensions are packed in 50 mL and 100 mL HDPE bottle packs, that comprise of natural translucent HDPE bottles with Child resistant closure caps. Each packet also contains a measuring cup with graduated markings. Bottles are labelled and packed in cartons.

7. HOLDER OF CERTIFICATE OF REGISTRATION

RANBAXY PHARMACEUTICALS (PTY) LTD

a Sun Pharma company

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

South Africa

Tel: +27 (0) 12 643 2000

8. REGISTRATION NUMBERS:

CEROXIM 250 Tablets: 34/20.1.1/0349

CEROXIM 500 Tablets: 34/20.1.1/0350

CEROXIM Suspension: 45/20.1.1/0965

CEROXIM Forte Suspension: 42/20.1.1/0966

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

CEROXIM 250/500 Tablets: 25 April 2003

CEROXIM Suspension: 26 November 2015

CEROXIM Forte Suspension: 26 November 2015

10. DATE OF REVISION OF THE TEXT

26 January 2023.

Ceroxim® 250 mg Tablets
Namibia: NS2 Reg.No.: 05/20.1.1/0191

Botswana: S2 Reg.No.: BOT 0801204

Ceroxim® 500 mg Tablets

Namibia: NS2 Reg.No.: 05/20.1.1/0192

Ceroxim® Suspension

Namibia: NS2 Reg.No.: 18/20.1.1/0063

Ceroxim® Forte Suspension

Namibia: NS2 Reg.No.: 18/20.1.1/0064