

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **CIBINQO**[®]

abrocitinib tablets

Read this carefully before you start taking **CIBINQO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CIBINQO**.

Serious Warnings and Precautions

CIBINQO may cause serious side effects, including:

- **Serious infections:** CIBINQO is a medicine that affects your immune system. CIBINQO can lower the ability of your immune system to fight infections. This can cause serious infections that can lead to hospitalization or death. The most common types of infections were caused by viruses. Before you take CIBINQO tell your healthcare professional if you have an infection or get infections that often come back. Your healthcare professional will assess the risks before you begin treatment with CIBINQO if you have a chronic and reoccurring infection. They will closely monitor you for symptoms of an infection during and after your treatment with CIBINQO. This includes monitoring you for symptoms of tuberculosis. Your healthcare professional may suspend your treatment if you develop a serious infection.
- **Cancer:** CIBINQO may increase your risk of getting cancer, by changing the way your immune system works. Before you take CIBINQO, tell your healthcare professional if you have ever had cancer. People taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors may have a higher risk of certain cancers including lymphoma.
- **Blood clots:** CIBINQO may increase your risk of getting blood clots in the veins of your legs (**deep vein thrombosis**), lungs (**pulmonary embolism**, or arteries (**arterial thrombosis**). These blood clots can be serious or life threatening. Your healthcare professional will assess your risk of getting blood clots and tell you if it is safe to take CIBINQO. Blood clots in the veins of the legs and lungs have happened more often in people who are taking JAK inhibitors.
- **Heart problems, Stroke and Death:** JAK inhibitors may increase your risk of heart problems including heart attack or your risk of stroke. These can lead to death.

See section “**Other warnings you should know about**” for more information on these serious side effects.

What is CIBINQO used for?

CIBINQO is used to treat patients 12 years of age and older with:

- Moderate to severe atopic dermatitis (a type of eczema).
- It includes relief of skin itching in these patients.

CIBINQO is only used in patients who:

- Have not responded sufficiently to other non-topical medicines

- Cannot take other non-topical medicines for this condition.

CIBINQO should be used with caution in elderly patients 65 years of age and over.

How does CIBINQO work?

CIBINQO interferes with an enzyme called Janus Kinase (JAK). It is a medicine known as a JAK inhibitor. Normally JAK enzymes help turn on your immune system when you need it. However, when it is too active this can also lead to inflammation that could result in swelling, redness and pain. CIBINQO works by attaching to the JAK enzyme to lower its activity.

What are the ingredients in CIBINQO?

Medicinal ingredients: abrocitinib

Non-medicinal ingredients: dibasic calcium phosphate anhydrous, hypromellose, iron oxide red, lactose monohydrate, Macrogol/PEG, magnesium stearate, microcrystalline cellulose, sodium starch glycolate, titanium dioxide and triacetin.

CIBINQO comes in the following dosage forms:

Film-coated tablets: 50 mg, 100 mg and 200 mg.

Do not use CIBINQO if:

- you are allergic to abrocitinib or to any of the other ingredients in CIBINQO. If you are not sure, talk to your healthcare professional before taking CIBINQO.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CIBINQO. Talk about any health conditions or problems you may have, including if you:

- are taking other immunosuppressant medicines such as methotrexate and cyclosporine or other JAK inhibitor medicines.
- have an infection or get infections that often come back.
- have hepatitis virus B or C infection.
- have liver problems.
- have kidney problems.
- have a low platelet count or white blood cell count.
- have or have had cancer.
- are 65 years of age or older.
- are a long-term current or past smoker.
- have a history of heart problems.

Other warnings you should know about:

CIBINQO may cause serious side effects, including:

- **Serious Infections:** Tell your healthcare professional if you have an infection or get infections that often come back. Taking CIBINQO increases your risk of developing serious infections such as herpes simplex, shingles (herpes zoster) and pneumonia. CIBINQO may also make infections such as shingles and herpes simplex come back. Your healthcare professional will closely monitor you for infection during and after your treatment. They may put you on antimicrobial therapy if you develop a new infection during treatment. They might also stop your treatment with CIBINQO. They will also screen you for the following infections before and during treatment with CIBINQO:

- **Tuberculosis (TB):** You should not take CIBINQO if you have an active TB infection. Your healthcare professional may put you on preventative medication before beginning treatment with CIBINQO. You will be given this if you are newly diagnosed with inactive TB or had an untreated previous diagnosis of inactive TB.
- **Viral hepatitis:** Tell your healthcare professional if you have hepatitis virus B or C infection. They will also screen you these infections before you start treatment with CIBINQO.

