LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nintedanib Glenmark (nintedanib)

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Summary Public Assessment Report

Nintedanib Glenmark
nintedanib

Capsule, soft, 100 mg, 150 mg

This is a summary of the public assessment report (PAR) for Nintedanib Glenmark. 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 Glenmark 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.

Nintedanib Glenmark 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 the following diseases:

- Idiopathic pulmonary fibrosis (IPF) in adults
- Other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype in adults
- Clinically significant, progressive fibrosing interstitial lung diseases (ILDs) in children and
- adolescents from 6 to 17 years old
- Systemic sclerosis associated interstitial lung disease (SSc-ILD) in adults, adolescents and children aged 6 years and older

How does Nintedanib Glenmark work?

Idiopathic pulmonary fibrosis (IPF) in adults
IPF is a condition in which the tissue in your lungs becomes thickened, stiff and scarred over time. As a result, scarring reduces the ability to transfer oxygen from the lungs into the bloodstream and it becomes difficult to breathe deeply. Nintedanib Glenmark helps to reduce further scarring and stiffening of the lungs.

Other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype in adults
Besides IPF, there are other conditions in which the tissue in your lungs becomes thickened, stiff, and scarred over time (lung fibrosis) and keeps worsening (progressive phenotype). Examples of these conditions are hypersensitivity pneumonitis, autoimmune ILDs (e.g. rheumatoid arthritis associated ILD), idiopathic nonspecific interstitial pneumonia, unclassifiable idiopathic interstitial pneumonia, and other ILDs. Nintedanib Glenmark helps to reduce further scarring and stiffening of the lungs.

Clinically significant, progressive fibrosing interstitial lung diseases (ILDs) in children and adolescents from 6 to 17 years old
Lung fibrosis may occur in patients with Childhood Interstitial Lung Disease (chILD). When this is the case, the tissue in the lungs of children and adolescents becomes thickened, stiff, and scarred over time. Nintedanib Glenmark helps to reduce further scarring and stiffening of the lungs.

Systemic sclerosis associated interstitial lung disease (SSc-ILD) in adults, adolescents and children aged 6 years and older
Systemic sclerosis (SSc), also known as scleroderma (and juvenile systemic sclerosis in children and adolescents), is a rare chronic autoimmune disease that affects connective tissue in many parts of the body. SSc causes fibrosis (scarring and stiffening) of the skin and other internal organs such as the lungs. When the lungs are affected by fibrosis, it is called interstitial lung disease (ILD), and so the

condition is called SSc-ILD. Fibrosis in the lungs reduces the ability to transfer oxygen into the bloodstream, and breathing capacity is reduced. Nintedanib Glenmark helps to reduce further scarring and stiffening of the lungs.

How is Nintedanib Glenmark used?
The pharmaceutical form is soft capsule 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 Glenmark have been shown in studies?

Because the product is a generic medicine, studies 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 Glenmark?

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 Glenmark 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 Glenmark?

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.

For more details, please see the full PAR for Nintedanib Glenmark on the following website: MRI - Home.

Other information about Nintedanib Glenmark

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

This summary was last updated in 2026-02.