

REQUIREMENTS for summary of product characteristics for medicinal product

1. Summary of Product Characteristics (SPC) - information for healthcare professionals on how to use the medicinal product safely and effectively, which is approved at applicant's request.
2. The summary of product characteristics for medicinal product shall be clearly worded in Ukrainian.
3. The summary of product characteristics for medicinal product, structure of which is given in annex 19 to the Procedure shall include the following information:
 - 3.1. Name of medicinal product, which may include strength and pharmaceutical form if applicable.
 - 3.2. Full details of the qualitative (in terms of the active substance (s) and excipients) and quantitative composition (in terms of the active substance(s)) using common names for each presentation of medicinal product (strength and package)
 - 3.3. Pharmaceutical form.
 - 3.4. Clinical particulars:
 - 3.4.1. Therapeutic indications.
 - 3.4.2. Posology and method of administration for adults and children (if applicable).
 - 3.4.3. Contraindications.
 - 3.4.4. Special warnings and precautions for use and, in the case of medical immunobiological products, precautions to be taken by doctors handling such products and administering them to patients, together with any precautions to be taken by the patient.
 - 3.4.5. Interaction with other medicinal products and other forms of interactions.
 - 3.4.6. Use during pregnancy and lactation.
 - 3.4.7. Effects on ability to drive and to use machines.
 - 3.4.8. Adverse reactions.
 - 3.4.9. Overdose (symptoms, emergency procedures, antidotes).
 - 3.5. Pharmacological properties:
 - 3.5.1. Pharmacotherapeutic group. ATC code:
 - 3.5.2. Pharmacodynamic properties.
 - 3.5.3. Pharmacokinetic properties.
 - 3.5.4. Preclinical safety data.
 - 3.6. Pharmaceutical particulars:
 - 3.6.1. List of excipients.
 - 3.6.2. Major incompatibilities.
 - 3.6.3. Shelf life (when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time).
 - 3.6.4. Special precautions for storage.
 - 3.6.5. Nature and contents of immediate package (container).
 - 3.6.6. Special precautions for disposal of a (un)used medicinal product or waste materials derived from such medicinal product, if appropriate.
 - 3.7. Registration certificate holder.

Manufacturer of medicinal product (name and location of manufacturer and address where he carries out his activity (manufacturer responsible for batch release of medicinal product (s) to be specified).

3.8. Registration certificate number(s)

3.9. Date of the first registration or re-registration of medicinal product.

3.10. Date of revision of the text of the summary of product characteristics.

3.11. For radiopharmaceutical medicinal products, full details of internal radiation dosimetry.

3.12. For radiopharmaceutical medicinal products - additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use medicinal product will conform with its specifications.

{ Annex 22 in wording of MoH Ukraine Order №460 as of 23.07.2015 }