Part VI: Summary of risk management plan for Nortriptyline Double-E Pharma 10 mg and 25 mg film-coated tablets

This is a summary of risk management plan for Nortriptyline Double-E Pharma 10 mg and 25 mg filmcoated tablets. The RMP details important risks of Nortriptyline Double-E Pharma 10 mg and 25 mg filmcoated tablets, how these risks can be minimised, and how more information will be obtained Nortriptyline's Double-E Pharma 10 mg and 25 mg film-coated tablets, risks and uncertainties (missing information).

Nortriptyline's Double-E Pharma 10 mg and 25 mg film-coated tablets SmPC and its PIL give essential information to healthcare professionals and patients on how Nortriptyline Double-E Pharma film-coated tablets should be used.

I. The medicine and what it is used for

Nortriptyline is a tricyclic antidepressant. Nortriptyline, a secondary amine, is also the most active metabolite of amitriptyline. Nortriptyline is a stronger inhibitor of presynaptic noradrenaline reuptake than of serotonin reuptake, while amitriptyline inhibits noradrenaline and serotonin reuptake to similar effects. Nortriptyline is less anticholinergic than amitriptyline but has a rather strong antihistaminergic effect and enhances the effects of catecholamines.

Nortriptyline Double-E Pharma is indicated for use in adults for the treatment of depressive episodes.

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

Important risks of Nortriptyline's Double-E Pharma 10 mg and 25 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about nortriptyline's 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 PIL 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.

If important information that may affect the safe use of the product is not yet available, it is listed under 'missing information'.

II.A. List of important risks and missing information

Important risks of Nortriptyline Double-E Pharma 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 nortriptyline 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 (e.g. on the long-term use of the medicine).

List of safety concerns	
Important identified risks	• None
Potential identified risks	• None
Missing information	• None

II.B. Summary of important risks

The safety information in the proposed PI 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 Nortriptyline Double-E Pharma 10 mg or 25 mg film-coated tablets. ***II.C.2. Other studies in post-authorisation development plan***

There are no studies required for Nortriptyline Double-E Pharma 10 mg and 25 mg film-coated tablets, nor such studies are performed by Double-E Pharma Limited.