

CMI for Pseudoephedrine-Containing Products

In addition to preparing a CMI for pseudoephedrine, individual core CMIs have been developed for ingredients that are in currently available pseudoephedrine-containing products. That is:

- Bromhexine
- Codeine
- Dextromethorphan
- Guaiphenesin
- Ibuprofen
- Paracetamol
- Pholcodine
- Pseudoephedrine
- Sedating antihistamines – Chlorpheniramine maleate, Dexchlorpheniramine maleate, Diphenhydramine hydrochloride, Doxylamine succinate, Promethazine hydrochloride, and Triprolidine hydrochloride

To put together a CMI for a specific pseudoephedrine-containing product, sponsors will be required to 'cut and paste' relevant information from each of the core CMIs to a new product specific document.

The final CMI must include information on each of the ingredients. In the case of pregnancy classification and use in lactation, the more restrictive details should be included.

Please also refer to the instructions for compiling PIs from the individual core PI documents.