PART VI- Summary of the risk management plan

Summary of risk management plan for Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten.

This is a summary of risk management plan for Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten. The RMP details important risks of Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten, how these risks can be minimised, and how more information will be obtained about Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten, risks and uncertainties (missing information).

Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten should be used.

I. The medicine and what it is used for

Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten is authorised for oral contraception It contains Gestodene – Ethinylestradiol as active substance and it is given by oral route.

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

Important risks of Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten, together with measures to minimise such 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.

In the case of Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten, these measures are supplemented with additional risk minimization measures mentioned under relevant important risk, below:

•Venous thromboembolism (Annex 6)
-**Direct Healthcare Professionals Communication**
-**Check-list for prescribers**
-**Patient information card**

•Arterial ththromboembolism (Annex 6)
-**Direct Healthcare Professionals Communication**
-**Check-list for prescribers**
-**Patient information card**

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten 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 Nhytideta 0,075 mg/ 0,20 mg tabletten, Nhytida 0,075 mg / 0,030 mg tabletten, Marynarka 0,075 mg /0,020 mg tabletten. 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 (e.g. on the long-term use of the medicine).

Table 3. Summary of Safety Concerns: list of important risk and missing information.

Gestodene + ethinylestradiol	Safety concerns	Additional Pharmacovigilance	Additional Risk Minimisation
Important Identified Risk	Thromboembolism arterial	No	**Yes**
	Thromboembolism venous	No	**Yes**
	Liver tumours	No	No
	Breast cancer	No	No
	Aggravation of hereditary angioedema	No	No
	Liver function disturbances	No	No
	Pancreatitis	No	No
	Increase in blood pressure	No	No
	Cervical cancer		
Important Potential Risk	Worsening of depression/depressed mood	No	No
	Crohn's disease and ulcerative colitis	No	No
Missing information	None		

II.B Summary of important risks

Venous thromboembolism	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4, 4.8. PL section 2. Additional risk minimisation measures **Check list for prescribers** **Patient alert card** **DHPC**
Arterial thromboembolism	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4, 4.8. PL section 2. Additional risk minimisation measures **Check list for prescribers** **Patient alert card** **DHPC**
Liver tumours	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4, 4.8. PL section 2. Additional risk minimisation measures None
Breast cancer	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4, 4.8. PL section 2. Additional risk minimisation measures None

Aggravation of hereditary angioedema	
Risk minimisation measures	Routine risk minimisation measures PL section 2. Additional risk minimisation measures None
Liver function disturbances	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4. PL section 2. Additional risk minimisation measures None
Pancreatitis	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4. PL section 2. Additional risk minimisation measures None
Increase in blood pressure	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4, 4.8. PL section 4. Additional risk minimisation measures None
Cervical cancer	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4. PL section 2. Additional risk minimisation measures

	None
Crohn's disease and ulcerative colitis	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4. PL section 2. Additional risk minimisation measures None
Worsening of depression/depressed mood	
Risk minimisation measures	Routine risk minimisation measures SmPC: Section 4.4, 4.8. PL section 2. Additional risk minimisation measures None

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 Gestodene – Ethinylestradiol 0.075 mg / 0.020 – 0.030 mg tablets.

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

There are no studies required for Gestodene – Ethinylestradiol 0.075 mg / 0.020 – 0.030 mg tablets.