

Section: 1. Anaesthetics, preoperative medicines and medical gases > 1.1. General anaesthetics and oxygen > 1.1.1. General anaesthetics and oxygen > Inhalational medicines

EMLc

Codes ATC: N01AB01

Indication	Anaesthetics and therapeutic gases	Code ICD11: XM1880792884
INN	Halothane	
Type de médicament	Gas	
Type de liste	Liste de base (EML) (EMLc)	
Formulations	Respiratory > Inhalation > liquid:	
Historique des statuts LME	Ajouté pour la première fois en 1977 (TRS 615) Modifié en 2005 (TRS 933) Modifié en 2007 (TRS 950) Modifié en 2011 (TRS 965) Retiré en 2025 (TRS 1064)	
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	Halothane	↗
DrugBank	Halothane	↗

Recommandation du comité d'experts

The Expert Committee recalled the recommendation of the 2023 Expert Committee to remove halothane from the Model Lists in 2025 unless an application was received in support of its retention. This recommendation was based on halothane's limited role among anaesthetic gases and the availability and listing of safer alternatives on the EML and EMLc which are associated with lower greenhouse gas emissions (e.g. sevoflurane). The Committee considered the application from the World Federation of Societies of Anaesthesiologists to maintain listing of halothane until 2027 to allow more time for Member States in which halothane is still used to implement the change at the clinical, operational, and budgetary levels. The application highlighted that halothane is still used in resource-constrained settings because of its relatively lower cost and because anaesthesia providers in such settings are familiar with its use. The Committee acknowledged that in those settings where halothane is still used, phasing out and transitioning to the use of alternative anaesthetic agents is a stepwise and multifactorial process which may be lengthy. The Committee noted and welcomed the actions described in the application to support the phasing out of halothane and encouraged their timely implementation. However, the Committee considered that it was appropriate to uphold the 2023 Committee's recommendation to remove halothane from the Model Lists in 2025 to reinforce the importance of prioritizing alternative inhalational anaesthetic agents with lower propensity for environmental impact and stimulate necessary actions to achieve this change. The Committee acknowledged and accepted that some countries might continue to include halothane in their national essential medicines lists and that local circumstances may necessitate and justify its ongoing inclusion in these lists and use in clinical practice during a necessary transition period. Therefore, the Expert Committee recommended the removal of halothane from the EML and EMLc to support efforts to reduce the impact of essential anaesthetic gases on climate change.

Contexte

The application requested to delay the recommended removal of halothane from the EML and EMLc until 2027. While strongly advocating for phasing out of halothane in clinical practice, the applicants highlighted that halothane is no longer available in upper-middle and high-income countries. However, halothane continues to be used in low-resource settings due to its relatively lower cost and familiarity with the medicine by anaesthesia providers in such settings. The applicants argued that transitioning to new anaesthetic agents will require initiatives targeted to anaesthesia providers in low-resource setting, and sufficient time for Ministries of Health and Finance to make appropriate budgetary allocations and to purchase and implement operational aspects of supplying alternatives. In 2023, the Expert Committee considered an application from Abbvie Biopharmaceuticals GmbH for the addition of sevoflurane to the EML and EMLc as an inhalational gas for general anaesthesia. The Committee recommended the inclusion of sevoflurane on the core list of the EML and EMLc as an inhalational anaesthetic based on evidence of similar efficacy and safety to isoflurane, and a lower global warming potential than the currently listed alternatives. In consideration of the volatile anaesthetics included on the Model Lists, the Committee noted that halothane is no longer used in many countries because of its harm profile. The Committee also noted that the price difference between halothane, isoflurane and sevoflurane has decreased since sevoflurane was previously considered for inclusion in the Model Lists in 2011. The Committee considered that more efficient use of sevoflurane in preference to halothane and isoflurane can contribute to reducing greenhouse gas emissions. In addition, given the limited role of halothane among anaesthetic gases, the Committee recommended that halothane be flagged for deletion from the Model Lists without further discussion in 2025, unless an application is received in support of its retention.

