Summary of the risk management plan for Nintedanib esilate, 100 mg and 150 mg,

Soft capsules

This is a summary of the risk management plan (RMP) for nintedanib esilate, 100 mg and 150 mg, soft capsules. The RMP details important risks of nintedanib esilate, soft capsules how these risks can be minimized, and how more information will be obtained about nintedanib esilate, soft capsules's risks and uncertainties (missing information).

Nintedanib esilate, soft capsules' summary of product characteristics (SmPCs) and its package leaflet give essential information to healthcare professionals and patients on how nintedanib esilate, soft capsules should be used.

Important new concerns or changes to the current ones will be included in updates of nintedenib esilate, soft capsules' RMP.

I. The medicine and what it is used for

Nintedenib esilate, soft capsules are authorized for:

- Nintedanib esilate is indicated in adults for the treatment of idiopathic pulmonary fibrosis (IPF).
- Nintedanib esilate is also indicated in adults for the treatment of other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.
- Nintedanib esilate is indicated in adults for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD).

It contains nintedanib esilate as an active substance and is taken orally as soft capsules (100 mg and 150 mg).

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of nintedenib esilate, soft capsules together with measures to minimize such risks and the proposed studies for learning more about nintedenib esilate, soft capsules' risks, are outlined below.

Measures to minimize 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 minimize its risks.

Together, these measures constitute *routine risk minimization* 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 esilate, soft capsules is not yet available, it is listed under 'missing information' below.

II.A: List of important risks and missing information

Important risks of nintedanib esilate, soft capsules are risks that need special risk management activities to further investigate or minimize 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 nintedanib esilate, soft capsules. 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 (VTE)
	• Arterial thromboembolism (ATE) 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-authorization development plan

II.C.1. Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of nintedanib esilate, soft capsules.

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

There are no studies required for nintedanib esilate, soft capsules.