

“Product Information as approved by the CMDh on 23 July 2014”

Annex III

Amendments to relevant sections of the product information

Amendments to relevant sections of the product information of methadone tablets containing low molecular weight povidone (K25 or K30)

A. Summary of Product Characteristics

Section 4.2 Posology and method of administration

[The following text should be included in this section]

This product is for oral use only, and must not be injected.

Section 6.1 List of excipients

[Information about the type of povidone, e.g. K25 or K30, should be included in this section.]

B. Package Leaflet

Section 3. How to use <Invented Name>?

[The following text should be included in this section]

This product is for oral use only, and must not be injected.