Retinol

Essential medicine status

Section: 27. Vitamins and minerals

EMLc | ATC codes: A11CA01

Indication	Vitamin A deficiency ICD11 code: 5B55.Z
INN	Retinol
Medicine type	Chemical agent
List type	Core (EML) (EMLc)
Formulations	Parenteral > General injections > IM: 100000 IU in 2 mL ampoule (as palmitate) water-miscible injection Oral > Liquid: 100000 IU per mL (as palmitate) oral oily solution in multidose dispenser Oral > Solid: 10000 IU (as palmitate) sugar-coated tablet ; 200000 IU (as palmitate) capsule ; 50000 IU (as palmitate) capsule (EML) ; 100000 IU (as palmitate) capsule
EML status history	First added in 1977 (TRS 615) Changed in 1979 (TRS 641) Changed in 1987 (TRS 770) Changed in 2003 (TRS 920) Changed in 2007 (TRS 946) Changed in 2007 (TRS 950) Changed in 2009 (TRS 958)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents.
Wikipedia	Retinol
DrugBank	Retinol (Vitamin A)

Summary of evidence and Expert Committee recommendations

The WHO Department of Child and Adolescent Health and Development commissioned a review of the evidence of potential benefi t of prophylactic/routine administration of vitamin A to neonates and infants younger than six months, with a view to updating the current recommendations about its use. The proposal to delete the 50 000 IU formulation currently on the EMLc arose from the results of the review. Expert comments were provided by Dr Stuart MacLeod and Dr Robert Petersen. The two reports, (1) provided as confidential drafts to the Subcommittee, were the manuscript version of the systematic review of neonatal vitamin A supplementation (2) and the report to WHO on the benefits and safety of vitamin A supplementation in the first six months of life (3). Both are comprehensive systematic reviews and both found that the existing evidence shows no benefit of routine supplementation in terms of mortality or morbidity in these age groups. The Subcommittee noted that administration of this drug to young infants has been associated with an increased occurrence of bulging fontanelle. Five additional Cochrane Reviews were identified examining administration of vitamin A to other subgroups of children: low birth weight infants, children with cystic fibrosis, children with measles, for prevention of lower respiratory tract infections, and non measles pneumonia in children under seven years of age (4-8). In low-birth-weight children, most studies reported use of intramuscular vitamin A. There was a trend towards benefit in terms of survival and reduced oxygen requirement, but most of the outcomes analysed were not statistically significant. No studies were identified in the review of cystic fibrosis. In the review of treatment of measles, vitamin A was administered at doses of 100 000 or 200 000 IU and was found to reduce mortality. The reviews of non-measles pneumonia and lower respiratory tract infections found no evidence of benefit of vitamin A supplementation in children under seven years of age.

The EMLc Subcommittee considered that there was no clear need for a 50 000 IU oral dose for routine prophylaxis against vitamin A deficiency during the first six months of life. The 50 000 IU dosage form is also not appropriate for routine supplementation in children over six months of age for whom the recommended dose is 100 000 or 200 000 IU. Therefore the only potential use for the low-dose capsule would be for the outpatient treatment of clinically proven vitamin A deficiency in neonates and infants under six months of age; a condition that is exceedingly rare. The Subcommittee recommended that the 50 000 IU dosage form be deleted from the EMLc. References: 1. Gogia S, Sachdev HS. Neonatal vitamin A supplementation for prevention of mortality and morbidity in infancy: systematic review of randomised controlled trials. BMJ, 2009;338:b919. 1. Gogia S, Sachdev H. Neonatal vitamin A supplementation for the prevention of mortality and morbidity in infancy: systematic review of randomized controlled trials 2008. New Delhi, Department of Paediatrics and Clinical Epidemiology, Sitaram Bhartia Institute of Science and Research. (Manuscript under review for publication). 3. Gogia S, Sachdev H. Benefi ts and safety of vitamin A supplementation in the first half of infancy: systematic reviews of randomized controlled trials. (Unpublished draft submitted to the World Health Organization.) 4. Darlow BA, Graham PJ. Vitamin A supplementation to prevent mortality and short- and long-term morbidity in very low birthweight infants. Cochrane Database of Systematic Review, 2007; Issue 4. Art. No.: CD000501. DOI: 10.1002/14651858.CD000501.pub2. 5. O'Neil CB, Shevill E, Chang AB. Vitamin A supplementation for cystic fibrosis. Cochrane Database of Systematic Reviews, 2008; Issue 1. Art. No.: CD006751. DOI: 10.1002/14651858.CD006751.pub2. 6. Huiming Y, Chaomin W, Meng M. Vitamin A for treating measles in children. Cochrane Database of Systematic Reviews, 2005; Issue 4. Art. No.: CD001479. DOI: 10.1002/14651858.CD001479.pub3. 7. Chen H et al. Vitamin A for preventing acute lower respiratory tract infections in children up to seven years of age. Cochrane Database of Systematic Reviews, 2008; Issue 1. Art. No.: CD006090. DOI: 10.1002/14651858.CD006090.pub2. 8. Ni J, Wei J, Wu T. Vitamin A for non-measles pneumonia in children. Cochrane Database of Systematic Reviews, 2005; Issue 3. Art. No.:CD003700. DOI: 10.1002/14651858.CD003700.pub2.