Sulfadiazine

Section: 6. Anti-infective medicines > 6.5. Antiprotozoal medicines > 6.5.4. Antipneumocystosis and antitoxoplasmosis medicines

EMLc | Codes ATC: J01EC02

Indication	Toxoplasmosis Code ICD11: 1F57.Z
INN	Sulfadiazine
Type de médicament	Chemical agent
Groupes d'antibiotiques	A ACCESS
Type de liste	Liste de base
Formulations	**Oral > Solid:** 500 mg
Historique des statuts LME	Ajouté pour la première fois en 2009 (TRS 958)
Sexe	Tous
Âge	Aussi recommandé pour les enfants
Équivalence thérapeutique	La recommandation concerne ce médicament spécifique
Renseignements sur le brevet	Patents have expired in most jurisdictions Lire la suite sur les brevets.
Wikipédia	Sulfadiazine
DrugBank	Sulfadiazine

Résumé des preuves et recommandation du comité d'experts

Sulfadiazine wad added to the core list of the EML and the EMLc for the treatment of toxoplasmosis in 2009. The EMLc Subcommittee considered the review of sulfadiazine for the treatment of toxoplasmosis in children. It had been noted in 2007 that sulfadiazine was not licensed for the treatment of toxoplasmosis in children, and therefore a review of its use in children with particular regard to the treatment of toxoplasmosis was requested. Evidence cited in the Secretariat's review to support the efficacy of sulfadiazine in the management of toxoplasma encephalitis included a Cochrane Review (1) and several other randomized controlled trials involving adults with HIV (2), however there was limited evidence for its superiority over trimethoprim–sulfamethoxazole for this indication. Studies of the management of congenital toxoplasmosis included several longitudinal cohort studies (3, 4, 5), which demonstrated sulfadiazine to be an efficacious and safe treatment for infected neonates. An improved outcome was seen in the majority of infected infants who were treated with combination sulfadiazine therapy; however outcome was shown to be dependent on the duration of treatment and the degree of disability at birth. The Subcommittee noted that there was no evidence to support the use of sulfadiazine in the treatment of nocardia or other infections. Sulfadiazine treatment appeared to be well tolerated, with adverse reactions reported in approximately 5% of patients. No systematic reviews comparing oral versus intravenous sulfadiazine were identified, however it was noted that the majority of guidelines, including the CDC and the British National Formulary 2006, recommend oral sulfadiazine in the management of toxoplasmosis. The majority of an oral dose is rapidly absorbed from the gastrointestinal tract and therefore no justification for an intravenous form could be

made. The Subcommittee agreed that there was sufficient evidence for the clinical efficacy and safety of oral sulfadiazine in children for the treatment of congenital toxoplasmosis. It was decided that intravenous sulfadiazine should be removed from the EMLc and the oral tablet formulation should be deleted from Section 6.2.2 of the EMLc and moved to Section 6.5.4 (antitoxoplasmosis medicines). The need for an oral liquid formulation of sulfadiazine was also identified.

1. Dedicoat M et al. Management of toxoplasmic encephalitis in HV-infected adults (with an emphasis on resource-poor settings). Cochrane Database of Systematic Reviews, 2006, Issue 3. Art. No.: CD005420. 2. Arens J et al. Treating AIDs-associated cerebral toxoplasmosis — pyrimethamine plus sulfadiazine compared with co-trimoxazole, and outcome with adjunctive glucorticoids. South African Medical Journal, 2007, 97:956–8. 3. Phan L et al. Longitudinal study of new eye lesions in treated congenital toxoplasmosis. Opthalmology, 2008, 115:553–9:e8. 4. Mcleod R et al. Outcome of treatment for congenital toxoplasmosis, 1981–2004: the National Collaborative Chigago-Based, Congenital Toxoplasmosis Study. Clinical Infectious Diseases : an offi cial publication of the Infectious Diseases Society of America, 2006, 42:1383–94. 5. Galanakis E et al. Outcome of toxoplasmosis acquired during pregnancy following treatment in both pregnancy and early infancy. Fetal Diagnosis and Therapy, 2007, 22:444–8.

