

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Ofev?

Ofev capsules contain the active ingredient nintedanib.

Ofev is used to treat some chronic lung conditions and/or is used in combination with another medicine to treat patients with a type of lung cancer called non-small cell lung cancer (NSCLC).

For more information, see Section [1. Why am I using Ofev?](#) in the full CMI.

2. What should I know before I take Ofev?

Do not use if you have ever had an allergic reaction to nintedanib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take Ofev?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ofev and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Ofev?

Take one dose in the morning and one dose in the evening with food. Your doctor will tell you what dose to take.

More instructions can be found in Section [4. How do I take Ofev?](#) in the full CMI.

5. What should I know while taking Ofev?

Things you should do	<ul style="list-style-type: none">Remind any healthcare provider that you see that you are taking Ofev.Use effective contraception when taking Ofev and for at least 3 months after you stop using it.
Things you should not do	<ul style="list-style-type: none">Do not breastfeed while taking Ofev.
Driving or using machines	<ul style="list-style-type: none">Be careful driving or operating machinery until you know how Ofev affects you.
Looking after your medicine	<ul style="list-style-type: none">Store it in a cool dry place (below 25°C), away from moisture, heat, or sunlight.

For more information, see Section [5. What should I know while taking Ofev?](#) in the full CMI.

6. Are there any side effects?

Ofev can have side effects, depending on the condition being treated and how your body reacts.

Some side effects may need immediate medical attention, including severe allergic reactions, major bleeding, infections with fever and/or chills, problems with your circulation, heart, kidney, liver, and pancreas.

Common side effects may include diarrhoea, nausea, stomach pain, vomiting, decreased appetite, headache, weight loss, and high blood pressure.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ofev. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Ofev.**

Where to find information in this leaflet:

- [1. Why am I using Ofev?](#)
- [2. What should I know before I take Ofev?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Ofev?](#)
- [5. What should I know while taking Ofev?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Ofev?

Ofev contains the active ingredient nintedanib. Ofev belongs to the group of medicines called tyrosine kinase inhibitors and is used to treat various conditions.

Idiopathic pulmonary fibrosis (IPF)

IPF is a condition in which lung tissue becomes thickened, stiffened and scarred over time, causing shortness of breath.

Ofev helps to reduce further 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)

This is also known as scleroderma associated ILD. It is a rare chronic autoimmune disease that affects connective tissue in many parts of the body. Systemic sclerosis (SSc) causes scarring and stiffening of the skin and other internal organs. When the lungs are affected, it is called Interstitial Lung Disease (ILD), and so the condition is called SSc-ILD. This condition 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.

Non-small cell lung cancer (NSCLC)

Ofev is used in combination with docetaxel to treat a type of NSCLC in adults who have previous treatment with another medicine but the tumour has started to grow back or has spread to other parts of the body.

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

If you are taking Ofev in combination with docetaxel, please read the docetaxel leaflet also.

2. What should I know before I take Ofev?

Warnings

Do not use Ofev if you are:

- allergic to nintedanib, lecithin, peanut or soya, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you have or have had any of the following conditions:

- liver problems
- blood clots
- problems with your kidneys, or if increased protein has been found in your urine
- bleeding problems, particularly recent bleeding in the lung
- heart problems (such as a heart attack)
- swelling and weakening of part of a blood vessel (aneurysm) or a tear in a blood vessel
- hole in the wall of your gut (gastrointestinal perforation)
- ulcer in the stomach or duodenum
- diverticular disease (a common condition where small pouches or pockets form in the wall of the large intestine)
- previous surgery in your stomach (abdominal) area or other recent surgery
- cancer that has spread to the brain.

Check with your doctor if you take:

- blood-thinning medicines (such as warfarin, heparin, or low dose aspirin) to prevent blood clotting
- medicines used to relieve pain, swelling and redness (the symptoms of inflammation), including those to treat arthritis (anti-inflammatory medicines or NSAIDs)

- medicines such as prednisone and cortisone ("corticosteroids"), which reduce the activity of the immune system
- medicines used to treat constipation or bowel movements, or other medicines/dietary supplements that can cause diarrhoea
- any other medicine(s) for another condition(s).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take Ofev if you are pregnant or plan to become pregnant.

Ofev may affect your developing baby if you take it during pregnancy.

If you are a woman of child-bearing age, your doctor may ask you to take a pregnancy test to confirm that you are **not** pregnant before starting treatment with Ofev.

Do not breastfeed if you are taking Ofev. Talk to your doctor if you are breastfeeding or intend to breastfeed. The active ingredient in Ofev may pass into breast milk and there is a possibility that your baby might be affected.

Contraception

You must avoid becoming pregnant while taking Ofev and use effective contraception when starting/taking Ofev, and for at least 3 months after you stop using it.