Talk to your healthcare professional if you get any symptoms of an infection including, shingles, herpes simplex, pneumonia or other infection while you are taking CIBINQO.

- **Cancer:** Before you take CIBINQO, tell your healthcare professional if you have or have had cancer. CIBINQO may increase your risk of getting certain cancers. If you smoke, this might further increase your risk of getting certain cancers while taking CIBINQO. Your healthcare professional may want to examine your skin regularly for any sign of cancer.
- **Blood Clots:** CIBINQO may increase your risk of getting blood clots in the veins of your legs or lungs. Your healthcare professional will assess your risk of getting blood clots and tell you if it is safe to take CIBINQO. While you are taking CIBINQO, your healthcare professional will continue to assess your risk of getting blood clots. You are more likely to get blood clots while taking CIBINQO if you:
 - Are immobile for a long time.
 - Have major surgery.
 - Are 65 years of age or older.
 - Have had blood clots in the veins of your legs or lungs in the past.
 - Have an inherited blood clotting disorder.
 - Take hormone therapy or birth control pills.
 - Are a long-term current or past smoker.
 - Have certain kinds of cancer.

Stop taking CIBINQO and talk to your healthcare professional right away if you get any symptoms of blood clots in the veins of your legs (**deep vein thrombosis**) or lungs (**pulmonary embolism**) while you are taking CIBINQO.

- **Heart problems, Stroke and Death:** CIBINQO may increase your risk of heart attacks and stroke. You may be more likely to get these if you are 65 years of age or older, are or were a long-term smoker, or have a history of heart problems. Talk to your healthcare professional about these risk factors.

Stop taking CIBINQO and get immediate medical help if you develop any symptoms of a heart attack during treatment with CIBINQO.

See the “**Serious side effects and what to do about them**” table for more information on these and other serious side effects.

Vaccinations:

You should not receive live or attenuated vaccines while receiving CIBINQO or immediately before you start treatment. Your immunizations should be up to date before taking CIBINQO. This includes vaccines for shingles. Talk to your healthcare professional before taking CIBINQO if you are planning to receive a vaccine.

Pregnancy:

Before taking CIBINQO, tell your healthcare professional if you are pregnant, think you might be pregnant or are planning to become pregnant. You should avoid becoming pregnant while you are taking CIBINQO and for at least 1 month after stopping treatment. This is because CIBINQO may harm your unborn baby. Use effective birth control during treatment and for at least 1 month after your last dose of CIBINQO. Talk to your healthcare professional about effective birth control methods. Tell your healthcare professional right away if you become pregnant or think you may be pregnant while taking CIBINQO.

Breastfeeding:

Before you take CIBINQO, tell your healthcare professional if you are breastfeeding or plan to breastfeed. You should not breastfeed while you are taking CIBINQO. This is because it may pass into your breastmilk and harm your baby. Talk to your healthcare professional about the best way to feed your baby if you are taking CIBINQO.

Monitoring and tests:

Your healthcare professional should do blood tests before you start taking CIBINQO and also while you are taking CIBINQO. You should not take CIBINQO if your white blood cell count or platelet count is too low. Your healthcare professional may stop or interrupt your treatment for a period of time depending on your blood test results. Your healthcare professional will also monitor your blood lipid levels while you are taking CIBINQO.

Driving and using machines:

CIBINQO may cause dizziness, which can affect how well you drive or use machines. Do NOT drive or use dangerous machines until you know how CIBINQO affects you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with CIBINQO:

- Fluconazole, used to treat fungal or yeast infections.
- Fluvoxamine, used for the treatment of some psychiatric disorders.
- Amiodarone, used to treat heart rhythm problems.
- Fluoxetine, used for the treatment of some psychiatric disorders.
- Miconazole, used to treat fungal or yeast infections.
- Rifampicin, used to treat tuberculosis (TB) and other infections.

