PACKAGE LEAFLET

Package leaflet: Information for the patient

Nintedanib Norton 100 mg soft capsules
nintedanib

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

1. What Nintedanib Norton is and what it is used for

Nintedanib Norton 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
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 Norton 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 Norton 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 Norton 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 Norton helps to reduce further scarring and stiffening of the lungs.

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

Do not take Nintedanib Norton
- if you are pregnant,
- if you are allergic to nintedanib, peanut or soya, or any of the other ingredients of this medicine (listed in section 6)

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,
- if you take blood-thinning medicines (such as warfarin, phenprocoumon or heparin) to prevent blood clotting,
- 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. Nintedanib may affect the way your wounds heal. Therefore, your treatment with Nintedanib Norton 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.

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

Inform your doctor immediately while taking this medicine,
- if you get diarrhoea. Treating diarrhoea early is important (see section 4 “Possible side effects”);
- 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 or diarrhea as these could be symptoms of a bowel inflammation from inadequate blood supply;
- if you have pain, swelling, reddening, warmth of a limb 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).

Children and adolescents
Nintedanib Norton should not be taken by children under 6 years of age.
Your doctor may perform regular dental examinations at least every 6 months until development of teeth is completed, and monitor your growth annually (bone imaging) while you take this medicine.

Other medicines and Nintedanib Norton
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 Norton 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 "Possible side effects");):
- 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 Norton:
- an antibiotic used to treat tuberculosis (rifampicin)
- medicines to treat seizures (carbamazepine, phenytoin)
- a herbal medicine to treat depression (St. John's Wort)

Pregnancy and breast-feeding
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 Norton. 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 Norton, while they are taking Nintedanib Norton 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 Norton.

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

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

Nintedanib Norton contains soya lecithin
If you are allergic to soya or peanut, do not take this medicine (see section 2 'Do not take Nintedanib Norton').

3. How to take Nintedanib Norton

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

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 'How to store Nintedanib Norton).
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 100 mg twice daily (a total of 200 mg per day). Do not take more than the recommended dose of two Nintedanib Norton 100 mg capsules per day.

If you do not tolerate the recommended dose of two Nintedanib Norton 100 mg capsules per day (see possible side effects in section 4) your doctor may advise you to stop taking this medicine. Do not reduce the dose or stop the treatment by yourself without consulting your doctor first.

Use in children and adolescents
The recommended dose depends on the weight of the patient.
Tell your doctor if any time during the treatment the weight of the patient is below 13.5 kg. Tell your doctor if you have liver problems.
Your doctor will determine the correct dose. Your doctor may adjust the dose as treatment progresses. If you do not tolerate the recommended dose of nintedanib capsules per day (see possible side effects in section 4) your doctor may reduce the daily dose of nintedanib.
Do not reduce the dose or stop the treatment by yourself without consulting your doctor first.
Weight-Based dosing for nintedanib capsules in children and adolescents:

Weight range in kilograms (kg)	Nintedanib dose in milligrams (mg)
13.5 - 22.9 kg	50 mg (two 25 mg capsules*) twice daily
23.0 - 33.4 kg	75 mg (three 25 mg capsules*) twice daily
33.5 - 57.4 kg	100 mg (one 100 mg capsule or four 25 mg capsules*) twice daily
57.5 kg and above	150 mg (one 150 mg capsule or six 25 mg capsules*) twice daily

* **25 mg capsules:** Other nintedanib-containing medicinal products are available at 25 mg strength

If you take more Nintedanib Norton than you should
Contact your doctor or pharmacist immediately.

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

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

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.

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

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)
- Fibrosing interstitial lung diseases (ILDs) in children and adolescents

Side effects in children and adolescents were similar to side effects in adult patients.
Talk to your doctor if you get any side effects.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nintedanib Norton

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 after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.
Store in the original package in order to protect from light.

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 “How to take Nintedanib Norton”).

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 Norton contains
The active substance is nintedanib. Each soft capsule contains 100 mg nintedanib (as esilate).
The excipients are:
- Capsules shell: Gelatin, glycerol (E422), titanium dioxide (E171), iron oxide red (E172), lecithin, soya bean (E322)
- Capsules content: Medium-chain triglycerides, lauroyl macrogolglycerides, lecithin soya bean (E322)

(see section 2, “Nintedanib Norton contains soya”)

What Nintedanib Norton looks like and contents of the pack

Nintedanib Norton 100 mg soft capsule is pale pink, opaque, oblong soft capsule of approximately 16 mm in length, marked with “TV8205”.

Nintedanib Norton is available in pack sizes of 30x1, 60x1 or 120x1 capsules in PVC/PCTFE/PVC – Aluminium perforated unit-dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Norton Waterford, T/A IVAX Pharmaceuticals Ireland,
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Manufacturer

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This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria:	Nintedanib ratiopharm GmbH 100 mg Weichkapseln
Belgium:	Nintedanib Teva Generics 100 mg zachte capsules / capsules molles / Weichkaspeln
Cyprus:	Nintedanib/Actavis
Czechia:	Nintedanib Teva GmbH
Germany:	Nintedanib-ratiopharm 100 mg Weichkapseln
Denmark:	Nintedanib Teva GmbH
Estonia:	Nintedanib TevaPharm
Greece:	Nintedanib/Actavis
Spain:	Nintedanib Tevagen 100 mg cápsulas blandas EFG
Finland:	Nintedanib ratiopharm GmbH 100 mg kapseli, pehmeä
France:	NINTEDANIB TEVA SANTE 100 mg, capsule molle
Croatia:	Nintedanib Teva GmbH 100 mg meke kapsule
Hungary:	Nintedanib Teva 100 mg lágy kapszula
Iceland:	Nintedanib Teva GmbH
Ireland:	Nintedanib Norton 100 mg soft capsules
Italy:	Nintedanib Teva Italia
Lithuania:	Nintedanib TevaPharm 100 mg minkštosios kapsulės
Latvia:	Nintedanib TevaPharm 100 mg mīkstās kapsulas
Luxembourg:	Nintedanib Teva Generics 100 mg capsules molles
Netherlands:	Nintedanib Teva 100 mg, zachte capsules
Norway:	Nintedanib Teva GmbH
Poland:	Nintedanib Teva Pharmaceuticals
Portugal:	Nintedanib Zidrium
Romania:	Nintedanib Teva GmBH 100 mg capsule moi
Sweden:	Nintedanib Teva GmbH
Solvenia:	Nintedanib Teva GmbH 100 mg mehke kapsule
Slovakia:	Nintedanib Teva GmbH 100 mg

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