Vomiting, diarrhoea, or other gastrointestinal conditions can affect the absorption of oral hormonal contraceptives, such as birth control pills, and may reduce their effectiveness. If you are experiencing these symptoms, talk to your doctor or pharmacist to discuss alternative methods of contraception.

Children and adolescents

Ofev is not approved for use in children or adolescents under 18 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines that may increase the effect of Ofev include:

- ketoconazole (a medicine used to treat fungal infections)
- erythromycin (a medicine used to treat bacterial infections).

Some medicines that may reduce the effect of Ofev include:

- rifampicin (a medicine used to treat tuberculosis: a bacterial infection that usually attacks the lungs)
- carbamazepine or phenytoin (medicines used to treat seizures or convulsions)

- herbal medicines derived from St John's Wort (used to treat mental health problems).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Ofev. You may need different amounts of your medicines, or you may need to take different medicines.

4. How do I take Ofev?

How much to take

- Your doctor will decide how many Ofev capsules you should take.
- Take Ofev exactly as your healthcare provider tells you to take it. The instructions may differ from the information contained in this leaflet.
- Use Ofev until your doctor tells you to stop.

NSCLC

The recommended starting dose of Ofev is two 100 mg capsules taken twice daily, about 12 hours apart (a total of 400 mg Ofev/day) on **Days 2 to 21 of a standard 21-day docetaxel treatment cycle.**

Your doctor may decrease your dose by 100 mg steps/day if you do not tolerate the dose prescribed.

IPF, Other chronic fibrosing ILD with a progressive phenotype, or SSc-ILD

The recommended starting dose of Ofev is one 150 mg capsule taken twice daily, about 12 hours apart (a total of 300 mg Ofev/day).

If you have problems with your liver or do not tolerate the dose prescribed, your doctor may decrease your dose to one 100 mg capsule twice daily (a total dose of 200 mg/day).

If you get severe side effects, your doctor may interrupt your treatment and then re-start your treatment at a lower dose or may tell you to discontinue taking Ofev completely.

When to take Ofev

Take one Ofev dose in the morning and another dose in the evening, about 12 hours apart, as prescribed by your doctor.

How to take Ofev

Take Ofev capsules with food.

Ofev may be taken with a small amount (teaspoon full) of cold or room temperature soft food, such as apple sauce or chocolate pudding.

Swallow the capsule(s) whole with a full glass of water. Do not chew, crush, or open the capsules.

If you or someone else accidentally comes into contact with the contents of an Ofev capsule, immediately wash hands well.

If you forget to take Ofev

Ofev should be taken regularly at the same times each day.

If you miss a dose at the usual time and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. If you are not sure what to do, ask your doctor or pharmacist.

Do not take a double dose to make up for the dose you missed.

If you take too much Ofev

If you think that you have taken too much Ofev, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Ofev?

Things you should do

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may want to run tests from time to time to check your progress and detect any unwanted side effects, especially in your blood or urine or due to liver function.

Remind any doctor, dentist or pharmacist you visit that you are using Ofev.

If you go into hospital, tell the medical staff that you are taking this medicine.

Call your doctor straight away if you:

- have diarrhoea (see "Diarrhoea" below)
- show signs of swelling of the face, lips, tongue and/or throat, and difficulty in breathing
- have headache, visual disturbances, seizure, lethargy, confusion, and other neurologic disturbances
- become pregnant or think you may be pregnant during treatment.

Diarrhoea

This is a very common side effect of Ofev and may become serious and life-threatening if untreated.

If you experience the early signs of diarrhoea, speak to your doctor and take anti-diarrhoeal medicine exactly as your doctor tells you.

Drink plenty of fluids to avoid dehydration and becoming unwell.

Things you should not do

Do not lower the Ofev dose without checking with your doctor first.

If you have lung cancer, do not take Ofev on Day 1 of the treatment cycle. That is, on the same day of docetaxel administration.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ofev affects you.

No studies of the effects of Ofev on the ability to drive and operate machinery have been performed.

You should not drive or operate machinery if you feel sick.

Drinking alcohol

There are no known effects between Ofev and alcohol.

Looking after your medicine

Keep Ofev capsules in the blister until it is time to take it. Follow the instructions in the carton on how to take care of your medicine properly.

Keep Ofev in a cool, dry place where the temperature stays below 25°C.

