

Rokiprim® solution for infusion

250 ml contain
800 mg Sulfametrole and
160 mg Trimethoprim

Lidaprim® forte film coated tablets

1 film coated tablet contains
800 mg Sulfametrole and
160 mg Trimethoprim

Properties:

- Broad antimicrobial spectrum^{1,2}
- Excellent tissue penetration¹
- Good efficacy against multiresistant bacteria and opportunistic microbes in immunocompromised patients (Pneumocystis jirovecii, Stenotrophomonas maltophilia, Burkholderia spp)¹

Indications:

- Urinary tract and renal infections
- Gastrointestinal infections: typhus, paratyphus A and B, diarrhoea (only if caused by enterotoxigenic Escherichia coli)
- Treatment of choice (both, primary and secondary) of pneumonia caused by pneumocystis jirovecii (carinii)
- Alternative treatment option for otorhinolaryngologic infections and respiratory tract infections: acute exacerbation of chronic bronchitis, otitis media
- Alternative treatment option for infection of the female and male genital organs including gonorrhoea
- Alternative treatment option for skin infections (with multiresistant staphylococci)

Use:

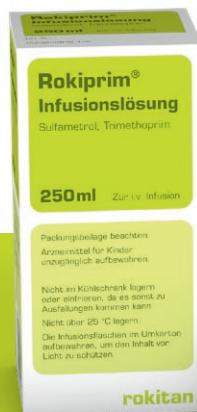
Adults:

Standard dosage: 2 x 250 ml daily
(at intervals of 12 hours)
Intensive therapy for severe infections:
3 x 250 ml daily (at intervals of 8 hours)

Use:

Adults and adolescents over 12 years of age:

Standard dosage: 2 x 1 film coated
tablets daily
Intensive care (severe infections):
2 x 2 film coated tablets daily



¹ Vouloumanou E et al. International Journal of Antimicrobial Agents 2011; 38: 197-216

² Livemore DM et al. J. Antimicrob. Chemother. 2014; 69: 1050-1056

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Rokiprim® solution for infusion

QUALITATIVE AND QUANTITATIVE COMPOSITION:

250 ml contain 800 mg Sulfametrole, 160 mg Trimethoprim.

Excipients: Sodium hydroxide, L-malic acid, Glycerol, water for injection

Therapeutic indications: For therapy of infections caused by organisms sensitive to trimethoprim and sulfonamide and when an intravenous treatment is indicated in adults, adolescents and children older than 8 weeks:

- Urinary tract and renal infections: acute uncomplicated infections of the kidneys and the lower urinary tract, Granuloma venereum
- Gastrointestinal infections: typhus, paratyphus A and B, shigellosis (sensitive stems of shigella flexneri and shigella sonnei when antibacterial therapy is indicated), diarrhoea (only if caused by enterotoxigenic Escherichia coli), Salmonella enteritis accompanied by sepsis in immunocompromised patients
- Alternative treatment option for otorhinolaryngologic infections and respiratory tract infections: acute exacerbation of chronic bronchitis, otitis media (if Sulfametrole 800 mg/Trimethoprim 160 mg solution for infusion is to be preferred for good reasons over a single antibiotic), treatment and prophylaxis (primary and secondary) of pneumonia caused by pneumocystis jirovecii (carinii)
- Alternative treatment option for infection of the female and male genital organs including gonorrhoea
- Alternative treatment option for skin infections (with multiresistant staphylococci).

Consideration should be given to official national and international guidance on the appropriate use of antibacterial agents when using Rokiprim.

Contraindications:

- Hypersensitivity to the active substances, other sulfonamides, TMP-analog (f.i. tetroxoprim) or to any of the mentioned excipients
- Intra-arterial application is contraindicated.
- Severe hepatic and renal impairment (creatinine clearance 15 ml/min), icterus, acute porphyria.
- Disorders of the haematopoietic system (agranulocytosis, aplastic anaemia, megaloblastic anaemia, haemolytic anaemia, thrombocytopenia, leukopenia, methaemoglobinaemia).
- Glucose-6-phosphate dehydrogenase deficiency (symptom: haemolytic anaemia).
- Erythema multiforme major (Stevens-Johnson syndrome), including a history with this disorder
- Concurrent use of dofetilide, erythromycin, halofantrine, pimozide, ziprasidone (see section 4.5).
- Porphyria, lupus erythematosus and predisposition for lupus-like reactions.
- Pregnancy and lactation, neonates during the first 8 weeks of life and premature babies according to date of birth – because of immaturity of the enzymatic system.
- Haemoglobin disorders including Hb-Cologne and Hb-Zurich.

