

Consumer Medicine Information (CMI) summary

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

1. Why am I using Giotrif?

Giotrif contains the active ingredient afatinib dimaleate. Giotrif is used to treat adult patients with a type of lung cancer called non-small cell lung cancer (NSCLC).

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

2. What should I know before I take Giotrif?

Do not take if you have ever had an allergic reaction to Giotrif or to 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 Giotrif?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Giotrif 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 Giotrif?

- The recommended dose is one tablet of Giotrif 40 mg each day. Your doctor may adjust your dose.
- Swallow the tablet with water. Do not crush or chew the tablet.

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

5. What should I know while taking Giotrif?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking Giotrif • If need to go to hospital, tell the medical staff that you are taking Giotrif • If you become pregnant while taking this Giotrif, tell your doctor immediately • Limit your exposure to sunlight while you are taking Giotrif.
Things you should not do	• Do not stop taking this medicine or lower the dosage without checking with your doctor • Do not take Giotrif 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.
Driving or using machines	• Be careful driving, operating machinery or doing jobs that require you to be alert until you know how Giotrif affects you.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 30°C • Keep your tablets in the blister pack until it is time to take them to protect from moisture and light.

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

6. Are there any side effects?

Tell your doctor immediately or go to Emergency at your nearest hospital if you experience sudden breathing difficulty or unexplained breathing problems associated with cough or fever, eye problems such as altered vision, pain and inflammation, severe upper stomach pain spreading to the back, severe diarrhoea, dehydration, nausea, vomiting, severe blisters and bleeding in the lips, eyes, mouth, nose and genitals, painful red areas of the skin, large blisters and peeling of the skin, fever and chills, aching muscles and generally feeling unwell.

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 Giotrif. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Giotrif.**

Where to find information in this leaflet:

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

1. Why am I taking Giotrif?

Giotrif contains the active ingredient afatinib dimaleate.

Giotrif belongs to a group of medicines called antineoplastic (or anti-cancer) agents.

It works by blocking the activity of a group of proteins from the ErbB family, which includes a protein called Epidermal Growth Factor Receptor (EGFR). These proteins are known to be involved in the growth and spread of cancer cells. By blocking the activity of these proteins Giotrif stops the cancer cells from growing and multiplying.

Giotrif is used to treat adult patients with a type of lung cancer called non-small cell lung cancer (NSCLC):

- of non-squamous type identified with a change (mutation) in the gene for EGFR. Giotrif can be prescribed to you as your first treatment or if your cancer has progressed after receiving chemotherapy
- of squamous type if your cancer has progressed after receiving chemotherapy.

2. What should I know before I take Giotrif?

Warnings

Do not take Giotrif if:

- you are allergic to afatinib dimaleate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take Giotrif

Check with your doctor if you:

- have any other medical
- have allergies to any other medicines, foods, preservatives or dyes
- have any liver problems
- have any kidney problems
- have a history of heart problems

- have a history of lung inflammation (interstitial lung disease)
- have a history of gastrointestinal problems
- have, or have had, cancer that has spread to the bowel
- are receiving medicines which could increase the risk of developing a hole in the wall of your gut, such as steroids (used to treat inflammation and allergies), NSAIDs (used to relieve pain, swelling and other symptoms of inflammation, including arthritis) or anti-angiogenic agents (used to treat cancer)
- use contact lenses and/or have a history of eye problems such as severe dry eyes, inflammation of the front part of the eye (cornea) or ulcers involving the front part of the eye
- cannot tolerate lactose monohydrate
- take any medicines for any other condition
- are not sure whether you should start taking this medicine.

If you have not told your doctor about any of the above, tell them before you start taking Giotrif.

Your doctor may want to take special precautions if you have any of the above conditions.

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?](#)

It is likely that your doctor will also prescribe an anti-diarrhoeal medicine (e.g. loperamide) for you to take in case you get diarrhoea after starting treatment with Giotrif.

Pregnancy and breastfeeding

Do not take Giotrif if you are pregnant.

Check with your doctor if you are pregnant or intend to become pregnant. Giotrif may affect your developing baby if you take it during pregnancy.

If you are a woman who could become pregnant, use adequate contraception during Giotrif treatment and for at least 2 weeks after taking the last dose.

Do not breast-feed if you are taking this medicine. The active ingredient in Giotrif may pass into breast milk and there is a possibility that your baby may be affected.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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 may interfere with Giotrif and affect how it works. These include:

- ritonavir, nelfinavir or saquinavir, medicines used to treat HIV infections
- ciclosporin or tacrolimus, medicines used to suppress the immune system
- ketoconazole or itraconazole, medicines used to treat fungal infections
- erythromycin or rifampicin, medicines used to treat infections
- verapamil, a medicine used to treat high blood pressure and angina
- amiodarone, a medicine used to treat irregular heartbeats
- carbamazepine, phenytoin or phenobarbital, medicines used to treat fits or convulsions
- herbal medicines derived from St John's wort (*Hypericum perforatum*)
- quinidine, a medicine used to treat irregular heartbeats
- sulfasalazine, a medicine used to treat inflammation
- rosuvastatin, a medicine used for lowering cholesterol.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Giotrif.

4. How do I take Giotrif?

How much to take

- The recommended dose is one tablet of Giotrif 40 mg each day.
- Your doctor may adjust (increase or decrease) your dose depending on how well you tolerate Giotrif. If you get severe diarrhoea or other intolerable side effects, your doctor may interrupt your treatment with Giotrif and then re-start your treatment at a lower dose.
- Follow the instructions provided and take Giotrif until your doctor tells you to stop.

