

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Ofev capsules.

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.medsafe.govt.nz/Consumers/cmi/CMIForm.asp and may contain important information about the medicine and its use 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 belongs to a group of medicines called tyrosine kinase inhibitors.

Ofev is used to treat a variety of lung tissue disorders as explained below.

NON-SMALL CELL LUNG CANCER (NSCLC)

Ofev is used in combination with another medicine to treat some “adenocarcinoma” types of lung cancers. It is used in adult patients who have already received another treatment for this cancer but the tumour has returned or has spread. Ofev is the next treatment given.

Ofev blocks the activity of specific proteins that are involved in the development of new blood vessels, which cancer cells need for the supply of food and oxygen.

When used in combination with docetaxel, Ofev can stop the growth and the spread of these lung cancer cells.

Please read the docetaxel leaflet if you are taking Ofev with docetaxel to treat your lung cancer.

IDIOPATHIC PULMONARY FIBROSIS (IPF)

IPF is a serious lung condition that occurs without a known cause (“idiopathic”).

IPF causes permanent thickening, stiffening and scarring of your lungs over time. This damage makes lungs unable to fully expand. As a result, it becomes difficult to breathe deeply, take in oxygen and transfer it into the bloodstream.

Ofev is used to treat IPF. It helps to reduce further scarring and stiffening of the lungs.

OTHER PROGRESSIVE FIBROSING INTERSTITIAL LUNG DISEASES (PF-ILDs)

These are a group of long-term breathing disorders in lung tissues. Inflammation causes lung tissue thickening, stiffening and scarring (lung fibrosis), all which worsen (progress) over time.

Some examples of these conditions are:

- hypersensitivity (allergic reaction) pneumonitis
- autoimmune ILDs – these occur when your immune system attacks lung tissues. An example is rheumatoid arthritis (RA)-associated ILD
- idiopathic nonspecific interstitial pneumonia (NSIP)
- unclassifiable idiopathic interstitial pneumonia, and
- other ILDs.

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

SYSTEMIC SCLEROSIS ASSOCIATED WITH 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 causes scarring and stiffening (fibrosis) of the skin and other internal organs. When the lungs are affected, the condition is called Systemic sclerosis (SSc)

associated with Interstitial Lung Disease (ILD), shortened to SSc-ILD.

Fibrosis in the lungs reduces the ability to transfer oxygen into the bloodstream, and breathing capacity is reduced.

Ofev is used for the treatment of SSc-ILD and helps to reduce further scarring and stiffening of the lungs.

MORE INFORMATION

Ask your doctor if you have any questions about why Ofev 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 (the active ingredient)
- soya lecithin or peanuts
- any of the other ingredients listed at the end of this leaflet.

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

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

The safety and effectiveness in children younger than 18 years have 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.

PREGNANCY

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

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

If you are a woman of child-bearing age, you must take a pregnancy test to confirm that you are not pregnant before you start taking this medicine.

CONTRACEPTION

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.

If you experience vomiting and/or diarrhoea, talk to your doctor to discuss an alternative and more appropriate method of contraception.

BREASTFEEDING

Do not breastfeed if you are taking this medicine.

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.

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 or have had any of the following conditions now or in the past:

- liver problems
- problems with your kidneys or if an increased amount of protein has been detected in your urine

- bleeding problems, particularly recent bleeding in the lung
- blood clots
- cancer that has spread to the brain
- heart problems (for example a heart attack)
- an aneurysm (swelling and weakening of part of a blood vessel wall) or a tear in a blood vessel (dissection)
- a hole in the wall of your gut (gastrointestinal perforation)
- ulcers in the stomach or duodenum
- diverticular disease (a common condition where small pouches or pockets form in the wall of the large intestine)
- previous stomach (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 Ofev.
- allergies to any other medicines, foods, preservatives, or dyes.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicine(s), including any vitamin(s), or supplement(s) 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:

- medicines to prevent blood clots, such as aspirin (low dose), warfarin, or heparin
- medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis, such as anti-inflammatory drugs, NSAIDs
- medicines such as prednisone and cortisone (“corticosteroids”)

which reduce the activity of the immune system.

- laxatives, stool softeners, or any drugs that can cause diarrhoea
- 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 seizures or convulsions
- herbal medicines derived from St John's Wort, also called *Hypericum perforatum*.

