Baricitinib is a Janus kinase (JAK) inhibitor, which modifies the immune system’s inflammatory signalling.

**Clinical indications**

Baricitinib may be indicated in adults with confirmed severe or critical COVID-19. The effectiveness of baricitinib in children is uncertain.

**Available formulation and storage**

- Baricitinib is available in 1, 2 or 4 mg tablets.
- Store tablets at room temperature (20–25 °C).
- Dispersed tablets are stable in water for up to 4 hours.

**Contraindications and thresholds for discontinuation of treatment with baricitinib**

- The manufacturer advises against the use of baricitinib in children under 2 years. WHO makes no recommendation on its use in children due to a lack of data.
- Hypersensitivity to the active substance or to any of the excipients.
- Haemodialysis, or severe renal impairment defined as: creatinine clearance (CrCl) < 15 mL/min (adult patients)
- Known active tuberculosis infection
- Uncontrolled, confirmed or suspected severe systemic infection (other than COVID-19).
- Alanine aminotransferase (ALT) or Aspartate aminotransferase (AST) > 10 x upper limit of normal.
- Blood clot (arterial thrombosis, deep vein thrombosis, pulmonary embolism) within the last 12 weeks.
- Absolute neutrophil count (ANC) ≤ 0.5 x10^9/L.
- Absolute lymphocyte count (ALC) ≤ 0.2 x10^9/L.
- Haemoglobin < 8g/dL.
- Ongoing treatment with another JAK inhibitor for chronic condition.
- Ongoing treatment with another JAK inhibitor of disease modifying anti-rheumatic drug (DMARD) for inflammatory arthritis.

**Administration of baricitinib with other COVID-19 therapeutics**

- In patients with severe or critical COVID-19, WHO recommends corticosteroids and interleukin 6 (IL-6) receptor blockers (tocilizumab or sarilumab).
- Baricitinib can be given as an alternative or used in conjunction with IL-6 receptor blockers.

For detailed information, see WHO Therapeutics and COVID-19: living guideline. https://www.who.int/teams/health-care-readiness-clinical-unit/covid-19/therapeutics

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**Dosage and route**

**Route**
- The preferred route of administration is by mouth by tablet.
- If a patient is unable to swallow tablets, the tablet may be dispersed in water and administered orally, or given via nasogastric, orogastric or gastrostomy tube.

**Dose**
- The recommended dose is 4 mg daily orally in adults with eGFR ≥ 60 mL/min/1.73 m². Adjust the dose in patients with renal impairment (see table below).
- The effectiveness of baricitinib in children remains uncertain.

**Duration**
- The duration of therapy is 14 days or the last day of hospital admission if discharge occurs sooner.

<table>
<thead>
<tr>
<th>eGFR (mL/min/1.73 m²)</th>
<th>Recommended dose x 14 days or until discharge (whichever first)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 60</td>
<td>4 mg orally daily</td>
</tr>
<tr>
<td>30–60</td>
<td>2 mg orally daily</td>
</tr>
<tr>
<td>15–30</td>
<td>1 mg orally daily</td>
</tr>
<tr>
<td>≤ 15 or haemodialysis</td>
<td>Not recommended</td>
</tr>
<tr>
<td>Continuous renal replacement therapy (CRRT)</td>
<td>1–2 mg orally daily (dependent on dialysate rate)</td>
</tr>
</tbody>
</table>

**Dose adjustment**
- Baricitinib has not been studied in patients with severe hepatic impairment and it is unknown if dosage adjustment is needed in these patients.
- For patients taking strong organic anion transporter 3 (OAT3) inhibitors (e.g. probenecid), there are drug interactions which warrant dose reductions.

**Care for women and persons who can get pregnant, pregnant and breastfeeding patients**

**Women and persons who can get pregnant**
- Persons who can get pregnant should be advised to take appropriate precautions to avoid becoming pregnant during treatment with baricitinib and for at least 1 week after the final treatment.

**During pregnancy**
- There are limited data on the safety of baricitinib in pregnancy, and risk to the fetus cannot be ruled out.
- The decision regarding use of this therapeutic should be made between the pregnant person and their health care worker while discussing whether the potential benefit justifies the potential risk to the patient and fetus.
- Tocilizumab (an IL-6 receptor blocker) has a clearer safety profile in pregnancy, and should be considered.

**Breastfeeding persons**
- No information is currently available on the presence of baricitinib in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production.
- IL-6 blockers (tocilizumab and sarilumab) should be used in preference to baricitinib where possible.
- If a decision is made to use baricitinib, the patient should be instructed not to breastfeed while under treatment. The child should be fed with appropriate breastmilk substitutes, informed by feasibility, safety, sustainability, cultural context, acceptability to mother and service availability.
- Assistance should be provided after treatment for relactation to re-establish a milk supply and continue breastfeeding.