

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.



This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I using CIBINQO?

CIBINQO contains the active ingredient abrocitinib. Abrocitinib is used to treat adults with moderate-to-severe atopic dermatitis, also known as atopic eczema. For more information, see Section [1. Why am I using CIBINQO?](#) in the full CMI.

2. What should I know before I use CIBINQO?

Do not use if you have ever had an allergic reaction to abrocitinib or any of the ingredients listed at the end of the CMI, if you are taking antiplatelet therapies (except for low dose aspirin) during first 3 months of treatment, in combination with biological disease-modifying anti-rheumatic drugs (bDMARDs), if you have a serious infection, including tuberculosis, if you have severe liver problems, or if you are pregnant or breastfeeding. Talk to your doctor if you have any other medical conditions particularly heart disease or risk factors, a history of deep vein thrombosis (DVT) or pulmonary embolism (PE), cancer, take any other medicines, smoke or have smoked in the past, or plan to become pregnant. For more information, see Section [2. What should I know before I use CIBINQO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with CIBINQO 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 use CIBINQO?

The recommended dose is either 100 mg or 200 mg once daily, depending on your doctor's assessment of your treatment needs, how your condition is being controlled and what other medical conditions you have.

Your doctor may increase or decrease your dose. If you are taking 200 mg, your doctor will decrease your dose to 100 mg once a day when your condition is well controlled. Swallow the tablets whole with a full glass of water. Do not split, crush, chew or break the tablet before swallowing. More instructions can be found in Section [4. How do I use CIBINQO?](#) in the full CMI.

5. What should I know while using CIBINQO?

Things you should do	<ul style="list-style-type: none">• Remind any doctor or dentist you visit that you are using CIBINQO.• Check with your doctor before taking CIBINQO if you have recently had or plan to have a vaccination (immunisation), you have an infection, tuberculosis, shingles, hepatitis B or C, have had or have cancer and if your liver does not work as well as it should or if you have had blood clots in the veins of your legs (DVT) or lungs (pulmonary embolism).
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Things you should not do	<ul style="list-style-type: none"> Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none"> CIBINQO has no or negligible influence on the ability to drive and use machines.
Drinking alcohol	<ul style="list-style-type: none"> Be careful when drinking alcohol at the same time as taking CIBINQO until you know how CIBINQO affects you.
Looking after your medicine	<ul style="list-style-type: none"> Keep your tablets in the pack until it is time to take them. Keep your tablets in a cool dry place where the temperature stays below 30°C.

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

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Side effects include nausea, vomiting, headache and dizziness, shingles, a rapidly spreading painful skin rash, sores

or blisters (with or without a fever), blood clots in the lungs, legs or pelvis with symptoms such as a painful swollen leg, chest pain or shortness of breath. 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.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

WARNING:

This medicine should only be used if there are no other suitable treatment alternatives in patients:

- **with a history of heart disease or stroke or any other risk factors for heart disease (such as current or past, long-time smokers)**
- **with risk factors for cancer (for example, patients who have cancer or a history of cancer)**
- **who are 65 years of age and older.**

CIBINQO

Active ingredient(s): *Abrocitinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using CIBINQO. **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 CIBINQO.**

Where to find information in this leaflet:

1. Why am I using CIBINQO?
2. What should I know before I use CIBINQO?
3. What if I am taking other medicines?
4. How do I use CIBINQO?
5. What should I know while using CIBINQO?
6. Are there any side effects?
7. Product details

1. Why am I using CIBINQO?

CIBINQO contains the active ingredient abrocitinib. This medicine belongs to a group of medicines called Janus kinase inhibitors.

Abrocitinib is used to treat adults with moderate-to-severe atopic dermatitis, also known as atopic eczema.

CIBINQO may be used with eczema medicines that you apply to the skin or it may be used on its own.

It works by reducing inflammation and itch in atopic dermatitis.

Using CIBINQO for atopic dermatitis (atopic eczema) can improve the condition of your skin and reduce itching.

CIBINQO has also been shown to improve symptoms of pain, anxiety, and depression associated with atopic dermatitis.

In addition, CIBINQO helps improve your sleep disturbance and overall quality of life.

