LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nintedanib Reddy
(nintedanib esilate)

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Summary Public Assessment Report

Nintedanib Reddy
nintedanib esilate, nintedanib

Capsule, soft, 100 mg, 150 mg

This is a summary of the public assessment report (PAR) for Nintedanib Reddy. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Nintedanib Reddy and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Ofev.

The product is used in the treatment of:
- Idiopathic pulmonary fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype and non-small cell lung cancer (NSCLC) in adults.
- Systemic sclerosis associated interstitial lung disease (SSc-ILD) in adults, adolescents and children aged 6 years and older.
- Clinically significant, progressive fibrosing interstitial lung diseases (ILDs) in children and adolescents from 6 to 17 years old.

How does Nintedanib Reddy work?
The product works by reducing further scarring and stiffening of the lungs. In NSCLC in adults, it can also help stop the growth and spread of the cancer.

How is Nintedanib Reddy used?
The pharmaceutical form is capsule (soft) for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Nintedanib Reddy have been shown in studies?
Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Ofev. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Nintedanib Reddy?
Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Nintedanib Reddy approved?
It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Ofev, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Nintedanib Reddy?
A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

The Applicant has committed to submit an updated ERA that is in line with the 2024 CHMP ERA guidelines within two years post approval: For more details, please see the full PAR for Nintedanib Reddy on the following website: MRI - Home.

Other information about Nintedanib Reddy
The full PAR for Nintedanib Reddy can be found on the following website: MRI - Home. For more information about treatment with Nintedanib Reddy, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2025-06.