Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for NINTEDANIB TEVA GMBH

This is a summary of the risk management plan (RMP) for NINTEDANIB TEVA GMBH (hereinafter referred to as Nintedanib). The RMP details important risks of Nintedanib, how these risks can be minimised, and how more information will be obtained about Nintedanib's risks and uncertainties (missing information).

Nintedanib's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Nintedanib should be used.

Important new concerns or changes to the current ones will be included in updates of Nintedanib's RMP.

I. The Medicine and What It is used for

Nintedanib is authorised:

- in adults for the treatment of idiopathic pulmonary fibrosis (IPF);
- in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype;
- in adults, adolescents and children aged 6 years and older for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD)
- in children and adolescents from 6 to 17 years old for the treatment of clinically significant, progressive fibrosing interstitial lung diseases (ILDs) (see SmPC for the full indication).

It contains Nintedanib as the active substance and it is taken orally.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Nintedanib, together with measures to minimise such risks and the proposed studies for learning more about Nintedanib'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 is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Nintedanib 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. 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	• DILI • Bleeding • Myocardial infarction • Weight decreased in paediatric population
Important potential risks	• Venous thromboembolism • Arterial thromboembolism excluding myocardial infarction • Perforation • Hepatic failure • Effect on bone development and growth in paediatric population • Effect on tooth development disorders in paediatric population
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 which are conditions of the marketing authorisation or specific obligation of Nintedanib.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Nintedanib.