

Your name: _____

Prescriber's name: _____

Prescriber's phone number: _____

CIBINQO start date: _____

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 patients aged 65 years or older.

Safety information for patients taking CIBINQO

- This leaflet contains important safety information you should be aware of before starting, during, and after treatment
- For more information, read the Patient Medication Information leaflet included in each pack of CIBINQO
- If any of the information is not clear, ask your doctor or pharmacist any questions you may have

Keep this leaflet with you and show it to any healthcare professional involved in your medical care – for example, your pharmacist or an emergency doctor.

This material was developed by Pfizer, as part of the risk minimization plan for CIBINQO. This material is not intended for promotional use.

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 type 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 bosis**), lungs (**pulmonary embolism [PE]**), 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 a medicine in the class of medicines called Janus kinase (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 “Other warnings you should know about” for more information.

Do not use CIBINQO if you are allergic to **abrocitinib** or any of the **other ingredients** in CIBINQO, including:

- Dibasic calcium phosphate anhydrous
- Hypromellose
- Iron oxide red
- Lactose monohydrate
- Macrogol/PEG
- Magnesium stearate
- Microcrystalline cellulose
- Sodium starch glycolate
- Titanium dioxide
- Triacetin

If you are unsure, talk to your doctor before taking CIBINQO

Serious side effects and what to do about them



Talk to your healthcare professional if you experience any of the following serious side effects:

COMMON	Herpes simplex (infection of the genitals, eyes or skin caused by the herpes simplex virus) Symptoms include: 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, small red blisters or sores on any skin area
	Infections Symptoms include: fever, chills, muscle aches, flu-like symptoms, cough, sore throat, diarrhea or stomach pain, feeling tired
UNCOMMON	Cancer including skin cancer
	Lymphopenia (low white blood cells) Symptoms include: get infections more easily
	Pneumonia (lung infection) Symptoms include: chest pain when you breathe 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) Symptoms include: 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) Symptoms include: bruising or bleeding



Stop taking CIBINQO and get immediate medical help if you experience any of the following serious side effects:

UNCOMMON	Myocardial infarction (heart attack) Symptoms include: 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
	Blood clots <ul style="list-style-type: none">• Deep vein thrombosis (blood clot in legs) Symptoms include: swelling, pain, leg may be warm to the touch and may appear red• Pulmonary embolism (blood clot in lungs) Symptoms include: chest pain that may increase with deep breathing, cough, coughing up sputum, shortness of breath

If you have a troublesome symptom or side effect that isn't listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

For a list of the **most common side effects**, please see **the back** of this leaflet.

Before taking CIBINQO, talk to your healthcare professional about any health conditions or problems you may have, including the topics listed below



- 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
- All the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines

Other warnings you should know about



Serious infections

Your healthcare professional 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 for these infections before you start treatment with CIBINQO.

Monitoring and tests

Your healthcare provider should do blood tests before you start taking CIBINQO and 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.

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 doctor before taking CIBINQO if you are planning to receive a vaccine.

Blood clots

Your healthcare professional will assess your risk of developing blood clots before you begin treatment. You are more likely to get blood clots while taking CIBINQO if you are immobile for a long period of time, have major surgery, are older, are obese, have had blood clots in the veins of your legs or lungs in the past, have an inherited blood clotting disorder or take hormone therapy or birth control pills. 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. See “Serious side effects and what to do about them” for symptoms.

Heart problems, stroke and death

CIBINQO may increase your risk of heart attacks and stroke. You are more likely to get these if you have certain risk factors, including if you smoke. 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” for symptoms.

Pregnancy

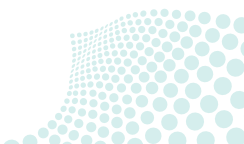
Before taking CIBINQO, tell your healthcare professional if you are pregnant, think you might be pregnant or are planning to become pregnant. You should avoid becoming pregnant while you are taking CIBINQO and for at least 1 month after stopping treatment. This is because CIBINQO may harm your unborn 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.

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.



Possible side effects

All the possible side effects you may feel when taking CIBINQO are not listed in this leaflet. If you experience any side effects not listed here, contact your healthcare professional.

Side effects with CIBINQO may include:

- Acne
- Cold sores (also called “herpes simplex”)
- Dizziness
- Headache
- Nausea
- Upper abdominal pain
- Vomiting

CIBINQO can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

For more information, read the Patient Medication Information leaflet included in each pack of CIBINQO.

