PATIENT INFORMATION LEAFLET

SCHEDULING STATUS | S4 |

Boehringer Ingelheim

OFEV® 100 mg soft gelatin capsules
OFEV® 150 mg soft gelatin capsules

nintedanib
Sugar free

Read all of this leaflet carefully before you start taking OFEV

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- OFEV has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What OFEV is and what it is used for

OFEV contains the active substance nintedanib and it is used for the 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) in adults.

Idiopathic Pulmonary Fibrosis (IPF)

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. OFEV helps to reduce scarring and stiffening of the lungs.

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

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. OFEV helps to reduce further scarring and stiffening of the lungs.

Systemic sclerosis associated interstitial lung disease (SSc-ILD)

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. OFEV helps to reduce further scarring and stiffening of the lungs.

2. What you need to know before you take OFEV

Do not take OFEV

- if you are hypersensitive (allergic) to nintedanib, peanuts or soya or any of the other ingredients of OFEV (listed in section 6).
- Do not take OFEV if you are pregnant.

Warnings and precautions

Take special care and talk to your doctor or pharmacist before taking OFEV:

- if you have or ever had liver problems,
- if you have or ever had problems with your kidneys, or if an increased amount of protein has been detected in your urine,
- if you have or ever 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 ever had problems with your heart (for example a heart attack) as your doctor will do tests to monitor your heart function,
- if you have recently had surgery. Nintedanib may affect the way your wounds heal. Therefore your treatment with OFEV will usually be stopped for a while if you are having a surgery. Your doctor will decide when to resume your treatment with OFEV,
- 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 OFEV.

Inform your doctor immediately while taking OFEV:

- 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. These 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 being concomitantly treated with anti-inflammatory drugs (NSAIDs) (used for pain relief and swelling) or steroids (used for inflammation and allergies), as this may increase the risk of gastrointestinal perforation;
- if you have a combination of severe pain or cramping in your stomach, red blood in your stool or diarrhoea as these could be symptoms of a bowel inflammation from inadequate blood supply;
- if you have pain, swelling, reddening, warmth of a limb as these 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 these 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).

Children and adolescents
OFEV should not be taken by children and adolescents under 18 years of age.

Other medicines and OFEV
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

OFEV 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 (ciclosporin).

The following medicines are examples that may lower the levels of nintedanib in your blood and thus may reduce the effectiveness of OFEV:
- an antibiotic used to treat tuberculosis (rifampicin)
- medicines to treat seizures (carbamazepine, phenytoin)
- a herbal medicine to treat depression (St. John's wort).

OFEV with food and drink
Take OFEV with food. Swallow the capsules whole with water. See section 3 "How to take OFEV".

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, consult your doctor, pharmacist or other healthcare provider for advice before taking OFEV.

Pregnancy
Do not take OFEV 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 OFEV. 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 OFEV, while they are taking OFEV 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 OFEV.

Breastfeeding
Do not breastfeed your infant during the treatment with OFEV since there may be a risk for harm to the breastfeeding child.

Driving and using machines
OFEV may influence your ability to drive and use machines.
You should not drive or use machines if you feel sick or until you know how OFEV affects you.

OFEV contains soya lecithin
If you are allergic to soya or peanuts, do not take OFEV (see section 2).

3. How to take OFEV
Do not share medicines prescribed for you with any other person.

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

The usual dose is one capsule of 150 mg 12 hourly (a total of 300 mg per day).
Take the capsules 12 hours apart at 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).

Do not take more than the usual dose of one OFEV 150 mg capsule 12 hourly.

If you do not tolerate the recommended dose of one OFEV 150 mg capsule 12 hourly (see possible side effects in section 4) your doctor may reduce the daily dose of OFEV.

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

Your doctor may reduce your usual dose to 100 mg 12 hourly (a total of 200 mg per day). In this case your doctor will prescribe OFEV 100 mg capsules for your treatment. Do not take more than the usual dose of one OFEV 100 mg capsule 12 hourly if your daily dose was reduced to 200 mg per day.

If you do not tolerate the recommended dose of one OFEV 100 mg capsule 12 hourly (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.

Your doctor will tell you how long your treatment with OFEV will last. Do not stop treatment early because it will affect the management of your condition.
If you have the impression that the effect of OFEV is too strong or too weak, tell your doctor or pharmacist.

If you take more OFEV than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take OFEV
Do not take two capsules together if you have forgotten to take your earlier dose. You should take your next 100 mg or 150 mg dose of OFEV as planned at the next scheduled time recommended by your doctor or pharmacist.

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

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

4. Possible side effects
OFEV can have side effects.
Not all side effects reported for OFEV are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OFEV, please consult your healthcare provider for advice.

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

Diarrhoea is frequently experienced
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 OFEV:

Idiopathic pulmonary fibrosis (IPF)
Frequent
- Feeling sick (nausea)
- Pain in the lower body (abdomen)
- Abnormal liver test results
- Vomiting
- Loss of appetite
- Weight loss
- Bleeding
- Rash
- Headache

Less frequent
- 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)

Other chronic fibrosing interstitial lung diseases (ILDs) with a progressive phenotype
Frequent
- Feeling sick (nausea)
- Vomiting
- Loss of appetite
- Pain in the lower body (abdomen)
- Abnormal liver test results
- Weight loss
- High blood pressure (hypertension)
- Bleeding
- Serious liver problems
- Rash
- Headache

Less frequent
- 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)

Systemic sclerosis associated interstitial lung disease (SSc-ILD)
Frequent
- Feeling sick (nausea)
- Vomiting
- Pain in the lower body (abdomen)
- Abnormal liver test results
- Bleeding
- High blood pressure (hypertension)
- Loss of appetite
- Weight loss
- Headache

Less frequent
- 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)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help

provide more information on the safety of OFEV. Suspected adverse reactions can also be reported directly to the holder of the certificate of registration using the email address pv_local_south_africa@boehringer-ingelheim.com.

5. How to store OFEV

Store at or below 25 °C.
Store in the original package in order to protect from moisture.
In order to protect from moisture, do not store in the bathroom.
Store all medicines out of reach of children.

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 use after the expiry date stated on the carton and the blister strips.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OFEV contains

The active substance is nintedanib.
Each soft gelatin capsule contains 100 mg or 150 mg nintedanib (as esilate).

The other ingredients are:
Capsule fill: Triglycerides, medium-chain, hard fat, soya lecithin (E322)
Capsule shell: Gelatin, glycerol (85 %), titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)

What OFEV looks like and contents of the pack

OFEV 100 mg soft gelatin capsules are peach-coloured, opaque, oblong soft gelatin capsules marked in dark grey on one side with the Boehringer Ingelheim company symbol and “100”, and containing a bright yellow viscous suspension.
OFEV 150 mg soft gelatin capsules are brown-coloured, opaque, oblong soft gelatin capsules marked in dark grey on one side with the Boehringer Ingelheim company symbol and “150”, and containing a bright yellow viscous suspension.

OFEV soft gelatin capsules are packed in blister strips, consisting of a printed aluminium lidding foil and an aluminium-based forming foil.
Each blister strip consists of 10 soft gelatin capsules; 6 blister strips are packed per printed cardboard carton, in packs of 60 capsules.

Holder of Certificate of Registration

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