FAVLYXA™
(fluorouracil) injection

AVYXA

Ordering Information

To order FAVLYXA™ (fluorouracil) injection, please contact one of the authorized specialty distributors below:

2,500 mg/100 mL
NDC: 83831-0164-10

250 mg/10 mL
NDC: 83831-0143-01

Institutions/Hospitals	2,500 mg/100 mL	250 mg/10 mL
ASD Healthcare (Cencora)	10311267	10309111
Cardinal Health Specialty	6150791	N/A
McKesson Plasma & Biologics	3137288	N/A
Physician Offices	**2,500 mg/100 mL**	**250 mg/10 mL**
BioCare	1003374	N/A
Cardinal Health Specialty	6150791	N/A
McKesson Specialty	5023228	N/A
Oncology Supply (Cencora)	10311318	10309008

Highlights[1]

- No pre-heating required due to lower risk of precipitation when exposed to low temperatures
- Stable liquid formulation available in a 25 mg/mL concentration
- 2,500 mg/100 mL strength is supplied as multi-dose vials
- Diluted infusion solution is stable for a maximum of 24 hours
- Partially used vials are stable for up to 28 days at 20°C to 25°C (68°F to 77°F)

J-CODE

J9999

Unique J-Code Expected October 2026

Please see Important Safety Information including **Boxed Warning**, on page 2-3 and full Prescribing Information for FAVLYXA.

INDICATIONS AND IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

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INDICATIONS

FAVLYXA™ is indicated for the treatment of patients with:

- Adenocarcinoma of the Colon and Rectum
- Adenocarcinoma of the Breast
- Gastric Adenocarcinoma
- Pancreatic Adenocarcinoma

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS ADVERSE REACTIONS OR DEATH IN PATIENTS WITH COMPLETE DPD DEFICIENCY

- **Increased risk of serious adverse reactions or death in patients with complete DPD deficiency.**
- **Test patients for genetic variants of *DPYD* prior to initiating FAVLYXA unless immediate treatment is necessary. Avoid use of FAVLYXA in patients with certain homozygous or compound heterozygous *DPYD* variants that result in complete DPD deficiency.**

WARNINGS AND PRECAUTIONS

Serious Adverse Reactions or Death from Dihydropyrimidine Dehydrogenase (DPD) Deficiency

Patients with certain homozygous or compound heterozygous variants in the *DPYD* gene known to result in complete or near complete absence of DPD activity (complete DPD deficiency) are at increased risk for acute early-onset toxicity and serious, including fatal adverse reactions due to FAVLYXA (e.g., mucositis, diarrhea, neutropenia, and neurotoxicity). Patients with partial DPD activity (partial DPD deficiency) may also have increased risk of serious or fatal adverse reactions.

Prior to initiating FAVLYXA, test patients for genetic variants of the *DPYD* gene unless immediate treatment is necessary. Serious adverse reactions may still occur even if no *DPYD* variants are identified.

Avoid use of FAVLYXA in patients with certain homozygous or compound heterozygous *DPYD* variants that result in complete DPD deficiency.

Withhold or permanently discontinue FAVLYXA based on clinical assessment of the onset, duration, and severity of adverse events in patients with evidence of acute early-onset or unusually severe reactions. No fluorouracil dose has been proven safe for patients with complete DPD deficiency. For patients with partial DPD deficiency, individualize the dosage and modify based on tolerability and intent of treatment.

An FDA-authorized test for the detection of genetic variants of the *DPYD* gene to identify patients at risk of serious adverse reactions with FAVLYXA treatment is not currently available. Currently available tests used to identify *DPYD* variants may vary in accuracy and design (e.g., which *DPYD* variant(s) they identify).

Cardiotoxicity

FAVLYXA can cause cardiotoxicity, including angina, myocardial infarction/ischemia, arrhythmia, and heart failure, based on postmarketing reports. Reported risk factors for cardiotoxicity are administration by continuous infusion rather than intravenous bolus and presence of coronary artery disease. Withhold FAVLYXA for cardiotoxicity. The risks of resumption of FAVLYXA in patients with cardiotoxicity that has resolved have not been established.

Hyperammonemic Encephalopathy

FAVLYXA can cause hyperammonemic encephalopathy in the absence of liver disease or other identifiable cause, based on postmarketing reports. Signs or symptoms of hyperammonemic encephalopathy began within 72 hours after initiation of FAVLYXA infusion; these included altered mental status, confusion, disorientation, coma, or ataxia, in the presence of concomitant elevated serum ammonia level. Withhold FAVLYXA for hyperammonemic encephalopathy and initiate ammonia-lowering therapy. The risks of resumption of FAVLYXA in patients with hyperammonemic encephalopathy that has resolved have not been established.

Neurologic Toxicity

FAVLYXA can cause neurologic toxicity, including acute cerebellar syndrome and other neurologic events, based on postmarketing reports. Neurologic symptoms included confusion, disorientation, ataxia, or visual disturbances. Withhold FAVLYXA for neurologic toxicity. There are insufficient data on the risks of resumption of FAVLYXA in patients with neurologic toxicity that has resolved.

