LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nintedanib Eignapharma (nintedanib esilate)

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Summary Public Assessment Report

Nintedanib Eignapharma
nintedanib, nintedanib esilate

Capsule, soft, 100 mg, 150 mg

This is a summary of the public assessment report (PAR) for Nintedanib Eignapharma. 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 Eignapharma 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
- Systemic sclerosis associated interstitial lung disease (SSc-ILD)

How does Nintedanib Eignapharma work?

Nintedanib Eignapharma contains the active substance nintedanib, a medicine belonging to the class of so-called tyrosine kinase inhibitors. Nintedanib Eignapharma helps to reduce further scarring and stiffening of the lungs.

How is Nintedanib Eignapharma 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 Eignapharma 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 Eignapharma?

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 Eignapharma 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 Eignapharma?

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.

Other information about Nintedanib Eignapharma

The full PAR for Nintedanib Eignapharma can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Nintedanib Eignapharma , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-06.