Part VI: Summary of the risk management plan

Summary of risk management plan for Nintedanib Teva 100/150 mg mjúk hylki (Nintedanib)

This is a summary of the risk management plan (RMP) for Nintedanib Teva 100/150 mg mjúk hylki. The RMP details important risks of Nintedanib Teva 100/150 mg mjúk hylki, how these risks can be minimised, and how more information will be obtained about Nintedanib Teva 100/150 mg mjúk hylki's risks and uncertainties (missing information).

Nintedanib Teva 100/150 mg mjúk hylki's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Nintedanib Teva 100/150 mg mjúk hylki should be used.

Important new concerns or changes to the current ones will be included in updates of Nintedanib Teva 100/150 mg mjúk hylki's RMP.

I. The medicine and what it is used for

Nintedanib Teva 100/150 mg mjúk hylki is authorised for the treatment of idiopathic pulmonary fibrosis, for treatment of systemic sclerosis associated interstitial lung disease, and for treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype (see SmPC for the full indication).

It contains nintedanib 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 Nintedanib Teva 100/150 mg mjúk hylki, together with measures to minimise such risks and the proposed studies for learning more about Nintedanib Teva 100/150 mg mjúk hylki'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.

If important information that may affect the safe use of Nintedanib Teva 100/150 mg mjúk hylki is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Nintedanib Teva 100/150 mg mjúk hylki are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 Nintedanib Teva 100/150 mg mjúk hylki. 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	• Drug-induced liver injury (DILI) • Bleeding • Myocardial infarction
Important potential risks	• Venous thromboembolism • Arterial thromboembolism excluding myocardial infarction • Perforation • Hepatic failure • Effect on bone development and growth if used off-label in paediatric patients <18 years-of-age • Effect on teeth development if used off-label in paediatric patients <18 years-of-age
Missing information	• Treatment of SSc-ILD patients with pulmonary hypertension

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 that are conditions of the marketing authorization or specific obligation of Nintedanib Teva 100/150 mg mjúk hylki.

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

There are no studies required for the Applicant's Nintedanib Teva 100/150 mg mjúk hylki.