LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nintedanib Newbury
(nintedanib, nintedanib esilate)

SE/H/02854/001-002

The Summary Public Assessment Report was written in 2024 by the previous RMS (IS) after initial procedure IS/H/0547/001-002/DC and is attached at the end of this document. RMS transfer from IS to SE was completed 18-05-2026.

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

CMDh/305/2013
March 2018, Rev.02

Summary Public Assessment Report

Generics

NINTEDANIB NEWBURY
Nintedanib esylate

IS/H/0547/001-002/DC

Date: 08.02.2024

Summary Public Assessment Report

Generics

NINTEDANIB NEWBURY
Nintedanib esylate, NINTEDANIB NEWBURY, soft capsule, 100 mg and 150 mg

This is a summary of the public assessment report (PAR) for NINTEDANIB NEWBURY. It explains how NINTEDANIB NEWBURY was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use NINTEDANIB NEWBURY.

For practical information about using NINTEDANIB NEWBURY, patients should read the package leaflet or contact their doctor or pharmacist.

What is NINTEDANIB NEWBURY and what is it used for?

NINTEDANIB NEWBURY is a 'generic medicine'. This means that NINTEDANIB NEWBURY is similar to a 'reference medicine' already authorised in the European Economic Area (EEA) called Ofev.

NINTEDANIB NEWBURY is

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

How does NINTEDANIB NEWBURY work?

The product belongs to the Pharmacotherapeutic group: Antineoplastic agents, protein kinase inhibitors, ATC code: L01EX09

NINTEDANIB NEWBURY contains the active substance nintedanib, a medicine belonging to the class of so-called tyrosine kinase inhibitors, and it is used for the treatment of idiopathic pulmonary fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype and systemic sclerosis associated interstitial lung disease (SSc-ILD) in adults.

How is NINTEDANIB NEWBURY used?

The pharmaceutical form of NINTEDANIB NEWBURY is soft capsules and the route of administration is for oral use.

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

The medicine can only be obtained with a prescription.

What benefits of NINTEDANIB NEWBURY have been shown in studies?
Because NINTEDANIB NEWBURY 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.

The company provided data from the published literature on nintedanib.

What are the possible side effects of NINTEDANIB NEWBURY?

Because NINTEDANIB NEWBURY is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

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

Why is NINTEDANIB NEWBURY approved?

It was concluded that, in accordance with EU requirements, NINTEDANIB NEWBURY has been shown to have comparable quality and to be bioequivalent/be comparable to reference medicine. Therefore, the Icelandic Medicines Agency decided that, as for reference medicine called Ofev, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of NINTEDANIB NEWBURY?

A risk management plan has been developed to ensure that NINTEDANIB NEWBURY 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 for NINTEDANIB NEWBURY, 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.

Other information about NINTEDANIB NEWBURY

The procedure NINTEDANIB NEWBURY was finalised on 21.12.2023.

The full PAR for NINTEDANIB NEWBURY can be found on the website for Human MRIndex. For more information about treatment with NINTEDANIB NEWBURY, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in February 2024.