Store it away from moisture, heat, or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Blood pressure: <ul style="list-style-type: none">• High blood pressure (may not be noted until checked by your doctor) Gut and digestion: <ul style="list-style-type: none">• Diarrhoea• Throwing up (vomiting)• Nausea• Stomach (abdominal) pain or discomfort• Sore/red mouth• Ulcers in the mouth• Inflammation of the mucous membranes lining the gut Metabolism: <ul style="list-style-type: none">• Decreased appetite	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> Weight loss <p>Infection:</p> <ul style="list-style-type: none"> Abscesses <p>Skin and hair:</p> <ul style="list-style-type: none"> Rash or itching Hair loss <p>Brain and nervous system:</p> <ul style="list-style-type: none"> Lethargy Headache <p>Urine:</p> <ul style="list-style-type: none"> Signs of increased protein in urine such as foamy urine, swelling, including in your hands, arms, legs, or feet, or sudden weight gain. 	

Serious side effects

Serious side effects	What to do
<p>Signs of a severe allergic reaction:</p> <ul style="list-style-type: none"> Swollen face, tongue, lips, or throat Difficulty swallowing or breathing Rash, itching. <p>Signs of a heart attack may include:</p> <ul style="list-style-type: none"> Chest pressure, pain, or discomfort, typically on the left side of the body Dull pain, chest tightness or discomfort that becomes more severe and does not go away Pain/discomfort in the jaw, neck, back, arm, or shoulder Fast heartbeat Sudden shortness of breath Nausea Vomiting Suddenly feeling light-headed, or unusually tired Fainting Sweating Similar feelings to heartburn. <p>Signs of a stroke:</p> <ul style="list-style-type: none"> Trouble speaking, understanding, walking, or seeing in 1 or both eyes Confusion Headache which is sudden and severe, and followed by vomiting and dizziness 	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> Numbness of the face, arm or leg (on 1 side of your body). <p>Signs of a blood clot:</p> <ul style="list-style-type: none"> Pain, swelling, reddening, warmth of a limb If a clot travels to the lungs, you may have chest pain and difficulty breathing. <p>Signs of neurological disturbances</p> <ul style="list-style-type: none"> visual disturbances seizure confusion lethargy other neurologic disturbances <p>Signs of severe diarrhoea:</p> <ul style="list-style-type: none"> More than 4 bowel movements in one day Diarrhoea that lasts more than 2 days after taking anti-diarrhoeal medication Black, tarry or bloody poo (stools) Unusual thirst Dry mouth or skin Fever (increase in body temperature). <p>Signs of inflammation of the pancreas:</p> <ul style="list-style-type: none"> Tenderness and severe upper stomach pain, often with nausea and vomiting <p>Signs of infection or infection in the blood:</p> <ul style="list-style-type: none"> Fever, chills, fast breathing, or a fast heartbeat <p>Signs of kidney failure:</p> <ul style="list-style-type: none"> Passing little or no urine Headache Dizziness Tiredness Swelling in your legs and feet or around your eyes Drowsiness Feeling sick (nausea) Throwing up (vomiting) Breathlessness Loss of appetite Weakness. <p>Signs of liver problems:</p> <ul style="list-style-type: none"> Yellowing of the skin and whites of the eyes ("jaundice") Dark or tea-coloured urine Feeling tired 	

Serious side effects	What to do
<ul style="list-style-type: none"> Loss of appetite Upper right stomach pain, discomfort and swelling Bleeding or bruising more easily than normal. <p>Signs of a low platelets in your blood:</p> <ul style="list-style-type: none"> Bleeding or bruising more easily than normal Any major bleeding. <p>Signs of bowel inflammation/ poor blood supply to the colon:</p> <ul style="list-style-type: none"> Severe pain or cramping in your stomach Urgent need to pass stool Red blood in your stool Diarrhoea Nausea Swollen belly. <p>Signs of a possible hole in the gut wall:</p> <ul style="list-style-type: none"> Severe pain or tenderness in your stomach area Fever and chills Feeling sick Throwing up Your belly feels full and tight ("bloating") Bloody stool. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Ofev contains

Active ingredient (main ingredient)	nintedanib esilate
Other ingredients	gelatin

(inactive ingredients)	glycerol 85% hard fat iron oxide red C177491 iron oxide yellow C177492 medium chain triglycerides titanium dioxide
Potential allergens	lecithin (inside the capsule)

Do not take this medicine if you are allergic to any of these ingredients.

What Ofev looks like

Ofev is supplied as soft gelatin capsules in two different strengths:

- Ofev 100 mg**
Peach-coloured, opaque, oblong, marked in dark grey with the Boehringer Ingelheim company logo and with "100"; AUST R 226065.
- Ofev 150 mg**
Brown-coloured, opaque, oblong, marked in dark grey with the Boehringer Ingelheim company logo and with "150"; AUST R 226068.

All Ofev capsules contain a bright yellow viscous suspension.

Ofev is packed in blister cartons each containing 60 capsules.

Who distributes Ofev

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

78 Waterloo Road

North Ryde NSW 2113

Website: www.boehringer-ingelheim.com.au

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