

Package leaflet: Information for the patient

Nintedanib 150 mg soft capsules nintedanib

Nintedanib 150 mg soft capsules will also be referred to in this leaflet as Nintedanib capsules.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Nintedanib capsules are and what they are used for
2. What you need to know before you take Nintedanib capsules
3. How to take Nintedanib capsules
4. Possible side effects
5. How to store Nintedanib capsules
6. Contents of the pack and other information

1. What Nintedanib capsules are and what they are used for

Nintedanib capsules contain 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

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 capsules help 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 capsules help to reduce further scarring and stiffening of the lungs.

Systemic sclerosis associated interstitial lung disease (SSc-ILD) in adults

Systemic sclerosis (SSc), also known as scleroderma, 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 capsules help to reduce further scarring and stiffening of the lungs.

Non-small cell lung cancer (NSCLC) in adults

By blocking the activity of a group of proteins which are involved in the development of new blood vessels that cancer cells need to supply them with nutrition and oxygen, nintedanib can help stop the growth and spread of the cancer.

Nintedanib capsules are used in combination with another cancer medicine (docetaxel) to treat a cancer of the lung called non-small cell lung cancer (NSCLC). It is for adult patients whose NSCLC is

of a certain type (“*adenocarcinoma*”) and who had already received one treatment with another medicine to treat this cancer but whose tumour started to grow again.

2. What you need to know before you take Nintedanib capsules

Do not take Nintedanib capsules

- if you are allergic to nintedanib or any of the other ingredients of this medicine (listed in section 6).
- for the treatment of IPF, ILD or SSc-ILD if you are pregnant.

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine

- if you have or have had liver problems.
- if you have or have had problems with your kidneys, or if an increased amount of protein has been detected in your urine.
- if you have or have had bleeding problems, particularly recent bleeding in the lung.
- if you take blood-thinning medicines (such as warfarin, phenprocoumon, heparin or acetylsalicylic acid) to prevent blood clotting. Treatment with Nintedanib capsules may lead to a higher risk of bleeding.
- if you take pirfenidone as this may increase the risk of having diarrhoea, nausea, vomiting and liver problems.
- if you have or have had problems with your heart (for example a heart attack).
- if you have recently had surgery or plan to have a surgery. Nintedanib may affect the way your wounds heal. Therefore, your treatment with Nintedanib capsules will usually be stopped for a while if you are having a surgery. Your doctor will decide when to resume your treatment with this medicine.
- if you have high blood pressure.
- if you have abnormally high blood pressure in the blood vessels of the lungs (pulmonary hypertension).
- if you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.
- if you have cancer that has spread to the brain.

Based on this information your doctor may do some blood tests, for example to check your liver function and to determine how fast your blood can clot. Your doctor will discuss the results of these tests with you and decide whether you may receive Nintedanib capsules.

Inform your doctor immediately while taking this medicine

- if you get diarrhoea. Treating diarrhoea early is important (see section 4).
- if you vomit or feel sick (nausea).
- if you have unexplained symptoms such as yellowing of your skin or the white part of your eyes (jaundice), dark or brown (tea coloured) urine, pain on the upper right side of your stomach area (abdomen), bleeding or bruising more easily than normal, or feeling tired. This could be symptoms of serious liver problems.
- if you have severe pain in your stomach, fever, chills, sickness, vomiting, or abdominal rigidity or bloating, as these could be symptoms of a hole in the wall of your gut (‘gastrointestinal perforation’). Also, tell your doctor if you had peptic ulcers or diverticular disease in the past, or are concomitantly treated with anti-inflammatory drugs (NSAIDs) (used to treat pain relief and swelling) or steroids (used for inflammation and allergies), as this may increase this risk.
- if you have a combination of severe pain or cramping in your stomach, red blood in your stool, diarrhoea, constipation, nausea or vomiting as these could be symptoms of a bowel inflammation from reduced blood flow (‘ischaemic colitis’).
- if you have pain, swelling, reddening, warmth of a limb or if you experience chest pain and difficulty to breathe as this could be symptoms of a blood clot in one of your veins (a type of blood vessel).

- if you have chest pressure or pain, typically on the left side of the body, pain in the neck, jaw, shoulder or arm, a fast heartbeat, shortness of breath, nausea, vomiting, as this could be symptoms of a heart attack.
- if you have any major bleeding.
- if you experience bruising, bleeding, fever, fatigue and confusion. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA).
- if you experience symptoms such as headache, vision changes, confusion, seizure or other neurologic disturbances such as weakness in an arm or a leg, with or without high blood pressure. This could be symptoms of a brain condition called posterior reversible encephalopathy syndrome (PRES).
- if you develop fever, chills, fast breathing or a fast heartbeat. These could be signs of infection or infection of the blood (sepsis) (see section 4).
- if any side effect(s) you may get (see section 4) becomes serious.

