FIRST TIME GENERIC APPROVAL

Brand Name	Fotolyn™
Generic Name	pralatrexate
Drug Manufacturer	Fresenius Kabi USA, LLC

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

November 15, 2022

LAUNCH DATE

November 2022

REVIEW DESIGNATION

N/A

TYPE OF REVIEW

N/A

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Pralatrexate injection is a dihydrofolate reductase inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).
This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

MECHANISMS OF ACTION

Pralatrexate is a folate analog metabolic inhibitor that competitively inhibits dihydrofolate reductase. It is also a competitive inhibitor for polyglutamylation by the enzyme folylpolyglutamyl synthetase. This inhibition results in the depletion of thymidine and other biological molecules the synthesis of which depends on single carbon transfer.

DOSE FORM AND STRENGTH

Injection: 20 mg/1 mL or 40 mg/2 mL in a single-dose vial.

DOSE & ADMINISTRATION

- Supplement patients with vitamin B12 mg intramuscularly every 8-10 weeks starting 10 weeks before the first dose and folic acid 1 to 1.25 mg orally once daily starting 10 days before the first dose.

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- The recommended dosage of pralatrexate injection is 30 mg/m2 intravenously over 3 to 5 minutes once weekly for 6 weeks in 7-week cycles.
- For patients with severe renal impairment (GFR 15 to 29 mL/min/1.73 m2), reduce the pralatrexate injection dose to 15 mg/m2.