

The medicine is dispensed with a doctor’s prescription only

# Nintomed

## 100 mg

### Soft capsules

Nintedanib (as esylate)

Each Nintomed 100 mg capsule contains 100 mg nintedanib (as esylate)

# Nintomed

## 150 mg

### Soft capsules

Nintedanib (as esylate)

Each Nintomed 150 mg capsule contains 150 mg nintedanib (as esylate)

For a list of inactive ingredients and allergens in the preparation, see section 6 – “Additional information”. In addition, see section 2 – “Important information about some of the ingredients of the medicine”.

**Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others, it may harm them even if it seems to you that their medical condition is similar.

<p><b>Highly important information for women of childbearing age:</b></p> <ul style="list-style-type: none"><li><b>Nintomed may cause birth defects or death of the unborn baby. Do not become pregnant during treatment with Nintomed. Women who can become pregnant must have a pregnancy test before starting treatment with Nintomed.</b></li> <li><b>Women who can become pregnant must use highly effective contraception methods at the beginning of treatment, during treatment with Nintomed and for at least 3 months after taking the last dose. Talk to the doctor about which method of contraception is suitable for you during this period.</b></li> <li><b>Contraceptive pills may not be effective in women who suffer from vomiting, diarrhea or other problems that reduce the absorption of the medicine. If you suffer from any of these problems, consult the doctor regarding which contraceptive is especially effective and right for you.</b></li> <li><b>Inform the doctor immediately if you become pregnant or think you are pregnant during treatment with Nintomed.</b></li></ul>
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#### 1. **What is the medicine intended for?**

- The medicine is intended for treatment of a lung disease called idiopathic pulmonary fibrosis (IPF) in adults.
- The medicine is intended for treatment of adults with chronic (long lasting) fibrosing interstitial lung diseases (ILDs) with a progressive phenotype.
- The medicine is intended to slow the rate of decline in pulmonary function in people with systemic sclerosis associated with interstitial lung disease (SSc-ILD).

**Therapeutic class:** kinase inhibitor.

#### 2. **Before using the medicine**

<p><b>Do not use this medicine if:</b></p> <ul style="list-style-type: none"><li>You are sensitive (allergic) to the active ingredient nintedanib, to soy, to peanuts or to any of the other ingredients this medicine contains (for the list of inactive ingredients see section 6 – “Additional information” and under section 2 –“Important information about some of the ingredients of the medicine”).</li> <li>You are pregnant or breastfeeding. See information in the box above.</li></ul>
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#### Special warnings regarding the use of the medicine

**Before treatment with Nintomed, tell the doctor about all of your medical conditions, including if:**

- You suffer from liver problems.
- You suffer from heart problems.
- You have a history of blood clots.
- You have bleeding problems or a family history of bleeding problems.
- You have recently had surgery in the stomach area.
- You smoke.
- You are pregnant or planning to become pregnant. Nintomed may harm your unborn baby. Nintomed may cause birth defects or death of the unborn baby. Please see section “Highly important information for women of childbearing age” as well as the section “Pregnancy and breastfeeding”.
- You are breastfeeding or are planning to breastfeed. It is not known whether Nintomed passes into breast milk. **Do not** breastfeed during treatment with Nintomed. Please see section “Pregnancy and breastfeeding”.
- You suffer from hypertension.
- You suffer or have previously suffered from an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.
- You have an increased amount of protein in the urine (proteinuria).

Refer to a doctor **immediately** if during treatment with Nintomed you develop bruising, bleeding, fever, tiredness and confusion. This may be a sign of damage to blood vessels called thrombotic microangiopathy (thrombosis in small blood vessels).

For additional special warnings regarding the following serious side effects, see section 4 “Side effects”:

- Liver problems
- Diarrhea, nausea and vomiting
- Heart attack
- Stroke
- Bleeding problems
- Tear in the stomach or intestinal wall (perforation) and inflammation of the large intestine which impairs the blood flow to the area (ischemic colitis)
- Increased amount of protein in your urine (proteinuria)

#### Smoking

**If you are a smoker**, it is recommended to stop smoking before starting treatment with Nintomed and during treatment. Smoking may decrease the effectiveness of the treatment.

#### Children and adolescents

Nintomed is not intended for use in children and adolescents under the age of 18, since it is not known whether the medicine is safe and effective in children and adolescents.

#### Tests and follow-up

Your doctor should order certain blood tests before starting treatment with Nintomed.