Children and Adolescents

Nintedanib capsules should not be taken by children and adolescents under 18 years of age.

Other medicines and Nintedanib capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including herbal medicines and medicines obtained without a prescription.

Nintedanib capsules can interact with certain other medicines. The following medicines are examples that may increase the levels of nintedanib in your blood, and hence may increase the risk for side effects (see section 4):

- a medicine used to treat fungal infections (ketoconazole)
- a medicine used to treat bacterial infections (erythromycin)
- a medicine that affects your immune system (cyclosporine)

The following medicines are examples that may lower the levels of nintedanib in your blood and thus may reduce the effectiveness of Nintedanib capsules:

- an antibiotic used to treat tuberculosis (rifampicin)
- medicines to treat seizures (carbamazepine, phenytoin)
- a herbal medicine to treat depression (St. John's Wort)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take this medicine during pregnancy, as it can harm your unborn baby and cause birth defects.

You must have a pregnancy test done to ensure you are not pregnant before starting treatment with Nintedanib capsules. Please talk to your doctor.

Contraception

- Women who can become pregnant must use a highly effective method of birth control to prevent pregnancy when they start taking Nintedanib capsules, while they are taking Nintedanib capsules and for at least 3 months after stopping treatment.
- You should discuss the most appropriate methods of contraception for you with your doctor.
- Vomiting and/or diarrhoea or other gastrointestinal conditions can affect the absorption of oral hormonal contraceptives, such as birth control pills, and may reduce their effectiveness. Therefore, if experiencing these, talk to your doctor to discuss an alternative more appropriate method of contraception.
- Tell your doctor or pharmacist immediately if you become pregnant or think you may be pregnant during treatment with Nintedanib capsules.

Breast-feeding

Do not breast-feed during the treatment with Nintedanib capsules since there may be a risk of harm to the breast-fed child.

Fertility

The effect of this medicine on human fertility has not been investigated.

Driving and using machines

Nintedanib capsules may have minor influence on your ability to drive and use machines. You should not drive or use machines if you feel sick.

3. How to take Nintedanib capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For 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)

Take the capsules twice daily approximately 12 hours apart at about the same time every day, for example one capsule in the morning and one capsule in the evening. This ensures that a steady amount of nintedanib is maintained in your blood stream. Swallow the whole capsules with water and do not chew the capsules. It is recommended that you take the capsules with food, i.e. during or immediately before or after a meal. Do not open or crush the capsule (see section 5). For the ease of swallowing, you can take the capsules with a small amount (one teaspoonful) of cold or room temperature soft food, such as apple sauce or chocolate pudding. Swallow immediately and do not chew the capsule to ensure it stays intact.

Adults

The recommended dose is one capsule of 150 mg twice daily (a total of 300 mg per day). Do not take more than the recommended dose of two Nintedanib 150 mg capsules per day.

If you do not tolerate the recommended dose of two Nintedanib 150 mg capsules per day (see possible side effects in section 4), your doctor may reduce the daily dose of Nintedanib capsules. Do not reduce the dose or stop the treatment by yourself without consulting your doctor first.

Your doctor may reduce your recommended dose to two times 100 mg per day (a total of 200 mg per day). In this case your doctor will prescribe Nintedanib 100 mg capsules for your treatment. Do not take more than the recommended dose of two Nintedanib 100 mg capsules per day if your daily dose was reduced to 200 mg per day.

For treatment of non-small cell lung cancer (NSCLC)

Do not take Nintedanib capsules on the same day as your chemotherapy treatment with docetaxel.

Swallow the capsules whole with water and do not chew them. It is recommended to take the capsules with food, i.e. during or immediately before or after a meal. Do not open or crush the capsule (see section 5).

The recommended dose is two capsules per day (this is a total of 300 mg nintedanib per day). Do not take more than this dose.

This daily dose should be split into two doses of one capsule about 12 hours apart, for example one capsule in the morning and one capsule in the evening. The two doses should be taken at around the same time each day. Taking the medicine this way ensures that a steady amount of nintedanib is maintained in the body.

Dose reduction

If you cannot tolerate the recommended dose of 300 mg per day because of side effects (see section 4), your doctor may reduce your recommended daily dose of Nintedanib capsules to 200 mg per day (two capsules of 100 mg). In this case your doctor will prescribe Nintedanib 100 mg soft capsules for your treatment.

