Iodine

Section: 27. Vitamins and minerals

EMLc | ATC codes: H03CA

Indication	Iodine deficiency ICD11 code: 5B5K.3
Medicine type	Chemical agent
List type	Core
Formulations	**Parenteral > General injections > IM:** 480 mg per mL in 10 mL ampoule or vial iodized oil (oral or injectable)
EML status history	First added in 1989 (TRS 796) Changed in 1993 (TRS 850) Changed in 2007 (TRS 950) Changed in 2019 (TRS 1021) Changed in 2025 (TRS 1064)
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	Iodine
DrugBank	Iodine

Expert Committee recommendation

The Expert Committee noted that the primary strategy for elimination of iodine deficiency is universal salt iodization, but that implementation of salt iodization programmes may not be feasible in all settings. In this case, iodine supplementation or iodine-fortified foods may be required for susceptible patient groups such as pregnant and lactating women, women of child-bearing age, and young children. The Committee noted that an oral liquid formulation of iodized oil remains listed on the Model Lists as a treatment option for use in the prevention and treatment of iodine deficiency in such settings. The Committee noted that the applicant had withdrawn marketing authorizations for its product worldwide due to decreased medical need and a lack of demand. No other manufacturers were identified. The Expert Committee therefore recommended the deletion of iodine capsules 190 mg for prevention of iodine deficiency from the EML and EMLc ---------- Following the review of the age-appropriateness of formulations on the EMLc, the Expert Committee recommended: - the deletion of iodized oil 0.5 mL (240 mg iodine) in ampoules and 0.57 mL (308 mg iodine) in bottle formulations from the EML and EMLc; - modifying the listing description for iodized oil 480 mg/mL to better describe formulation characteristics.

Background

Iodine capsules for use in the prevention of iodine deficiency have been included on the EML since 1989 and on the EMLc since 2007. The Model Lists currently also include iodized oil for oral or injectable administration for this indication.

WHO guidelines

A 2007 joint statement by WHO and UNICEF recommended iodine supplementation for increasing iodine intake if iodized salt was not accessible in specific situations. Iodine supplements could be administered on a daily or annual basis using an iodized oil preparation in doses ranging from 90 micrograms per day or 200 mg per year for children younger than 2 years to 250 micrograms per day or 400 mg per year for women of reproductive age, and pregnant and lactating women (1)

Availability

The applicant (Guerbet, Villepinte, France) advised that due to decreasing medical needs over the years and the lack of demand for their product for the past 5 years, Guerbet has started withdrawing the marketing authorizations worldwide. Since 2022, all marketing authorization in export countries was withdrawn and Guerbet has applied for withdrawal of the last marketing authorization in France.

Other considerations

The Department of Nutrition and Food safety reviewed the application and advised that it did not oppose the removal of iodine capsules from the Model Lists. The department advised that it was not aware of any countries implementing iodine supplementation with iodized oil capsules. Additionally, outreach to partners did not reveal any country implementing iodized oil capsules.

1. Reaching optimal iodine nutrition in pregnant and lactating women and young children. Joint statement by the World Health Organization and the United Nations Children's Fund. Geneva: World Health Organization; 2007. (https://www.who.int/publications/m/item/WHO-statement-IDD-pregnantwomen-children).