2. What should I know before I use CIBINQO?

Warnings

Do not use CIBINQO if:

- You are allergic to abrocitinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have a serious infection, including tuberculosis.
- You have severe liver problems.
- You are pregnant or breast-feeding.

Check with your doctor if:

- You have an infection (fever, sweating, or chills, muscle aches, cough or shortness of breath, blood in your phlegm, weight loss, diarrhoea or stomach pain, burning when you urinate or urinating more often than usual, feeling very tired). CIBINQO can reduce your body's ability to fight infections and so may worsen an infection that you already have, or make it more likely for you to get a new infection.
- You have had tuberculosis or have been in close contact with someone with tuberculosis. Your doctor will test you for tuberculosis before starting CIBINQO and may retest during treatment.
- You have had a herpes infection (shingles), because CIBINQO may allow it to come back. Tell your doctor

if you get a painful skin rash with blisters as these can be signs of shingles.

- You have ever had hepatitis B or hepatitis C.
- You have recently had or plan to have a vaccination (immunisation). Live vaccines are not recommended while using CIBINQO.
- You have had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). CIBINQO increases the risk of deep vein thrombosis (DVT) and pulmonary embolism (PE). There are known risk factors that increase your baseline risk, these are: older age, obesity, past PE/DVT, clotting disorder, use of the oral contraceptive pill or hormone replacement therapy, if you are having major surgery or prolonged immobilisation. Tell your doctor if you get a painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the veins.
- You have cancer or have had any cancer.
- You smoke or have smoked in the past.
- You have, or have had heart problems.
- If you have or have had medical conditions associated with low platelet count, platelets that don't work well leading to the potential for bleeding, or if you take medications which make it harder for your blood to clot.

Your doctor will discuss with you if CIBINQO is appropriate for you.

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

CIBINQO must not be used during pregnancy and breastfeeding.

You should use an effective method of contraception to avoid becoming pregnant during treatment with CIBINQO and for at least 1 month after the last dose of CIBINQO treatment.

You must not use CIBINQO while breast-feeding as it may pass into your breast milk.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Blood tests

Your doctor should do blood tests before you start taking CIBINQO and also while you are taking CIBINQO to check for the following:

- Low lymphocyte or neutrophil count. Lymphocytes and neutrophils are white blood cells that help the body fight off infections.
- Low haemoglobin. Haemoglobin is a part of red blood cells that carries oxygen to the body.
- Low platelet count. Platelets are small, colourless cell fragments in our blood that form clots and stop or prevent bleeding.

- Increase in the amount of blood fat (cholesterol) in the blood.

You should not take CIBINQO if your lymphocyte count or platelet count is too low. Your doctor may stop or interrupt your CIBINQO treatment for a period of time if there are changes in these blood test results.

You may also have changes in other laboratory tests, such as your blood cholesterol levels.

Skin Check

Non-melanoma skin cancer has been observed in patients taking CIBINQO. Your doctor may recommend that you have regular skin examinations while taking CIBINQO. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

Children

Do not give this medicine to a child below the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

Elderly

Patients aged 65 years and older may be at increased risk of infections, heart attack and some types of cancer. Your doctor may decide that CIBINQO is not suitable for you.

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 CIBINQO and affect how it works. These include:

- Fluvoxamine, a medicine used to treat depression
- Fluconazole, a medicine used to treat fungal infections
- Rifampin, a medicine used to treat bacterial infections
- Antiplatelet medicines, medicines that prevent blood clots from forming
- Antacids, famotidine or omeprazole, medicines used to treat stomach acid reflux
- Dabigatran, clopidogrel, medicines used for stroke
- Digoxin, a medicine used for heart failure
- Phenytoin, a medicine used to treat seizures or fits
- Ciclosporin, other Janus kinase inhibitors, such as baricitinib, upadacitinib, biologic antibody therapies, medicines that control the body's immune response used to treat asthma, rheumatoid arthritis, or atopic dermatitis
- Apalutamide, enzalutamide, medicines used for prostate cancer
- Efavirenz, a medicine used to treat HIV infection

These medicines may be affected by CIBINQO 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 CIBINQO.