- Probenecid, used to treat gout and renal problems.

How to take CIBINQO:

- Take CIBINQO exactly as your healthcare professional has told you to.
- Check with your healthcare professional if you are not sure.
- You can take CIBINQO with or without food. However, if you experience nausea taking CIBINQO with food might make your nausea better.
- Take CIBINQO at about the same time each day.
- Swallow tablets whole with water. Do not split, crush, or chew the tablets.
- CIBINQO can be used with or without prescribed topical medications for atopic dermatitis. Topical medications are lotions, creams, or ointments applied to your skin.
- If you have kidney problems, talk to your healthcare professional. You may need to take a lower dose.
- Your healthcare professional might also give you a lower dose if you are taking certain other medicines.

Usual dose:

Adolescents (between 12 and 18 years of age) and adults: The recommended starting dose is 100 mg or 200 mg once a day. Your healthcare professional will prescribe the dose that is right for you. They may change your dose depending on your condition and the risk of side effects.

Taking more than 200 mg in a day is not recommended.

Patients over 65 years of age should start with 100 mg in a day.

Overdose:

If you think you, or a person you are caring for, have taken too much CIBINQO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose, take it as soon as you remember. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Never take two doses at the same time.

What are possible side effects from using CIBINQO?

These are not all the possible side effects you may have when taking CIBINQO. If you experience any side effects not listed here, tell your healthcare professional.

Side effects with CIBINQO may include:

- acne
- cold sores (also known as oral herpes simplex)
- dizziness
- headache
- nausea

- abdominal pain
- vomiting
- urinary tract infection
- nose or throat infection, pain in the nose or throat, runny or stuffy nose
- feeling tired
- red sores or blisters, often around the nose and mouth

CIBINQO can cause abnormal blood test results. Your healthcare professional may do blood tests before you start CIBINQO and while you take it. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Herpes simplex (infection of the genitals, eyes or skin caused by the herpes simplex virus): tingling, pain or itching in genital area, small red blisters or sores on penis, scrotum or vaginal area, redness, pain or swelling around the eye, blurred vision, watery eyes, tingling, pain or itching in genital area, small red blisters or sores on any skin area.		√	
Infections: fever, chills, muscle aches, flu-like symptoms, cough, sore throat, diarrhea or stomach pain, feeling tired.		√	
UNCOMMON			
Blood clots:			
• Deep vein thrombosis (blood clot in legs): swelling, pain, leg may be warm to the touch and may appear red.			√
• Pulmonary embolism (blood clot in lungs): chest pain that may increase with deep breathing, cough, coughing up bloody sputum, shortness of breath.			√
Cancer including skin cancer. Symptoms may be variable		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Myocardial infarction (heart attack): pressure or squeezing pain between the shoulder blades, in the chest, jaw, left arm or upper abdomen, shortness of breath, dizziness, fatigue, light-headedness, clammy skin, sweating, indigestion, anxiety, feeling faint and possible irregular heartbeat			√
Lymphopenia (low white blood cells): get infections more easily.		√	
Pneumonia: (lung infection): chest pain when you breath or cough, confusion, cough which may produce phlegm, fatigue, fever, sweating and shaking, chills, nausea, vomiting or diarrhea, shortness of breath.		√	
Shingles , also known as herpes zoster (skin infection): a painful skin rash of fluid-filled blisters, blisters appear along a strip of skin, itching or tingling of the skin.		√	
Thrombocytopenia (low blood platelets): bruising or bleeding		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store CIBINQO at room temperature between 15°C - 30°C.
- Store CIBINQO in the original package.
- Keep out of reach and sight of children.

If you want more information about CIBINQO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (www.pfizer.ca) or by calling 1-800-463-6001.
- For more information on the CIBINQO Education Program (Prescriber Brochure and Patient Card), please visit the CIBINQO website (www.cibinqo.ca).

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