Part VI: Summary of the risk management plan

Summary of risk management plan for capecitabine koanaa 150 mg and 500mg film-coated tablets.

This is a summary of the risk management plan (RMP) for capecitabine Koanaa 150 mg and500mg film-coated tablets. The RMP details important risks of capecitabine Koanaa 150 mg and500mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about capecitabine Koanaa 150 mg and 500mg film-coated tablets risks and uncertainties (missing information).

Capecitabine Koanaa 150 mg and 500mg film-coated tablets summary of product characteristics (SmPC) and its Package leaflet give essential information to healthcare professionals and patients on how capecitabine Koanaa 150 mg and 500mg film-coated tablets should be used.

I. The medicine and what it is used for

Capecitabine Koanaa 150 mg and 500mg film-coated tablets is authorised for the treatment of following indications:

- Capecitabine is indicated for the adjuvant treatment of patients following surgery of stage III (Dukes' stage C) colon cancer.
- Capecitabine is indicated for the treatment of metastatic colorectal cancer.
- Capecitabine is indicated for first-line treatment of advanced gastric cancer in combination with a platinum-based regimen.
- Capecitabine in combination with docetaxel for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline.
- Capecitabine is also indicated as monotherapy for the treatment of patients with locally advanced or metastatic breast cancer after failure of taxanes and an anthracycline-containing chemotherapy regimen or for whom further anthracycline therapy is not indicated.

It contains capecitabine as the active substance and it is administered by oral route administration, Capecitabine tablets should be swallowed with water within 30 minutes after a meal.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of capecitabine Koanaa 150 mg and500mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about capecitabine Koanaa 150 mg and 500mg film-coated tablets risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised pack size - the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine’s legal status - the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

II.A List of important risks and missing information

Important risks of Capecitabine Koanaa 150 mg and 500mg film-coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns

for which there is sufficient proof of a link with the use of Capecitabine Koanaa 150 mg and500mg film-coated tablets. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected.

Summary of safety concerns	
Important identified risks	Cardiac toxicity
	GI toxicity
	Palmar-plantar erythrodysesthesia (HFS)
	Increased Capecitabine toxicity with concomitant administration of sorivudine or analogues
	Toxicity in those with DPD deficiency
	Coronary and peripheral vasospasm
	Vascular Disorders (thrombosis / embolism)
	Corneal Disorder
	Severe cutaneous adverse reactions (SCARs) such as Stevens-Johnson syndrome, Toxic Epidermal Necrolysis and Bullous dermatitis
	Photosensitivity reactions
Important potential risks	Pancreatitis
Missing information	Use in pregnant and lactating women
	Use in children
	Safety in patients with hepatic impairment

The above stated list of safety specifications are obtained from the reference medicine, Xeloda RMP version 7.

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Capecitabine Koanaa 150 mg and500mg film-coated tablets.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Capecitabine Koanaa 150 mg and 500mg film-coated tablets.