**You should have a pregnancy test before starting treatment with Nintomed.**

Before starting treatment and during treatment with Nintomed, the doctor will perform blood tests to check your liver function.

#### Drug interactions

**If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.** Especially inform the doctor or pharmacist if you are taking:

- Ketoconazole (for treatment of fungal infection), erythromycin (an antibiotic) – may increase the level of Nintomed in the blood.
- Hypericum (St. John’s Wort, a herbal medicine for the treatment of depression), rifampicin (an antibiotic), carbamazepine and phenytoin (for treatment of epilepsy) – may decrease the level of Nintomed in the blood.
- Anticoagulants – the risk of bleeding may increase when combined with Nintomed.

Keep a list of the medicines that you are taking and show it to the doctor and pharmacist upon receiving a new medicine.

#### Use of the medicine and food

Take Nintomed capsules during mealtime. See section 3 – “How should you use the medicine”.

#### Pregnancy and breastfeeding

If you are pregnant, think you are pregnant or are planning to become pregnant, as well as if you are breastfeeding or planning to breastfeed, consult the doctor or pharmacist before starting to use this medicine. **Please see above “Highly important information for women of childbearing age”.** **Nintomed may cause birth defects or death of the unborn baby. Do not become pregnant during treatment with Nintomed.**

Do not breastfeed during treatment with Nintomed since the risk of harming your baby cannot be ruled out. It is not known whether Nintomed passes into breast milk.

#### Important information about some of the ingredients of the medicine

Nintomed contains soy lecithin. If you are allergic to peanuts or soy, do not use this medicine.

#### 3. **How should you use the medicine?**

Always use the preparation according to the doctor’s instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation. The dosage and treatment regimen will be determined by your doctor only.

The accepted dosage of Nintomed is 150 mg twice a day administered orally, 12 hours apart. Your doctor may decide to change the dosage according to your blood tests or side effects.

**Do not take** more than 300 mg Nintomed a day. **Do not exceed the recommended dose.**

Take the medicine during a meal. Swallow the capsule whole with a drink. **Do not chew or crush Nintomed capsules because of the bitter taste of the preparation.**

**Do not crush or open Nintomed capsules.** If you or your caregiver accidentally comes in contact with the capsule’s content, immediately wash your hands thoroughly.

**If you accidentally took a higher dose** or if a child accidentally swallowed the medicine, **immediately** refer to a doctor or proceed to the nearest hospital emergency room and bring the package of the medicine with you.

#### If you forgot to take the medicine

If you forgot to take this medicine at the required time, **do not take** the forgotten dose; take the next dose of Nintomed as planned at the scheduled time at the dosage recommended by the doctor.

Do not take a double dose. Follow the treatment as recommended by the doctor. Even if there is an improvement in your health condition, do not stop treatment with the medicine without consulting the doctor.

#### If you stop taking the medicine

Do not stop treatment with the medicine without consulting the doctor.

**Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.**

#### 4. **Side effects**

As with any medicine, using Nintomed may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

