

## **Summary of risk management plan for Norcapto 5 mg/ml soluzione orale (nortriptyline hydrochloride).**

This is a summary of the risk management plan (RMP) for the product Norcapto 5 mg/ml soluzione orale. The RMP details important risks of Norcapto 5 mg/ml soluzione orale, how these risks can be minimized, and how more information will be obtained Norcapto 5 mg/ml soluzione orale's risks and uncertainties (missing information).

Norcapto 5 mg/ml soluzione orale's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Norcapto 5 mg/ml soluzione orale should be used.

Important new concerns or changes to the current ones will be included in updates of Norcapto 5 mg/ml soluzione orale's RMP.

## **I. The medicine and what it is used for**

Norcapto 5 mg/ml soluzione orale is authorized for the relief of symptoms of depression. It contains nortriptyline hydrochloride as the active substance, and it is given by oral administration.

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

Important risks of Norcapto 5 mg/ml soluzione orale, together with measures to minimise such risks and the proposed studies for learning more about Norcapto 5 mg/ml soluzione orale'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 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 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 Norcapto 5 mg/ml soluzione orale 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 Norcapto 5 mg/ml soluzione orale. 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-Part VI-1 List of important and potential risks and missing information.**

| Summary of safety concerns        |  |
|-----------------------------------|--|
| <b>Important identified risks</b> | <ul style="list-style-type: none"><li>• Suicide/suicidal thoughts or clinical worsening</li><li>• Withdrawal symptoms (including neonatal ones)</li><li>• Cardiovascular disorders (myocardial infarction, cardiac arrhythmias and stroke)</li><li>• Serotonergic syndrome in concomitant use with MAO-inhibitors</li><li>• Increased risk of bone fractures</li></ul> |
| <b>Important potential risks</b>  | <ul style="list-style-type: none"><li>• Use during pregnancy and lactation</li></ul>   |
| <b>Missing information</b>        | <ul style="list-style-type: none"><li>• None</li></ul>   |

## 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 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 Norcapto 5 mg/ml soluzione orale.

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

There are no studies required for Norcapto 5 mg/ml soluzione orale.