Contraindications based on the pharmaceutical form (infusion): Congestive heart failure, toxic pulmonary and cerebral oedema, oliguria, anuria, hyperhydration, severe disorders of microcirculation.

Pharmacodynamic properties:

Pharmacotherapeutic group: Combinations of sulfonamides and trimethoprim, incl. derivatives, ATC code: J01EE03.

Marketing Application Holder: Rokitan GmbH, Große Mohrengasse 10, 1020 Wien, Tel: +43 1 2163275, Email: office@rokitan.com

Available on prescription in pharmacies only.

Information on the sections posology, special warnings and precautions for use, interaction with other medicinal products and other forms of interaction, fertility, pregnancy and lactation as well as on undesirable effects and habituation is given in the Summary of Product Characteristics.

Information update 03/2018

Lidaprim® forte film coated tablets

QUALITATIVE AND QUANTITATIVE COMPOSITION:

1 film coated tablet contains 800 mg Sulfametrole and 160 mg Trimethoprim.

Excipients: Magnesium stearate, Polyvidone K 90, maize starch, pregelatinised starch (maize starch), Titanium dioxide E 171, Polysorbate 80, talc, Hydroxypropyl methylcellulose 2910 (HP M 603)

Therapeutic indications: Lidaprim should only be used if the therapeutic benefit outweighs the possible risks. The use of a single antimicrobial substance should be considered.

For treatment of infections caused by Trimethoprim/Sulfonamide sensitive pathogens:

- Infections of kidneys and urinary tract: acute uncomplicated infections of kidneys and urinary tract, Granuloma venereum.
- Alternative therapy of infections of the ear, nose and throat and the respiratory tract: acute exacerbation of chronic bronchitis, otitis media (if Lidaprim is preferable to a single antibiotic of good reason), treatment and prophylaxis (primary and secondary) of a pneumocystis jirovecii (carinii), pneumonia.
- Alternative therapy of infections of the female and male genital organs including gonorrhoea.
- Infections of the gastrointestinal tract: typhoid, paratyphoid fever A and B, shigellosis (sensitive strains of Shigella flexneri and Shigella sonnei, if antibacterial therapy is indicated), diarrhoea (only if caused demonstrably by enterotoxin forming Escherichia coli), enteritis salmonellae with septic course of disease in immunocompromised patients.
- Alternative therapy of infections of the skin (with multiresistant staphylococci).

Consideration should be given to official national and international guidance on the appropriate use of antibacterial agents when using Lidaprim.

Contraindications:

- Hypersensitivity to the active substances, other sulfonamides, Trimethoprim analogues (e.g. tetroxoprim) or to any of the mentioned excipients
- Severe liver and renal impairment (creatinine clearance 15 ml/min), jaundice, acute porphyria.
- Impaired haemopoiesis (agranulocytosis, aplastic anaemia, megaloblastic anaemia, haemolytic anaemia, thrombopenia, leucopenia, methaemoglobinaemia).
- Glucose 6-phosphate dehydrogenase deficiency (symptom: haemolytic anaemia).
- Erythema exsudativum multiforme (Stevens Johnson syndrome), also in the previous medical history.
- Exsiccosis, particularly in the elderly, when sufficient supply of fluids is not possible.
- Co administration of dofetilide, erythromycin, halofantrine, pimozide, ziprasidone (see section 4.5 Interactions).
- Porphyria, lupus erythematosus and predisposition to lupus like reactions.
- Pregnancy and lactation, new-borns in the first 8 weeks and premature babies according to the due date – because of immaturity of the enzyme system.
- Haemoglobin anomalies including Hb Cologne and Hb Zurich.

Pharmacodynamic properties:

Pharmacotherapeutic group: Combinations of sulfonamides and Trimethoprim, incl. derivatives, ATC code: J01EE03.

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