When to take Giotrif

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take Giotrif on an empty stomach. Do not eat for at least 3 hours before taking your medicine and at least 1 hour after taking your medicine.

Food can interfere with the absorption of Giotrif.

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

How to take Giotrif

Swallow the tablet whole with a full glass of water. Do not chew or crush the tablets.

For patients with swallowing difficulties, the tablet can be dissolved in drinking water (non-sparkling). No other liquids should be used. Follow these instructions carefully:

1. Drop the tablet into half a glass of drinking water (non-sparkling). Do not break or crush the tablet
2. Stir the water occasionally for up to 15 minutes until the tablet is broken up into very small particles
3. Drink the liquid straight away
4. Rinse the empty glass with half a glass of drinking water and drink it.

If you forget to take Giotrif

Giotrif should be taken regularly at the same time each day. If it is less than 8 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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.

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 Giotrif

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

You should immediately:

- phone the Poisons Information Centre (Australia: 13 11 26; New Zealand: 0800 764 766), 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.

You may need urgent medical attention.

5. What should I know while taking Giotrif?

Things you should do

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Giotrif.

Tell any other doctors, dentists and pharmacists who treat you that you are taking Giotrif.

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

Call your doctor straight away if you:

- become pregnant while taking this medicine.

Things you should not do

- Do not take Giotrif to treat any other complaints unless your doctor tells you to.

- Do not give Giotrif to anyone else, even if they have the same condition as you.
- Do not stop taking Giotrif or lower the dosage without checking with your doctor.
- Do not give Giotrif to a child under the age of 18 years. 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.

Exposure to the sun

Limit your exposure to sunlight while you are taking Giotrif. When you are outdoors, wear a hat, protective clothing and sunscreen.

Giotrif may cause your skin to be much more sensitive to sunlight than it normally is. Rash or acne may occur or worsen in areas exposed to the sun.

Driving or using machines

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

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

Looking after your medicine

Keep your tablets in the blister pack until it is time to take them to protect from moisture and light.

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

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store it:

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

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.

Getting rid of any unwanted medicine

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

Do not take 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
• skin reactions such as acne-like rash, sometimes itchy with dry skin • mouth sores and inflammation • problems with your nails • loss of appetite or weight changes • bleeding from the nose • pain, redness swelling or peeling of the skin of your hands and feet • burning sensations during urination and frequent, urgent need to urinate • abnormal taste sensations • stomach pain, indigestion, heartburn • lip inflammation • runny nose • muscle spasms • fever • nausea • vomiting.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• any signs and symptoms of dehydration such as headache, dizziness, tiredness or decreased urine output • severe skin reactions such as peeling or blistering of the skin • 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 • sudden or worsening eye problems such as irritated, red, runny or itchy eyes, blurred vision, swollen or crusty eyelid, or dry eye • a combination of any of the following: breathlessness, swelling of the feet, ankles, legs or stomach, feeling tired, a feeling like your heart is racing or throbbing. • diarrhoea (usually occurs within the first 2 to 6 weeks of treatment) Diarrhoea is a very common side effect of Giotrif and this is sometimes severe. You may become	Speak to your doctor as soon as possible if you notice any of these serious side effects.

Serious side effects	What to do
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 the 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.	

Very serious side effects

Very serious side effects	What to do
- sudden difficulty in breathing or unexplained breathing problems associated with cough or fever. Some patients taking Giotrif have experienced a rare form of lung inflammation called interstitial lung disease which is a serious side effect. This side effect is uncommon. - severe upper stomach pain radiating to the back, nausea, vomiting, or fever (which may be symptoms of an inflamed pancreas) - severe blisters and bleeding in the lips, eyes, mouth, nose and genitals - painful red areas of the skin, large blisters and peeling of the skin, accompanied by fever and chills, aching muscles and generally feeling unwell. These side effects are uncommon. You may need urgent medical attention or hospitalisation.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.

Giotrif 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 or pharmacist if you notice anything else that is making you feel unwell.

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

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects in Australia to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

In New Zealand, side effects can be reported at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

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

What Giotrif contains

Active ingredient (main ingredient)	afatinib dimaleate
Other ingredients (inactive ingredients)	Each tablet also contains: - microcrystalline cellulose - colloidal anhydrous silica - crospovidone - magnesium stearate. The tablets also have a film-coating which contains: - hypromellose - macrogol 400 - titanium dioxide - purified talc - polysorbate 80 - colourant containing indigo carmine aluminium lake (only used for 30 mg and 40 mg tablets).
Potential allergens	lactose monohydrate

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

What Giotrif looks like

Giotrif is available in three strengths of film-coated tablets:

Giotrif 20 mg (AUST R 201314) - white to slightly yellowish, round tablets, imprinted with a "T20" code on one side and the company logo on the other side.

Giotrif 30 mg (AUST R 201318) - dark blue, round tablets, imprinted with a "T30" code on one side and the company logo on the other side.

Giotrif 40 mg (AUST R 201315) - light blue, round tablets, imprinted with a "T40" code on one side and the company logo on the other side.

Giotrif is packed in blister foils of 7*, 14* and 28 tablets. Each blister foil is packed together with a desiccant sachet in a protective foil pouch.

*Not distributed in Australia.

Who distributes Giotrif

Giotrif is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney

www.boehringer-ingelheim.com.au

Giotrif is supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Ltd

Auckland

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