**Nintomed may cause severe side effects, including:**

- If used to treat pregnant women, Nintomed may cause birth defects or death of the unborn baby (see the box at the beginning of the leaflet “Highly important information for women of childbearing age”).**
- Liver problems.** Refer to a doctor **immediately** if you suffer from unexplained side effects such as: yellowing of the skin or of the white part of the eyes (jaundice), dark or brown (tea-colored) urine, pain in the upper right side of the stomach area, bleeding or bruising more easily than usual, feeling tired, anorexia or decreased appetite. Before starting the treatment and during treatment with Nintomed, the doctor will perform blood tests to check the liver function.
- Diarrhea, nausea and vomiting (very common side effects – effects that occur in more than 1 user out of 10):** during the treatment with Nintomed, the doctor may recommend that you drink fluids or take medicines for treatment of these side effects. Tell the doctor if you suffer from diarrhea, nausea or vomiting or if these symptoms worsen or do not go away. **If you suffer from diarrhea, inform the doctor immediately upon the appearance of the first sign.** Tell the doctor if you are taking non-prescription laxatives, stool softeners and other medicines or nutritional supplements that may cause diarrhea.
- Heart attack (an effect that occurs in 1 to 10 users out of 100):** refer to a doctor **immediately** if you experience symptoms of a heart problem. These symptoms may include: chest pain or tightness in the chest, pain in the arms, back, neck or jaw or shortness of breath.
- Stroke.** Refer to a doctor **immediately** if you experience symptoms of a stroke. These symptoms may include: numbness or weakness on one side of your body, difficulty speaking, headache or dizziness.
- Bleeding problems.** Nintomed may increase your chance of bleeding problems. Tell the doctor if you suffer from abnormal bleeding, bruising or non-healing wounds. Tell the doctor if you are taking blood thinners, including prescription blood thinners and non-prescription aspirin.
- Tear in the stomach or intestinal wall (perforation) and inflammation of the large intestine which impairs the blood flow to the area (ischemic colitis).** Nintomed may increase your chance of a tear in the stomach or intestinal wall. Tell the doctor if you suffer from pain or swelling in the stomach area. **Inflammation of the large intestine which impairs the blood flow to the area** (ischemic colitis) has also been reported.
- Increased amount of protein in your urine (proteinuria).** Nintomed may increase your chance of having protein in the urine. Tell the doctor if you have any signs and symptoms of protein in the urine, such as: foamy urine, swelling, including in your hands, arms, legs or feet or sudden weight gain.
- Thrombosis in small blood vessels.** Refer to a doctor immediately if during treatment with Nintomed you develop bruising, bleeding, fever, tiredness and confusion. This may be a sign of damage to blood vessels called thrombotic microangiopathy (thrombosis in small blood vessels).

The additional side effects listed below are classified according to their frequency of appearing:

**Very common side effects – effects that occur in more than 1 user out of 10:**

- Stomach pain
- Increased liver enzymes
- Decreased appetite
- Weight loss
- Skin ulcers
- Tiredness
- Nasopharyngitis

**Common side effects – effects that occur in 1-10 users out of 100:**

- Headache
- Hypertension
- Back pain
- Dizziness
- Fever
- Inflammation of the upper respiratory tract
- Alopecia
- Inflammation of the bronchi (bronchitis)
- Underactive thyroid gland (hypothyroidism)
- Pneumonia
- Urinary tract inflammation
- Interstitial lung disease

**Uncommon side effects – effects that occur in 1-10 users out of 1,000:**

- Tumor in the lung

**Additional side effects reported post-marketing:**

- Low level of platelets in the blood (thrombocytopenia)
- Pancreatitis
- Liver injury (DILI)
- Posterior reversible encephalopathy syndrome – a brain condition with symptoms such as: headache, changes in vision, confusion, convulsions or other neurological disorders, such as: weakness in the arm or leg, with or without high blood pressure
- Increased amount of protein in the urine (proteinuria)
- Itch
- Rash
- Serious bleeding events (some of which are life-threatening) and non-serious bleeding events
- Enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.**

#### Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage ([www.health.gov.il](http://www.health.gov.il)), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

#### 5. **How to store the medicine?**

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the carton and the blister package. The expiry date refers to the last day of that month.

#### Storage conditions:

Store below 25°C.

Do not use this medicine if the package is damaged.

Do not discard medicines in wastewater or domestic trash. Ask the pharmacist how to dispose of medicines you no longer use.

These measures will help protect the environment.

#### 6. **Additional information**

- In addition to the active ingredient, the medicine also contains: Triglycerides, hard fat, soya lecithin. Gelatin shell Nintomed 100 mg: gelatin, purified water, glycerol, titanium dioxide, yellow iron oxide, red iron oxide. Gelatin shell Nintomed 150 mg: gelatin, purified water, glycerol, yellow iron oxide, red iron oxide, titanium dioxide. Imprinting ink: Opacode® WB black (Ferroso ferric oxide, HPMC 2910/Hypromellose)
- What does the medicine look like and what are the contents of the package? Nintomed 100 mg: peach opaque color, oblong shape, soft gelatin capsule imprinted with “N100” in black. Nintomed 150 mg: brown opaque color, oblong shape, soft gelatin capsule imprinted with “N150” in black. The medicine is supplied in a package, as described: Carton packages that contain trays/blisters with a total of 60 soft capsules.
- License holder and importer: Inovamed Pharma Ltd., P.O. Box 2349, Bnei Brak.
- Manufacturer: Eugia Pharma Specialties Ltd., Hyderabad, India.
- Revised in February 2025.
- Registration numbers of the medicines in the national drug registry of the Ministry of Health: Nintomed 100 mg: 177-66-37877 Nintomed 150 mg: 177-67-37878