Diarrhea

FAVLYXA can cause severe diarrhea. Withhold FAVLYXA for Grade 3 or 4 diarrhea until resolved or decreased in intensity to Grade 1, then resume FAVLYXA at a reduced dose. Administer fluids, electrolyte replacement, or antidiarrheal treatments as necessary.

Palmar-Plantar Erythrodysesthesia (Hand-Foot Syndrome)

FAVLYXA can cause palmar-plantar erythrodysesthesia, also known as hand-foot syndrome (HFS). Symptoms of HFS include a tingling sensation, pain, swelling, and erythema with tenderness, and desquamation. HFS occurs more commonly when fluorouracil is administered as a continuous infusion than when fluorouracil is administered as a bolus injection, and has been reported to occur more frequently in patients with previous exposure to chemotherapy. HFS is generally observed after 8 to 9 weeks of fluorouracil administration but may occur earlier. Institute supportive measures for symptomatic relief of HFS. Withhold FAVLYXA administration for Grade 2 or 3 HFS; resume FAVLYXA at a reduced dose when HFS is completely resolved or decreased in severity to Grade 1.

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IMPORTANT SAFETY INFORMATION (continued)

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Myelosuppression

FAVLYXA can cause severe and fatal myelosuppression which may include neutropenia, thrombocytopenia, and anemia. The nadir in neutrophil counts commonly occurs between 9 and 14 days after fluorouracil administration. Obtain complete blood counts prior to each treatment cycle, weekly if administered on a weekly or similar schedule, and as needed. Withhold FAVLYXA until Grade 4 myelosuppression resolves; resume FAVLYXA at a reduced dose when myelosuppression has resolved or improved to Grade 1 in severity.

Mucositis

FAVLYXA can cause mucositis, stomatitis or esophagopharyngitis, which may lead to mucosal sloughing or ulceration.

The incidence is reported to be higher with administration of fluorouracil by intravenous bolus compared with administration by continuous infusion. Withhold FAVLYXA administration for Grade 3 or 4 mucositis; resume FAVLYXA at a reduced dose once mucositis has resolved or decreased in severity to Grade 1.

Increased Risk of Bleeding with Concomitant Use of Warfarin

Altered coagulation parameters and/or bleeding, including death, have been reported during concomitant use of warfarin and fluorouracil. Monitor INR more frequently and adjust the dose of warfarin in patients receiving concomitant warfarin.

Embryofetal Toxicity

FAVLYXA can cause fetal harm when administered during pregnancy. Advise females of reproductive potential to use effective contraception during treatment with FAVLYXA and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with FAVLYXA and for 3 months after the last dose.

ADVERSE REACTIONS

Please see the Warnings and Precautions listed above, and full prescribing information for FAVLYXA.

DRUG INTERACTIONS

Effect of FAVLYXA on Other Drugs

Vitamin K Antagonists

Monitor INR and PT more frequently in patients receiving FAVLYXA and warfarin. Elevated INR and PT have been reported in patients taking fluorouracil concomitantly with warfarin.

USE IN SPECIFIC POPULATIONS

Pregnancy

FAVLYXA can cause fetal harm when administered during pregnancy.

Lactation

Because of the potential for serious adverse reactions in the breastfed child, advise patients not to breastfeed during treatment with FAVLYXA and for 1 week after the last dose.

Females and Males of Reproductive Potential

FAVLYXA can cause fetal harm when administered to a pregnant woman.

Pregnancy Testing: Verify that females of reproductive potential are not pregnant prior to initiating FAVLYXA.

Contraception: Advise females of reproductive potential to use effective contraception during treatment with FAVLYXA and for 6 months after the last dose. Based on genotoxicity findings, advise males with female partners of reproductive potential to use effective contraception during treatment with FAVLYXA and for 3 months after the last dose.

Infertility: Based on animal studies, FAVLYXA may impair fertility in females and males of reproductive potential.

OVERDOSAGE

Administer uridine triacetate within 96 hours following the end of FAVLYXA infusion for management of fluorouracil overdose.

DOSAGE AND ADMINISTRATION

FAVLYXA is a hazardous drug. Follow applicable special handling and disposal procedures.

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Avoid use of FAVLYXA in patients known to have certain homozygous or compound heterozygous *DPYD* variants that result in complete DPD deficiency. No FAVLYXA dose has been proven safe for patients with complete DPD deficiency. For patients with partial DPD deficiency, individualize the dosage and modify based on tolerability and intent of treatment.

Please see FAVLYXA full Prescribing Information, including BOXED WARNING.

To report SUSPECTED ADVERSE REACTIONS, contact AVYXA Pharma, LLC at 1-888-520-0954 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Reference: 1. AVYXA Pharma, LLC. FAVLYXA (fluorouracil) Injection, Full Prescribing Information. Revised 07/2026.

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250 mg/10 mL
NDC: 83831-0143-01

AVYXA Pharma, LLC offers resources to help your patients start and stay on prescribed therapy. We are dedicated to providing your patients with ongoing support to help them access AVYXA Pharma, LLC medications as prescribed.

Contact your Account Manager to connect with a Field Reimbursement Manager for the latest payer coverage for patients and assistance with billing and coding.

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AVYXA

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