




| | | EMLc | Codes ATC: N02AA01 |
|------------------------------|---|-------------------------|--------------------|
| Indication | Pain | Code ICD11: ML0Z | |
| Type de médicament | Chemical agent | | |
| Type de liste | Liste de base (EML) (EMLc) | | |
| Formulations | Oral > Liquid: 10 mg per 5 mL (morphine hydrochloride or morphine sulfate) Oral > Solid: 10 mg immediate release (morphine sulfate) ; 10 to 200 mg slow release (morphine hydrochloride or morphine sulfate) Oral > Other: 20 to 200 mg slow release granules to mix with water (morphine sulfate) Parenteral > General injections > unspecified: 10 mg in 1 mL ampoule (morphine hydrochloride or morphine sulfate) | | |
| Historique des statuts LME | Ajouté pour la première fois en 1977 (TRS 615) Modifié en 1979 (TRS 641) Modifié en 1984 (TRS 722) Modifié en 2003 (TRS 920) Modifié en 2007 (TRS 946) Modifié en 2007 (TRS 950) Modifié en 2013 (TRS 985) Modifié en 2015 (TRS 994) | | |
| Sexe | Tous | | |
| Âge | Aussi recommandé pour les enfants | | |
| Équivalence thérapeutique | hydromorpone (Codes ATC: N02AA03) oxycodone (Codes ATC: N02AA05) | | |
| Renseignements sur le brevet | Patents have expired in most jurisdictions Lire la suite sur les brevets.  | | |
| Wikipédia | Morphine  | | |
| DrugBank | Morphine  | | |

Résumé des preuves et recommandation du comité d'experts

An application was submitted by Dr Willem Scholten (until October 2012, team leader, Access to Controlled Medicines, WHO), requesting modification of the wording of the EML and EMLc listings for certain opioid analgesics – morphine, hydromorphone and oxycodone. Expert reviews of the application were prepared by two members of the Expert Committee. No public comments on the application were received. In applications to the 19th Expert Committee in 2013, Dr Scholten proposed the addition of hydromorphone and oxycodone as examples of the opioid class, requesting that this be expressed in the Model Lists with a footnote to the square box listing of morphine stating “two or more alternatives to morphine should be available”. Following consideration of these applications, the 19th Expert Committee recommended the addition of a square box symbol to the listings for morphine, with a note that alternatives be limited to hydromorphone and oxycodone. The rationale for this recommendation is documented in the report of the 2013 Expert Committee meeting. The current application provided copies of the 2013 applications for hydromorphone and oxycodone, which had not named any alternative opioids or provided any new data to support the request to modify the wording of the current listing. The Committee noted that the proposed modification to the current wording would, in effect, allow any opioid to be available as an alternative to morphine on the WHO Model Lists and, if adopted by countries, on national lists. The Committee considered that, within the same pharmacological class, individual opioids can differ considerably in terms of characteristics that include (but are not limited to) pharmacology, potency, formulation, and suitability for paediatric use. The Committee considered that all opioids could not be thought of as simply interchangeable within class. The Committee advised that changing the current listing to allow additional alternatives to morphine would require submission of appropriate data

demonstrating similar clinical performance. In the absence of any new evidence to support the inclusion of additional opioids as alternatives to morphine on the EML and EMLc, the Committee did not recommend any changes to the listing for morphine (and, by extension, hydromorphone and oxycodone) at this time.

