

**1. Patient information leaflet (PIL) vs Summary of product characteristics (SPC)**

Use the European Medicines Agency website ([ema.europa.eu](http://ema.europa.eu)) to answer the following questions and solve the problems. Find information about medical preparation AVAMYS. On EMA homepage, click on “Medicines”, “Human”, and then search the product. SPC and PIL can be found in “Product information”.

|   |     | SPC   | PIL  |
|---|-----|---|--|
| Number of pages   |     |   |  |
| <b>Is the information in the document?</b>  |     | <b>Give an example of the information you have found:</b> | <b>Is the information in the document?</b> |
| Mechanism of action   | Y/N |   | Y/N  |
| Pharmacokinetics  | Y/N |   | Y/N  |
| Undesirable effects   | Y/N |   | Y/N  |
| Excipients  | Y/N |   | Y/N  |
| Use in pregnancy  | Y/N |   | Y/N  |
| Compare and characterize the text of SPC and PIL from the linguistic point of view (e.g., the terminology used) |     |   |  |
| For whom is the document intended   |     | healthcare personnel/patients                             | healthcare personnel/patients              |

Find SPC of the medicinal product AERINAZE and give an example of the information found:

|  |  |
|--|--|
| <b>When the drug should NOT be used?</b> |  |
| <b>What is its mechanism of action?</b>  |  |
| <b>Symptoms of overdose</b>              |  |
| <b>Plasma proteins binding</b>           |  |

Find SPC of the medicinal product VIAGRA and find the information about adverse (undesired) effects:

| Trade name      | Very common adverse reactions | Common adverse reactions             |
|-----------------|-------------------------------|--------------------------------------|
| VIAGRA          |                               |                                      |
| INN of the drug |                               |                                      |
|                 |                               |                                      |
| Incidence       | ≥ 1 pers. out of              | ≥ 1 pers. out of to < 1 pers. out of |

## 2. Database of the Czech State Institute of Drugs Control, MHRA (UK) etc.

Look for the homepage of the Czech State Institute of Drugs Control ([www.sukl.cz](http://www.sukl.cz)), UK Medicines and Healthcare Products Regulatory Agency ([MHRA](http://www.mhra.gov.uk)) and the European Medicines Agency ([EMA](http://www.ema.europa.eu)) or [drugs.com](http://drugs.com). Try to use these databases to find medicinal products with the same active substance:

| Trade name       | INN of the drug | Products with the same drug |
|------------------|-----------------|-----------------------------|
| BRUFEN           |                 |                             |
| ZYRTEC or ZIRTEK |                 |                             |