You should take one capsule of this strength twice daily approximately 12 hours apart with food (for example in the morning and in the evening) at about the same time of the day.

Do not reduce the dose or stop the treatment yourself without consulting your doctor first.

In case your doctor has stopped your chemotherapy with docetaxel you should continue to take Nintedanib capsules twice daily.

If you take more Nintedanib capsules than you should

Contact your doctor or pharmacist immediately.

If you forget to take Nintedanib capsules

Do not take a double dose if you have forgotten to take your earlier dose. You should take your next dose of Nintedanib capsules as planned at the next scheduled time recommended by your doctor or pharmacist.

If you stop taking Nintedanib capsules

Do not stop taking Nintedanib capsules without consulting your doctor first. It is important to take this medicine every day, as long as your doctor prescribes it for you.

Non-small cell lung cancer (NSCLC)

If you do not take this medicine as prescribed by your doctor, this cancer treatment may not work properly.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Idiopathic pulmonary fibrosis (IPF), other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype and systemic sclerosis associated interstitial lung disease (SSc-ILD)

You need to pay special attention if you get the following side effects during treatment with Nintedanib capsules:

Diarrhoea (very common, may affect more than 1 in 10 people)

Diarrhoea may lead to dehydration: a loss of fluid and important salts (electrolytes, such as sodium or potassium) from your body. At the first signs of diarrhoea drink plenty of fluids and contact your doctor immediately. Start appropriate anti-diarrhoeal treatment, e.g. with loperamide, as soon as possible.

The following other side effects were observed during treatment with this medicine.

Talk to your doctor if you get any side effects.

Idiopathic pulmonary fibrosis (IPF)

Very common side effects (may affect more than 1 in 10 people)

- Feeling sick (nausea)
- Pain in the lower body (abdomen)

- Abnormal liver test results

Common side effects (may affect up to 1 in 10 people)

- Vomiting
- Loss of appetite
- Weight loss
- Bleeding
- Rash
- Headache

Uncommon side effects (may affect up to 1 in 100 people)

- Pancreatitis
- Inflammation of the large bowel
- Serious liver problems
- Low platelet count (thrombocytopenia)
- High blood pressure (hypertension)
- Jaundice, that is a yellow colour to the skin and whites of the eyes due to high levels of bilirubin
- Itching
- Heart attack
- Hair loss (alopecia)
- Increased amount of protein in your urine (proteinuria)

Not known (cannot be estimated from the available data)

- Renal failure
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)
- A brain condition with symptoms such as headache, vision changes, confusion, seizure or other neurologic disturbances such as weakness in an arm or a leg, with or without high blood pressure (posterior reversible encephalopathy syndrome)

Other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype

Very common side effects (may affect more than 1 in 10 people)

- Feeling sick (nausea)
- Vomiting
- Loss of appetite
- Pain in the lower body (abdomen)
- Abnormal liver test results

Common side effects (may affect up to 1 in 10 people)

- Weight loss
- High blood pressure (hypertension)
- Bleeding
- Serious liver problems
- Rash
- Headache

Uncommon side effects (may affect up to 1 in 100 people)

- Pancreatitis
- Inflammation of the large bowel
- Low platelet count (thrombocytopenia)
- Jaundice, that is a yellow colour to the skin and whites of the eyes due to high levels of bilirubin
- Itching
- Heart attack
- Hair loss (alopecia)

- Increased amount of protein in your urine (proteinuria)

Not known (cannot be estimated from the available data)

- Renal failure
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)
- A brain condition with symptoms such as headache, vision changes, confusion, seizure or other neurologic disturbances such as weakness in an arm or a leg, with or without high blood pressure (posterior reversible encephalopathy syndrome)

Systemic sclerosis associated interstitial lung disease (SSc-ILD)

Very common side effects (may affect more than 1 in 10 people)

- Feeling sick (nausea)
- Vomiting
- Pain in the lower body (abdomen)
- Abnormal liver test results

Common side effects (may affect up to 1 in 10 people)

- Bleeding
- High blood pressure (hypertension)
- Loss of appetite
- Weight loss
- Headache

Uncommon side effects (may affect up to 1 in 100 people)

- Inflammation of the large bowel
- Serious liver problems
- Renal failure
- Low platelet count (thrombocytopenia)
- Rash
- Itching

Not known (cannot be estimated from the available data)

