

## Guideline for filling the patient information leaflet

1. Sources:
  - a. Only government approved official documents (Summary of product characteristics, package leaflet, EPAR)
2. General wording
  - a. Use patient friendly language, avoid medical terms that are hard understand
  - b. Keep it short and simple
3. Indication:
  - a. Keep it simple
  - b. Do not put too many details (e.g., which line of therapy)
4. Dosage:
  - a. Use “additional information” for drugs with complicated dosage, e.g., Capecitabine with dosage per body surface area
5. Interactions:
  - a. Only put interactions with OTC drugs, herbs and food.
  - b. We know that OTC rules may differ from country to country.
  - c. But our general thought should be that interactions with chronic (usually prescription) medication like antidiabetics, antiepileptics, antiarrhythmic, antiretroviral drugs etc. should be checked by the physician prior to the prescription of the oral cancer drug and therefore do not belong in the leaflet
  - d. This also helps to respect point 2.b. = keep it simple and short
6. Side effects:
  - a. Only put those side effects that are very common (>1/10) and can be noticed by the patients themselves (e.g., no laboratory data)
7. Additional information:
  - a. We tried to generate as much space for additional information as possible
  - b. Use it, if necessary, but you must not fill it just for the sake of it. Again: keep it simple and short
8. Contact data:
  - a. Is left blank because it will be filled by the user who gives the leaflet to the patient (pharmacy or hospital stamp)