

# Ofev<sup>®</sup>

## Soft Capsules

nintedanib (as esilate)

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### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Ofev.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ofev against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from [www.medicines.org.au](http://www.medicines.org.au) (Australia) and may contain important information about the medicine and its use of which you should be aware.

**Keep this leaflet with the medicine.**

You may need to read it again.

## **What Ofev is used for**

Ofev contains the active ingredient nintedanib (as esilate).

Nintedanib is a tyrosine kinase inhibitor that works by blocking the activity of a group of proteins which are involved in the building and the growth of blood vessels. These blood vessels are necessary to provide growing cancer cells with nutrients and oxygen. By blocking the activity of these proteins, nintedanib can inhibit the growth and the spread of cancer cells.

Ofev is used in combination with the chemotherapy docetaxel to treat a type of lung cancer called Non-Small Cell Lung Cancer (NSCLC). It is used in adult patients with a certain type of lung cancer called adenocarcinoma who have already received one treatment with another medicine to treat this cancer but whose tumour started to grow again.

Ofev is also used for the treatment of 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 further scarring and stiffening of the lungs.

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.

Ofev is also used for the treatment of 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.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

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

## **Before you take Ofev**

### **When you must not take it**

#### **Do not take Ofev if you have an allergy to:**

- any medicine containing nintedanib esilate (the active ingredient)
- soya or peanut (Ofev contains soya lecithin)
- any of the other ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not take this medicine if you are pregnant, or think you may be pregnant or are planning to become pregnant.**

It may affect your developing baby if you take it during pregnancy (see section ‘Before you start to take it’ below).

**Do not breastfeed if you are taking this medicine.**

The active ingredient in Ofev may pass into breast milk and there is a possibility that your baby might be affected.

**Do not give this medicine to a child under the age of 18 years.**

Safety and effectiveness in children younger than 18 years has not been established.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

**Before you start to take it**

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you:**

- have or have had liver problems
- have or have had problems with your kidneys or if an increased amount of protein has been detected in your urine
- have or have had bleeding problems, particularly recent bleeding in the lung

- take blood-thinning medicines (such as warfarin or heparin) to prevent blood clotting
- have or have had cancer that has spread to the brain
- have or have had heart problems (for example a heart attack)
- have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel (dissection)
- have or have had a hole in the wall of your gut (gastrointestinal perforation)
- have or have had peptic ulcers or diverticular disease (a condition which affects the wall of the large intestine)
- take anti-inflammatory drugs (NSAIDs) (used for pain relief and to treat swelling) or steroids (used for inflammation and allergies).

**Tell your doctor if you have had previous abdominal surgery or any other recent surgery.**

Ofev may affect the way your wounds heal. Your treatment with Ofev will usually be interrupted if you are having surgery. Your doctor will decide when to resume your treatment with this medicine.

**If you have not told your doctor about any of the above, tell him/her before you start taking Ofev.**

**Before starting Ofev treatment, you must have a pregnancy test done to ensure you are not pregnant.**

**Talk to your doctor about effective methods of contraception.**

**You or your sexual partner must use a highly effective method of contraception to prevent pregnancy when starting Ofev treatment, during Ofev treatment and for at least 3 months after taking the last dose of Ofev.**

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 you experience these, talk to your doctor to discuss an alternative more appropriate method of contraception.

## **Taking other medicines**

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

Some medicines and Ofev may interfere with each other. These include:

- ketoconazole, a medicine used to treat fungal infections
- erythromycin, a medicine used to treat bacterial infections

- rifampicin, a medicine used to treat tuberculosis
- carbamazepine or phenytoin, medicines used to treat fits or convulsions
- herbal medicines derived from St John's Wort - (Hypericum perforatum).

These medicines may be affected by Ofev or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **How to take Ofev**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

## **How much to take**

### **NON-SMALL CELL LUNG CANCER**

The recommended dose of Ofev is two 100 mg capsules twice daily, about 12 hours apart (this is a total of 400 mg Ofev per day).

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

**IDIOPATHIC PULMONARY FIBROSIS, OTHER CHRONIC FIBROSING INTERSTITIAL LUNG DISEASES WITH A PROGRESSIVE PHENOTYPE, AND SYSTEMIC SCLEROSIS ASSOCIATED INTERSTITIAL LUNG DISEASE**

The recommended dose of Ofev is one 150 mg capsule twice daily, about 12 hours apart (this is a total of 300 mg Ofev per 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.

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.