You may need different amounts of your medicines, or you may need to take different medicines.

Your healthcare provider has more information on medicines to be careful with or avoid while taking Ofev.

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

Your doctor will tell you how many OFEV capsules to take for your condition.

NON-SMALL CELL LUNG CANCER

The recommended Ofev starting dose 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 if you do not tolerate the dose prescribed.

IPF; OTHER CHRONIC FIBROSING ILDs WITH A

PROGRESSIVE PHENOTYPE; or SSc-ILD

The recommended Ofev starting dose for these chronic lung conditions 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.

How to take it

Take the capsule with food.

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

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

NSCLC

Take Ofev twice a day (about 12 hours apart) on Days 2 to 21 of a standard 21-Day docetaxel treatment cycle.

Do NOT take Ofev on the same day of docetaxel administration (Day 1 of the docetaxel treatment cycle).

IPF; OTHER CHRONIC FIBROSING ILDs WITH A PROGRESSIVE PHENOTYPE; or SSc-ILD

Take Ofev twice each day (about 12 hours apart).

How long to take it

Ofev is a long-term treatment, possibly lasting for months to years, depending on your condition and how you respond.

Continue taking Ofev for as long as your doctor tells you.

If you have any further questions about how long to take this medicine, ask your doctor.

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 0800 764 766) 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

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

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.

Remind any doctors, dentists and pharmacists you visit that you are taking Ofev.

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.

Things you must not do

Do not stop taking Ofev or lower the dosage without checking with your doctor first.

If you don't take this medicine as told by your doctor, your condition may become worse.

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

Things to be careful of

Diarrhoea is a very common side effect of Ofev and is sometimes severe.

Treatment at the first signs of diarrhoea is important. 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
- speak to your doctor and take anti-diarrhoeal medicine exactly as your doctor tells you.

You must immediately ask your doctor for further advice if your diarrhoea:

- becomes severe (with more than 4 bowel movements each day) or
- is not under control within 48 hours after taking the anti-diarrhoeal medicine.

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 and throwing up (vomiting)
- decreased appetite
- weight loss
- abscesses (a swollen area containing pus)
- mouth sores and inflammation
- rash or itching
- headache
- hair loss.

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

- more than 4 bowel movements in one day or diarrhoea that lasts more than 2 days after taking an anti-diarrhoeal medicine
- symptoms of an allergic reaction, such as:
 - 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.
- any signs and symptoms of dehydration such as headache, dizziness, tiredness or decreased urine output

- fever, chills, fast breathing or a fast heartbeat, as 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, as this could be symptoms of a hole in the wall of your gut ('gastrointestinal perforation')
- 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)
- any major bleeding
- severe upper stomach pain, often with nausea and vomiting, as this could be symptoms of inflammation of the pancreas (pancreatitis)
- bleeding or bruising more easily than normal as these 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, as these could be symptoms of a heart attack
- any signs and symptoms of liver problems such as:
 - yellowing of the skin or whites of the eyes
 - dark urine
 - pain on the upper right side of your stomach area (abdomen)
 - bleeding or bruising more easily than normal
 - feeling unusually tired.

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 capsules are available in two different strengths:

- **Ofev 100 mg soft capsule**
Peach-coloured, opaque, oblong shaped, soft gelatin capsules printed in black on one side with the Boehringer Ingelheim company logo and with "100".
- **Ofev 150 mg soft capsule**
Brown-coloured, opaque, oblong shaped, soft gelatin capsules printed in black on one side with the Boehringer Ingelheim company logo and with "150".

Both strengths of Ofev 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 nintedanib 100 mg (as 120.40 mg nintedanib esilate).

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

Inactive ingredients:

Ofev capsules also contain the following ingredients:

- medium chain triglycerides
- hard fat
- lecithin (soya)
- gelatin
- glycerol (85%)
- titanium dioxide (E171)
- iron oxide red (E172)
- iron oxide yellow (E172).
- black printing ink containing:
 - iron oxide black (E172)
 - shellac glaze
 - propylene glycol (E1520).

Supplier

Ofev is supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Ltd
Auckland

This Consumer Medicine
Information was updated in June
2023.

Ofev[®] is the brand name of this
medicine. Ofev is a registered
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