# Summary of the risk management plan for

# Tranylcypromin Holsten 10 mg; 20 mg; 40 mg Filmtabletten

This is a summary of risk management plan for Tranylcypromin Holsten 10 mg, 20 mg, 40 mg film-coated tablets. The RMP details important risks of Tranylcypromin Holsten, how these risks can be minimised, and how more information will be obtained for Tranylcypromin's Holsten risks and uncertainties (missing information).

Tranylcypromin Holsten SmPC and PIL give essential information to healthcare professionals and patients on how Tranylcypromin Holsten film-coated tablets should be used.

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

Tranylcypromin Holsten is authorised for the treatment of major depressive episodes in patients with multi-resistant depressive disorder, where adequate treatment with 2 standard antidepressants (including tricyclic antidepressants) and augmentation with, for example, lithium has not been sufficiently effective (see SmPC for the full indication). It contains tranylcypromine sulphate as the active substance and it is given by oral use.

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

Important risks of Tranylcypromin's Holsten, together with measures to minimise such risks and the proposed studies for learning more about tranylcypromine'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.

In the case of Tranylcypromin Holsten, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks.

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 risk minimisation* measures.

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

### *II.A. List of important risks and missing information*

Important risks of Tranylcypromin Holsten 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 tranylcypromine 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 important risks and missing information** | |
|---|---|
| *Important identified risks* | 1. Hypertensive crisis<br>2. Occurrence of convulsion<br>3. Orthostatic hypotension<br>4. Serotonin syndrome |
| *Important potential risks* | 1. Exposure during pregnancy<br>2. Suicidal ideation, suicidal behaviour and acute toxicity<br>3. Withdrawal reactions (including delirium) |
| *Missing information* | 1. Exposure through human milk<br>2. Exposure to children and adolescents (<18 years old)<br>3. Renal toxicity |

## *II.B. Summary of important risks*

The safety information in the proposed product information is aligned with the reference medicinal product Jatroson.

## *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 Tranylcypromin Holsten.

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

There are no studies required for Tranylcypromin Holsten.