Patient Education

Baricitinib FDA Fact Sheet

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information

About this topic

Fact Sheet for Patients, Parents and Caregivers
Emergency Use Authorization (EUA) of Baricitinib

You (or your child) are being given a medicine called baricitinib to treat coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the risks and benefits of taking baricitinib, which you (or your child) have received or may receive.

Taking baricitinib may benefit certain people in the hospital with COVID-19. This Fact Sheet provides you with the significant known and potential risks and benefits of the emergency use of baricitinib for treatment of COVID-19. Healthcare providers can recommend or provide baricitinib to people they believe may benefit from it as authorized.

Read this Fact Sheet for information about baricitinib and talk to your healthcare provider if you have questions. It is your choice to take baricitinib, have your child receive baricitinib, or stop it at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. You can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?
The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

What is baricitinib?
Baricitinib is a prescription medicine that is FDA approved to treat:

- adult patients with moderately to severely active rheumatoid arthritis after treatment with at least one other medicine called a Tumor Necrosis Factor (TNF) antagonist has been used and did not work well enough or could not be tolerated.
- COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Baricitinib is still being studied in hospitalized children with COVID-19. There is limited information about the safety and effectiveness of using baricitinib to treat children in the hospital with COVID-19.

The FDA has authorized the emergency use of baricitinib for the treatment of COVID-19 in children under an Emergency Use Authorization (EUA). For more information on EUA, see the section "**What is an Emergency Use Authorization (EUA)?**" at the end of this Fact Sheet.

What should I tell my healthcare provider before taking baricitinib (or before my child receives baricitinib)?

Tell your healthcare provider about all of your (or your child's) medical conditions, including if you (or your child):

- Have an infection other than COVID-19. You (or your child) should not take baricitinib if you have an active tuberculosis infection.
- Have hepatitis B, hepatitis C, or HIV.
- Have ever had any type of cancer.
- Have had blood clots.
- Have kidney problems. You (or your child) should not take baricitinib if you have sudden, severe kidney problems or you (or your child) are on dialysis.
- Have liver problems.
- Have low red or white blood cell counts.
- Have recently received a vaccine.
- Are pregnant or breastfeeding.
- Are allergic to baricitinib.

Tell your healthcare provider about all the medicines you (or your child) take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Especially tell your healthcare provider if you (or your child) take:

- Probenecid
- Any medicines that affect your immune system

How should I (or my child) take baricitinib?

Baricitinib is given by mouth 1 time each day for 14 days or until you (or your child) are discharged from the hospital (whichever comes first), as instructed by your healthcare provider.

What are the important possible side effects of baricitinib?

Baricitinib may cause serious side effects, including:

- **Serious infections.** Baricitinib is a medicine that affects your (or your child's) immune system. Baricitinib can lower the ability of your (or your child's) immune system to fight infections other than COVID-19.
- **Blood clots.** Blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) can happen in some people taking baricitinib. This may be life threatening and cause death.
- **Changes in certain laboratory test results.** Your (or your child's) healthcare provider should do blood tests before you (or your child) start taking baricitinib to check how well your (or your child's) kidney and liver are working, as well as to check the number of white blood cells that help the body fight infections.
- **Allergic reactions.** Tell your (or your child's) healthcare provider right away if you (or your child) have symptoms such as rash, swelling of the lips, tongue, or throat, or hives

(raised red patches of skin that are often very itchy). This may mean you (or your child) are having an allergic reaction.

For more information see the Medication Guide for Olumiant® (baricitinib), at http://pi.lilly.com/us/olumiant-us-mg.pdf.

Tell your (or your child's) healthcare provider immediately if you (or your child) get:

- swelling, pain or tenderness in the leg
- sudden unexplained chest pain
- sudden worsening shortness of breath
- rash, swelling of your lips, tongue, or throat, or hives

What other treatment choices are there?

Veklury (remdesivir) is FDA-approved for the treatment of certain adults and children who are hospitalized with COVID-19. Talk with your doctor to see if Veklury is appropriate for you.

Like baricitinib, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-andresponse/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are authorized by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials for which you (or your child) may be eligible.

It is your choice for you (or your child) to be treated or not to be treated with baricitinib. Should you decide not to receive it or stop it at any time, it will not change your (or your child's) standard medical care.

What if I am pregnant or breastfeeding?

Baricitinib has not been studied in pregnant women or breastfeeding mothers. It is not known if baricitinib will harm your unborn baby or if baricitinib passes into your breast milk. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with baricitinib?

Tell your healthcare provider right away if you (or your child) have any side effect that bothers you (or them) or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Lilly by calling 1-855-LillyC19 (1-855-545-5921).

How can I learn more?

- Ask your healthcare provider
- Visit https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?

The United States FDA has made baricitinib available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Baricitinib for treatment of COVID-19 in hospitalized pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO, has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives.

All of these criteria must be met to allow for emergency use of the product during the COVID-19 pandemic. The EUA for baricitinib is in effect for the duration of the COVID-19 declaration justifying emergency use of baricitinib, unless terminated or revoked (after which baricitinib may no longer be used under the EUA).

Revised May 2022

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A4.0-BAR-NL0002-EUA PAT-YYYYMMDD

Baricitinib FDA Fact Sheet: https://www.fda.gov/media/143824/download

Report side effects to FDA MedWatch: www.fda.gov/medwatch

CDC: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Consumer Information Use and Disclaimer: We want you to understand more clearly each of the health conditions and procedures you may have. This patient leaflet is a summary of useful information to help you gain a better understanding of these health topics. Other information about this condition or procedure may be important for you to know. Please talk with your healthcare provider for more information about your special health needs.

Last Updated 5/31/22

Wolters Kluwer