4. How do I use CIBINQO?

How much to take

- Always take this medicine exactly as your doctor has told you.
- The recommended dose in adults is 100 mg or 200 mg once daily, based on your doctor's assessment of the treatment needs, clinical condition, your age, and whether you are at higher risk of blood clots, cancer and heart conditions when taking the medicine.
- Your doctor may decrease or increase the dose based on how you respond or how you tolerate the medicine.
- The maximum daily dose is 200 mg. If you are prescribed 200 mg, your doctor will decrease your dose to 100 mg once a day when your condition is well controlled.
- CIBINQO may be used with eczema medicines that you apply to the skin or it may be used on its own.
- If you have kidney problems considered moderate-to-severe by your doctor, or if you are prescribed certain other medicines (see Section [3. What if I am taking](#)

[other medicines?](#)), the dose of CIBINQO will be 50 mg or 100 mg once a day.

- Your doctor may also stop treatment temporarily or permanently if blood tests show low white blood cells or platelet counts.

When to take CIBINQO

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

Do not split, crush, chew or break the tablet before swallowing.

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.

It does not matter if you take this medicine before or after food. If you experience nausea (feeling sick in the stomach), taking your tablet with food may improve nausea.

If you forget to use CIBINQO

If you miss a dose and it is more than 12 hours before your next dose is due, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is less than 12 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much CIBINQO

If you think that you have used too much CIBINQO, 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 CIBINQO?

Things you should do

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Call your doctor straight away if:

- you become pregnant while taking this medicine.

Things you should not do

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

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

Driving or using machines

CIBINQO has no or negligible influence on the ability to drive and use machines.

Drinking alcohol

Tell your doctor if you drink alcohol.

Be careful when drinking alcohol until you know how CIBINQO affects you.

Looking after your medicine

Keep your tablets in the pack until it is time to take them.

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

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

Do not use this medicine after the expiry date.

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.

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.

Common side effects

Common side effects	What to do
<p>Stomach related:</p> <ul style="list-style-type: none">• Nausea, vomiting, upper abdominal pain <p>Nervous system:</p> <ul style="list-style-type: none">• Headache, dizziness <p>Infections:</p> <ul style="list-style-type: none">• Cold sores <p>Skin:</p> <ul style="list-style-type: none">• Acne	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Blood clots:</p> <ul style="list-style-type: none"> • Blood clots in the lungs, legs or pelvis with symptoms such as a painful swollen leg, chest pain or shortness of breath <p>Infections:</p> <ul style="list-style-type: none"> • Shingles (herpes zoster) painful skin rash with blisters and fever • Signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers <p>Cancers:</p> <ul style="list-style-type: none"> • Cancers, including skin cancers. The risk of cancer is higher if you are, or have ever been, a smoker. <p>Heart related:</p> <ul style="list-style-type: none"> • Increased cholesterol, increased 	<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
cardiovascular disease events	

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:

- Rapidly spreading painful rash, blisters or sores (with or without fever) known as eczema herpeticum or Kaposi's varicelliform eruption.

Some side effects may not give you any symptoms and can only be found when tests are done. Some of these side effects include:

- Low levels of platelets in the blood
- Low white blood cell count
- Increase in the amount of cholesterol in the blood

Your doctor will make sure that tests are done to watch for these side effects.

Your doctor may periodically check your skin for cancers.

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 CIBINQO contains

Active ingredient (main ingredient)	Abrocitinib
Other ingredients (inactive ingredients)	Tablet core Microcrystalline cellulose Calcium hydrogen phosphate Sodium starch glycollate Magnesium stearate Film-coat Hypromellose (E464) Titanium dioxide (E171) Lactose monohydrate Macrogol 3350

	Triacetin (E1518) Iron red oxide (E172)
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Do not take this medicine if you are allergic to any of these ingredients.

What CIBINQO looks like

CIBINQO 50 mg film-coated tablet is pink and oval in appearance with “PFE” on one side and “ABR 50” on the other.

CIBINQO 100 mg film-coated tablet is pink and round in appearance with “PFE” on one side and “ABR 100” on the other.

CIBINQO 200 mg film-coated tablet is pink and oval in appearance with “PFE” on one side and “ABR 200” on the other.

50 mg tablet: AUST R 346349

100 mg tablet: AUST R 346350

200 mg tablet: AUST R 346351

Who distributes CIBINQO

CIBINQO is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

www.pfizermedicalinformation.com.au

Toll Free Number: 1800 675 229

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