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1. What OFEV is used for

OFEV is used for the treatment of Idiopathic Pulmonary Fibrosis (IPF).

OFEV is used to treat people with other chronic (long lasting) fibrosing interstitial lung diseases (ILDs) in which lung fibrosis continues to worsen (progressive phenotype).

OFEV is used to slow the rate of decline in lung function in patients with systemic sclerosis-associated interstitial lung disease (SSc-ILD).

2. How OFEV works

OFEV capsules contain the active substance nintedanib, a medicine belonging to the class of tyrosine kinase inhibitors.

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.

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.

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 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 in all these disease conditions.

3. Before you use OFEV

- When you must not use it

- 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 8 - *Ingredients*).

Children and adolescents

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

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 OFEV. Please talk to your doctor.

Contraception:

Women who can become pregnant must use a highly effective method of birth control to prevent pregnancy 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. It is currently unknown whether nintedanib will reduce the effectiveness of hormonal contraceptives, such as birth control pills or devices, therefore, a barrier method of contraception (e.g. condoms) must also be used. Tell your doctor or pharmacist immediately if you become pregnant during treatment with OFEV.

Breast-feeding:

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

- Before you start use it

Talk to your doctor or pharmacist before taking OFEV,

- if you have or ever had liver problems,
- if you have or have had problems with your kidneys, or if an increased amount of proteins have been detected in your urine,
- if you have or ever had bleeding problems,
- if you take blood-thinning medicines (such as warfarin, or heparin) to prevent blood clotting,
- if you have or ever had problems with your heart (for example a heart attack),
- if you have recently had surgery (abdominal 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 this medicine.
- if you have high blood pressure,
- if you have a history of a hole in the wall of your gut (“gastrointestinal perforation”),
- if you have a history of peptic ulceration,

OFEV[®] Soft Capsules

Nintedanib (100 mg, 150 mg)

- if you have a history of diverticular disease,
- if you are receiving concomitant corticosteroids or NSAID.
- 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 this medicine,

- if you get diarrhoea. Treating diarrhoea early is important (see section 6);
- if you vomit or feel sick (nausea)(see section 6);
- 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 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).

- Taking other medicines

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.

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 6 - *Side Effects*):

- a medicine used to treat fungal infections (*ketconazole*)
- 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 OFEV:

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

4. How to use OFEV

- How much to use

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

The recommended dose is one capsule of 150 mg twice daily (a total of 300 mg per day). Take the capsules 12 hours apart at about the same time every day. It is recommended that you take the capsules with food. Swallow the whole capsules with water and do not chew.

OFEV capsules may be taken with a small amount (teaspoonful) of cold or room temperature soft food, such as apple sauce or chocolate pudding, and must be swallowed unchewed immediately, to ensure the capsule stays intact.

The capsule should not be opened or crushed. If contact with the content of the capsule occurs, hands should be washed immediately and thoroughly.

Do not take more than the recommended maximum daily dose of two OFEV 150 mg capsules per day.

If you do not tolerate the recommended dose of two OFEV 150 mg capsules per day (see possible side effects in section 6), 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 recommended dose to two times 100 mg per day (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 recommended dose of two OFEV 100 mg capsules per day if your daily dose was reduced to 200 mg per day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

OFEV[®] Soft Capsules

Nintedanib (100 mg, 150 mg)

Continue taking OFEV for as long as your doctor recommends.

- **If you forget to use it**

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

- **If you use too much (overdose)**

Contact your doctor or pharmacist immediately.

5. While you are using it

- **Things you must do**

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking OFEV.

Tell your doctor immediately if you become pregnant while taking this medication.

- **Things you must not do**

Do not stop taking OFEV 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.

- **Things to be careful of**

Driving and using machines

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

6. 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 OFEV:

Diarrhoea, nausea and vomiting 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 or vomiting, drink plenty of fluids and contact your doctor immediately. Start appropriate anti-diarrhoeal treatment, e.g. with loperamide, and anti-vomiting treatment as soon as possible. The following other side effects were observed under treatment with this medicine:

- Pain in the lower body (abdomen)
- Abnormal liver test results
- Loss of appetite
- Weight loss
- Bleeding
- Rash
- Headache
- Inflammation of the pancreas (Pancreatitis)
- Inflammation of the large bowel
- Serious liver problems
- Low blood 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
- Pruritus
- Hair loss (Alopecia)
- Increased amount of protein in your urine (Proteinuria)
- 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)

If any of the side effects gets serious or, if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by visiting the website npra.gov.my (Consumers→Reporting Side Effects to Medicines (ConSERF or Vaccine (AEFI))).

7. Storage and Disposal of OFEV

- **Storage**

Keep out of the reach and sight of children.

Do not store above 25°C.

Store in the original package in order to protect from moisture.

- **Disposal**

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

8. Product Description

- **What it looks like**

100 mg: Peach-colored, opaque, oblong, soft gelatin capsules, marked in dark grey on one side with Boehringer Ingelheim company symbol and with "100", and containing a bright yellow viscous suspension.

150 mg: Brown-colored, opaque, oblong, soft gelatin capsules, marked in dark grey on one side with Boehringer Ingelheim company symbol and with "150", and containing a bright yellow viscous suspension.

- **Ingredients**

- Active ingredient(s)
One soft capsule contains 100 mg or 150 mg nintedanib (as esilate).

- Inactive ingredients
Capsule content: Medium-chain triglycerides, hard fat, soya lecithin (E322)

Capsule shell: Gelatin, glycerol (85 %), titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)

- **MAL number(s):**

OFEV 100mg:
MAL16065014ACRZ

OFEV[®] Soft Capsules

Nintedanib (100 mg, 150 mg)

OFEV 150mg:
MAL16065015ACRZ

9. Manufacturer

Manufactured by:
Catalent Germany Eberbach GmbH
Gammelsbacher Str. 2,
69412 Eberbach,
Germany

Packaged by:
Boehringer Ingelheim Pharma GmbH
& Co. KG
Binger Straße 173,
55216 Ingelheim am Rhein,
Germany

For:
Boehringer Ingelheim International
GmbH
Ingelheim am Rhein,
Germany

10. Product Registration Holder

Boehringer Ingelheim (Malaysia) Sdn.
Bhd.
Level 23A, Mercu Aspire,
No. 3, Jalan Bangsar, KL Eco City,
59200 Kuala Lumpur, Malaysia.

11. Date of revision

25 August 2025

12. Serial Number:

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