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 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 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. Older people and 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. Baricitinib is not FDA-approved to treat COVID-19.

Baricitinib is being studied for the treatment of certain people in the hospital with COVID-19. There is limited information about the safety and effectiveness of using baricitinib to treat people in the hospital with COVID-19.

The FDA has authorized the emergency use of baricitinib for the treatment of COVID-19 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?
Tell your healthcare provider about all of your medical conditions, including if you:

- Have an infection other than COVID-19. You 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 should not take baricitinib if you have sudden, severe kidney problems or you 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 take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Especially tell your healthcare provider if you take:

- Probenecid
- Any medicines that affect your immune system

How should I take baricitinib?
Baricitinib is given to you by mouth 1 time each day for 14 days or until you 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 immune system. Baricitinib can lower the ability of your 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 healthcare provider should do blood tests before you start taking baricitinib to check how well your kidney and liver are working, as well as low white blood cells that help the body fight infections.
- **Allergic reactions.** Tell your healthcare provider right away if you have symptoms such as rash, swelling of your lips, tongue, or throat, or hives (raised red patches of skin that are often very itchy). This may mean you 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 healthcare provider immediately if you 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?
A medicine to treat people in the hospital with COVID-19 has been FDA approved. Like baricitinib, FDA may allow for the emergency use of other medicines that are not approved by FDA to treat people in the hospital with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on the emergency use of other medicines that are not approved by FDA to treat people in the hospital with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice 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 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 if you have any side effect that bothers you 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 EUA as a treatment for certain patients with COVID-19. 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, as a treatment for COVID-19, has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for baricitinib as a treatment for certain patients with COVID-19 is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

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