**Summary of Product Characteristics (SmPC) Assessment Report Template**

**<Product Name (INN and brand name)>**

**< Active Ingredient >**

**<Applicant Name>**

**<Dossier Reference Number>**

|  |  |
| --- | --- |
| **Lead Assessor** |  |
| **Other Assessors** |  |
| **Rapporteur** |  |
| **SmPC assessment started on** |  |
| **Date of report** |  |

# **1. General information**

1. The SmPC is prepared in conformity with the Registration Guideline Annex 4.

Yes  No

1. The information in the SmPC does not contradict with the national therapeutic guidelines

☐ Yes ☐ No ☐ Not Applicable

**Remark** Click or tap here to enter text.

# **2. Comments on the SmPC**

*Please comment on following sections of the SmPC, if appropriate.*

|  |  |  |
| --- | --- | --- |
| **No.** | **Sections of the SmPC** | **Comments** |
| 1. | Name of the medicinal product |  |
| 1.1 | Strength |  |
| 1.2 | Pharmaceutical form |  |
| 2. | Qualitative and quantitative composition |  |
| 3. | Pharmaceutical form |  |
| 4. | Clinical particulars |  |
| 4.1 | Therapeutic Indications |  |
| 4.2 | Posology and method of administration |  |
| 4.3 | Contraindications |  |
| 4.4 | Special warnings and precautions for use |  |
| 4.5 | Interaction with other medicinal products and other forms of interactions |  |
| 4.6 | Pregnancy and lactation |  |
| 4.7 | Effects on ability to drive and use machines |  |
| 4.8 | Undesirable effects |  |
| 4.9 | Overdose |  |
| 5. | Pharmacological properties |  |
| 5.1 | Pharmacodynamic properties |  |
| 5.2 | Pharmacokinetic properties |  |
| 5.3 | Preclinical safety data |  |
| 6. | Pharmaceutical particulars |  |
| 6.1 | List of excipients |  |
| 6.2 | Incompatibilities |  |
| 6.3 | Shelf life |  |
| 6.4 | Special precautions for storage |  |
| 6.5 | Nature and contents of container |  |
| 6.6 | Instructions for use and handling and disposal |  |
| 7. | Name and address of manufacturer |  |
| 8. | Marketing authorization number(s) |  |
| 9. | Category of distribution |  |
| 10. | Date of revision of the text |  |

# **2. Recommendations**

Click or tap here to enter text.