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

## **How to take it**

**Take the capsules with food.**

**Swallow the capsules whole with a full glass of water.**

**Do not chew, crush or open the capsules. If contact with the content of the capsule occurs, wash your hands immediately and thoroughly.**

## **When to take it**

### **NON-SMALL CELL LUNG CANCER**

**Ofev should be taken twice a day (about 12 hours apart) on days 2 to 21 of a standard 21-day docetaxel treatment cycle. Ofev must not be taken on the same day of docetaxel administration. That is, it should NOT be taken on day 1 of the treatment cycle.**

### **IDIOPATHIC PULMONARY FIBROSIS, OTHER CHRONIC FIBROSING INTERSTITIAL LUNG DISEASES WITH A PROGRESSIVE PHENOTYPE, AND SYSTEMIC SCLEROSIS ASSOCIATED INTERSTITIAL LUNG DISEASE**

**Ofev should be taken twice a day (about 12 hours apart).**

## **How long to take it**

**Continue taking your medicine for as long as your doctor tells you.**

## **If you forget to take it**

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

**This may increase the chance of you getting an unwanted side effect.**

**Take your next dose of Ofev as planned at the next scheduled time and at the dose recommended by your doctor or pharmacist.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your pharmacist for some hints.**

### **If you take too much (overdose)**

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Ofev. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

## **While you are taking Ofev**

### **Things you must do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ofev.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**

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

**If you or your partner becomes pregnant or if you think you or your partner may be pregnant while taking this medicine, tell your doctor immediately.**

**Keep all of your doctor's appointments so that your progress can be checked.**

## **Things you must not do**

**Do not take Ofev to treat any other complaints unless your doctor tells you to.**

**Do not give your medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

If you do not take this medicine as prescribed by your doctor your cancer may resume growing again earlier.

## **Things to be careful of**

**Be careful driving or operating machinery 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.

## **Side effects**

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Ofev.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- nausea
- vomiting
- decreased appetite
- weight decrease
- abscesses (a swollen area containing pus)
- mouth sores and inflammation
- rash or itching
- headache

- hair loss.

Ofev may be associated with changes in your blood, urine or liver test results. Your doctor may want to perform tests from time to time to check on your progress and detect any unwanted side effects.

**Tell your doctor immediately if you notice any of the following:**

- diarrhoea, treatment of diarrhoea at the first signs is important
- any signs and symptoms of dehydration such as headache, dizziness, tiredness or decreased urine output
- fever, chills, fast breathing or a fast heartbeat, these could be signs of infection or infection of the blood (sepsis)
- severe pain in your stomach area, fever, chills, sickness, vomiting, or abdominal rigidity or bloating, this could be symptoms of a hole in the wall of your gut ('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 bowel inflammation from inadequate blood supply (ischaemic colitis)
- passing little or no urine, swelling in your legs and feet or around your eyes, drowsiness, nausea, vomiting, breathlessness, loss of appetite and weakness. These could

be signs or symptoms of kidney disease (renal failure) which could become serious and life threatening

- pain, swelling, reddening, warmth of a limb, this could be symptoms of a blood clot in one of your veins (a type of blood vessel)
- any major bleeding
- severe upper stomach pain, often with nausea and vomiting, this could be symptoms of inflammation of the pancreas (pancreatitis)
- bleeding or bruising more easily than normal, this could be signs of low blood platelet count (thrombocytopenia)
- 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, this could be symptoms of a heart attack
- any signs and symptoms of liver problems such as yellow skin or eyes and dark 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.

Diarrhoea is a very common side effect of Ofev and is sometimes severe. You may become dehydrated if you experience severe or persistent diarrhoea and this could become serious and life-threatening if untreated.

**As soon as you notice any signs of diarrhoea, you should drink plenty of fluids and take anti-diarrhoeal medicine**

**exactly as your doctor tells you to help treat your diarrhoea.**

**You must immediately ask your doctor for further advice if your diarrhoea becomes severe (with more than 4 bowel movements each day) or if your diarrhoea is not under control within 48 hours after taking the anti-diarrhoeal medicine.**

**Tell your doctor or pharmacist if you notice anything that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

## **After taking Ofev**

### **Storage**

**Keep your capsules in the blister pack until it is time to take them to protect from moisture.**

If you take the capsules out of the pack they may not keep well.

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

**Do not store Ofev or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

## **Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Disposal**

**If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## **Product description**

### **What it looks like**

Ofev is the brand name of your medicine.

Ofev is available in two strengths of capsules:

Ofev 100 mg - peach-coloured, opaque, oblong, soft gelatin capsules imprinted in black on one side with the Boehringer Ingelheim company logo and with "100". The capsules contain a bright yellow viscous suspension.

Ofev 150 mg - brown-coloured, opaque, oblong, soft gelatin capsules imprinted in black on one side with the Boehringer Ingelheim company logo and with "150". The capsules contain a bright yellow viscous suspension.

Ofev is available in blister packs of 60 capsules. Each pack contains 6 blister strips containing 10 capsules per strip.

## Ingredients

Active ingredient:

Ofev 100 mg capsule contains 100 mg of nintedanib (as 120.40 mg nintedanib esilate).

Ofev 150 mg capsule contains 150 mg of nintedanib (as 180.60 mg nintedanib esilate).

Inactive ingredients:

Ofev capsules also contain the following ingredients:

- medium chain triglycerides
- hard fat
- lecithin
- gelatin
- glycerol 85%
- titanium dioxide
- iron oxide red CI77491
- iron oxide yellow CI77492.

Black printing ink containing:

- iron oxide black CI77499

- shellac
- ethanol
- propylene glycol.

## **Supplier**

Ofev is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney, Australia

[www.boehringer-ingelheim.com.au](http://www.boehringer-ingelheim.com.au)

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## **Australian Registration Numbers:**

Ofev 100 mg: AUST R 226065

Ofev 150 mg: AUST R 226068