Authorized Distributors of Record

You can take an active role in ensuring the security of the pharmaceutical supply chain by sourcing products only from Authorized Distributors that have entered into distribution agreements with Eli Lilly and Company (Lilly).

Under the EUA, baricitinib is available as 1 mg and 2 mg tablets.

Baricitinib Emergency Use Distribution Network

Authorized Lilly Specialty Distributors*	Contact Information
AmerisourceBergen Specialty Group	**ASD Healthcare** p: 800-746-6273 f: 800-547-9413 www.asdhealthcare.com
Cardinal Health Specialty Pharmaceutical Distribution	**Hospitals** p: 866-476-1340 f: 888-345-4916 www.cardinalhealth.com/specialtyonline
Cardinal Health Puerto Rico	**Hospitals – PR** p: 787-625-4244 f: 787-625-4398 https://cardinalhealth.pr
McKesson Specialty Care Distribution Corporation	**McKesson Plasma and Biologics** p: 877-625-2566 f: 888-752-7626 https://Connect.mckesson.com
Drogueria Betances (Puerto Rico)	**Institutional Sales** p: 787-653-0998 f: 787-744-7773 www.drogueriabetances.com

*Table current as of 05/13/2022.

Baricitinib is authorized for use under an Emergency Use Authorization (EUA) for treatment of coronavirus disease 2019 (COVID-19) in hospitalized pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Baricitinib has not been approved, but has been authorized for emergency use by the FDA for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

Baricitnib is authorized under an Emergency Use Authorization (EUA) only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of baricitnib under section 654(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

For information on the authorized use of baricitinib and mandatory requirements under the EUA, please review the:
FDA Letter of Authorization, Fact Sheet for Healthcare Providers, Fact Sheet for Patients, Parents and Caregivers (English), or Fact Sheet for Patients, Parents and Caregivers (Spanish)

Please see Important Safety Information on the following page, and click to access the Fact Sheet for Healthcare Providers and Fact Sheet for Patients, Parents and Caregivers

IMPORTANT SAFETY INFORMATION

The following provides essential safety information on the unapproved use of baricitinib under the Emergency Use Authorization.

WARNINGS

There are limited clinical data available for baricitinib in pediatric patients 2 to less than 18 years of age hospitalized with COVID-19 requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.

Serious Infections: There is limited information regarding use of baricitinib in patients with COVID-19 and concomitant active serious infections.

Serious infections, including viral reactivation, have occurred in patients with COVID-19 receiving baricitinib. Avoid the use of baricitinib with known active tuberculosis. Consider if the potential benefits outweigh the potential risks of baricitinib treatment in patients with active serious infections other than COVID-19 or chronic/recurrent infections.

Thrombosis: Serious venous thrombosis, including pulmonary embolism have been observed in COVID-19 patients treated with baricitinib and are known adverse drug reactions of baricitinib. If clinical features of deep vein thrombosis or pulmonary embolism occur, patients should be evaluated promptly and treated appropriately.

Abnormal Laboratory Values: There is limited information regarding use of baricitinib in patients with COVID-19 and any of the following clinical findings: absolute neutrophil count (ANC) <1000 cells/mm^3, absolute lymphocyte count (ALC) <200 cells/mm^3, and hemoglobin <8 g/dL.

Evaluate estimated glomerular filtration rate (eGFR), liver enzymes, and complete blood count at baseline and thereafter according to local patient management practice. Monitor closely when treating patients with abnormal baseline and post-baseline laboratory values. Follow dosage modifications as recommended in the Fact Sheet for Healthcare Providers for patients with abnormal renal, hematological and hepatic laboratory values. Manage patients according to routine clinical guidelines.

Vaccinations: Avoid use of live vaccines with baricitinib.

Hypersensitivity: If a serious hypersensitivity occurs, discontinue baricitinib while evaluating the potential causes of the reaction.

See **Warnings and Precautions** in the FDA-approved full Prescribing Information and Medication Guide for additional information on risks associated with baricitinib treatment.

SERIOUS SIDE EFFECTS

Serious venous thrombosis, including pulmonary embolism, and serious infections have been observed in COVID-19 patients treated with baricitinib and are known adverse drug reactions of baricitinib.

ADVERSE REACTIONS

During the first 29 days in COVID-19 clinical trials, adverse reactions that occurred in ≥1% of patients treated with baricitinib vs placebo, respectively, were alanine aminotransferase (ALT) ≥3 x upper limit of normal (ULN) (18.1% vs 16.0%), aspartate aminotransferase (AST) ≥3 x ULN (11.8% vs 9.4%), thrombocytosis >600,000 cells/mm^3 (7.9% vs 4.6%), creatine phosphokinase (CPK) >5 x ULN (4.5% vs 4.7%), neutropenia <1000 cells/mm^3 (2.2% vs 1.8%), deep vein thrombosis (1.5% vs 1.4%), pulmonary embolism (1.5% vs 0.8%), and urinary tract infection (1.5% vs 1.0%).

USE IN SPECIFIC POPULATIONS

Pregnancy: Baricitinib should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.

Renal Impairment: There are limited data for baricitinib in patients with severe renal impairment. Baricitinib is not recommended for patients who are on dialysis, have end-stage renal disease, or have acute kidney injury.

Hepatic Impairment: Baricitinib has not been studied in patients with severe hepatic impairment. Baricitinib should only be used in patients with severe hepatic impairment if the potential benefit outweighs the potential risk.

Please see Fact Sheet for Healthcare Providers and Fact Sheet for Patients, Parents and Caregivers (English) or Fact Sheet for Patients, Parents and Caregivers (Spanish).

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