Part VI: Summary of the risk management plan

Summary of risk management plan for Nintedanib Reddy (Nintedanib)

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

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

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

I. The medicine and what it is used for

Nintedanib Reddy is authorised in adults for the treatment of idiopathic pulmonary fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype, in children and adolescents from 6 to 17 years old for the treatment of clinically significant, progressive fibrosing interstitial lung diseases (ILDs), in adults, adolescents and children aged 6 years and older for the treatment of systemic sclerosis associated interstitial lung disease (SSc-ILD) and in combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology after first-line chemotherapy (see SmPC for the full indication). It contains nintedanib as the active substance and it is given by oral route of administration.

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

Important risks of Nintedanib Reddy, together with measures to minimise such risks and the proposed studies for learning more about Nintedanib Reddy'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.

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

II.A List of important risks and missing information

Important risks of Nintedanib Reddy 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 Reddy. 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);

Summary of safety concerns	
Important identified risks	• Diarrhoea (NSCLC) • Liver enzyme elevation and hyperbilirubinaemia including DILI (NSCLC) • DILI (IPF / ILD / SSc-ILD) • Neutropenia (NSCLC) • Sepsis (NSCLC) • Bleeding (IPF / ILD / SSc-ILD and NSCLC) • Hypertension (NSCLC) • Myocardial infarction (IPF / ILD / SSc-ILD and NSCLC) • VTE (NSCLC) • Perforation (GI and non-GI) (NSCLC) • Weight decreased in paediatric population (IPF / ILD / SSc-ILD)
Important potential risks	• Arterial thromboembolism excluding myocardial infarction (IPF / ILD / SSc-ILD and NSCLC) • Treatment in pregnant women and teratogenicity (NSCLC) • Venous thromboembolism (IPF / ILD /SSc-ILD) • Perforation (IPF / ILD / SSc-ILD) • Hepatic failure (IPF/ ILD / SSc-ILD and NSCLC) • Cardiac failure (NSCLC) • Effect on bone development and growth in paediatric population (IPF / ILD / SSc-ILD) • Effect on teeth development in paediatric population (IPF / ILD / SSc-ILD) • QT prolongation (NSCLC)
Missing information	• Treatment in breastfeeding women (NSCLC)

Summary of safety concerns	
	• Treatment of patients with moderate and severe hepatic impairment (Child Pugh B/C) (NSCLC) • Treatment of patients with renal impairment (NSCLC) • Treatment of patients with healing wounds (NSCLC) • Treatment of subpopulations with co-morbid CNS conditions such as dementia, depression, brain metastasis, or with co-morbid conditions such as arthritis and osteoporosis (NSCLC) • Treatment of patients weighing <50 kg (NSCLC) • Treatment of SSc-ILD patients with pulmonary hypertension (SSc-ILD)

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 Reddy.

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

There are no studies required for Nintedanib Reddy.