- Heart attack
- Pancreatitis
- Jaundice, that is a yellow colour to the skin and whites of the eyes due to high levels of bilirubin
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)
- Hair loss (alopecia)
- Increased amount of protein in your urine (proteinuria)
- A brain condition with symptoms such as headache, vision changes, confusion, seizure or other neurologic disturbances such as weakness in an arm or a leg, with or without high blood pressure (posterior reversible encephalopathy syndrome)

Non-small cell lung cancer (NSCLC)

You need to pay special attention if you get the following side effects during treatment with Nintedanib capsules:

- Diarrhoea (very common, may affect more than 1 in 10 people)
Diarrhoea may lead to a loss of fluid and important salts (electrolytes, such as sodium or potassium) in your body. At the first signs of diarrhoea drink plenty of fluids and contact your doctor immediately. Start appropriate anti-diarrhoeal treatment, e.g. with loperamide, as soon as possible after having contacted your doctor.

- **Febrile neutropenia and sepsis (common, may affect up to 1 in 10 people)**
Treatment with Nintedanib capsules may lead to a reduced number of a type of your white blood cells (neutropenia) which are important for the body's reaction against bacterial or fungal infections. As a consequence of neutropenia, fever (febrile neutropenia) and blood infection (sepsis) may occur. Tell your doctor immediately if you develop fever, chills, fast breathing or a fast heartbeat.
During treatment with Nintedanib capsules your doctor will regularly monitor your blood cells and examine you for signs of infection, such as inflammation, fever or tiredness.

The following side effects were observed under treatment with this medicine:

Very common side effects (may affect more than 1 in 10 people)

- Diarrhoea – please see above
- Painful, numb and/or tingling feeling in fingers and toes (peripheral neuropathy)
- Feeling sick (nausea)
- Throwing up (vomiting)
- Pain in the stomach (abdomen)
- Bleeding
- Decrease in the number of white blood cells (neutropenia)
- Inflammation of the mucous membranes lining the digestive tract including sores and ulcers in the mouth (mucositis, including stomatitis)
- Rash
- Decreased appetite
- Electrolyte imbalance
- Increased liver enzyme values (alanine aminotransferase, aspartate aminotransferase, blood alkaline phosphatase) in the blood as seen from blood tests
- Hair loss (alopecia)

Common side effects (may affect up to 1 in 10 people)

- Blood poisoning (sepsis) – please see above
- Decrease in the number of white blood cells accompanied by fever (febrile neutropenia)
- Blood clots in the veins (venous thromboembolism), especially in the legs (symptoms include pain, redness, swelling, and warmth of a limb), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing (if you notice any of these symptoms, seek medical advice immediately)
- High blood pressure (hypertension)
- Fluid loss (dehydration)
- Abscesses
- Low platelet count (thrombocytopenia)
- Jaundice (hyperbilirubinaemia)
- Increased liver enzyme values (gamma-glutamyltransferase) in the blood as seen from blood tests
- Weight loss
- Itching
- Headache
- Increased amount of protein in your urine (proteinuria)

Uncommon side effects (may affect up to 1 in 100 people)

- Occurrence of holes in the wall of your gut (gastrointestinal perforation)
- Serious liver problems
- Inflammation of the pancreas (pancreatitis)
- Myocardial infarction
- Renal failure

Not known (cannot be estimated from the available data)

- Inflammation of the large bowel
- An enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)
- A brain condition with symptoms such as headache, vision changes, confusion, seizure or other neurologic disturbances such as weakness in an arm or a leg, with or without high blood pressure (posterior reversible encephalopathy syndrome)

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nintedanib capsules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not use this medicine if you notice that the blister containing the capsules is opened or a capsule is broken.

If you are in contact with the content of the capsule, wash off your hands immediately with plenty of water (see section 3).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Nintedanib capsules contain

- The active substance is nintedanib. Each capsule contains nintedanib esilate equivalent to 150 mg nintedanib.
- The other ingredients are:
 - Capsule fill: triglycerides, medium-chain, hard fat, polysorbate 80 and sorbitan oleate.
 - Capsule shell: gelatin, glycerol, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172) and purified water.
 - Printing ink: Shellac glaze, iron oxide black (E172) and propylene glycol (E1520).

What Nintedanib capsules look like and contents of the pack

Brown coloured, opaque, oblong, soft gelatin capsules (approx. 17 mm x 7 mm) filled with bright yellow coloured suspension and imprinted with “150” in black ink.

The capsules are available in blister and perforated unit dose blister in following pack-sizes: 30, 60 and 120.

Not all pack-sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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