



AVOPEF™
(etoposide) injection



Ordering Information

To order AVOPEF (etoposide) injection, please contact one of the authorized specialty distributors below:



100 mg/5 mL
NDC: 83831-0144-05

Institutions/Hospitals	100 mg/5 mL
ASD Healthcare (Cencora)	10309112
Cardinal Health Specialty	6150551
McKesson Plasma & Biologics	3136728
Physician Offices	100 mg/5 mL
BioCare	1003372
Cardinal Health Specialty	6150551
McKesson Specialty	5023229
Oncology Supply (Cencora)	10309007

Highlights¹

- Free from preservative benzyl alcohol
- Supplied in multi-dose vials
- No reconstitution required and ready to use solution
- Partially used vials are stable for up to 28 days at 20°C to 25°C (68°F to 77°F)



**Unique J-Code Expected
October 2026**

INDICATIONS AND IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

INDICATIONS

Refractory Testicular Cancer

AVOPEF™, in combination with chemotherapy, is indicated for the treatment of refractory testicular cancer in adult patients.

Small Cell Lung Cancer

AVOPEF, in combination with chemotherapy and immunotherapy, is indicated for the first-line treatment of small cell lung cancer (SCLC) in adult patients.

IMPORTANT SAFETY INFORMATION

WARNING: SEVERE MYELOSUPPRESSION

- **AVOPEF can cause severe myelosuppression resulting in infection or bleeding.**
- **Do not administer AVOPEF to patients with absolute neutrophil counts of less than 500 cells/mm³ or platelets less than 50,000 cells/mm³.**
- **Monitor complete blood cell counts, prior to the administration of AVOPEF and before each subsequent cycle, and at appropriate intervals during and after therapy.**

WARNINGS AND PRECAUTIONS

Severe Myelosuppression

AVOPEF can cause severe and fatal myelosuppression, including neutropenia, febrile neutropenia, anemia, and thrombocytopenia.

Monitor complete blood counts with differential before each AVOPEF administration and at appropriate intervals during and after treatment with AVOPEF. Do not administer AVOPEF to patients with absolute neutrophil counts of less than 500 cells/mm³ or platelets less than 50,000 cells/mm³.

Hypersensitivity and Infusion-Related Reactions

AVOPEF can cause severe and fatal infusion-related reactions including anaphylactic reactions characterized by chills, fever, tachycardia, bronchospasm, dyspnea and hypotension. Hypertension and flushing have occurred.

At the first sign of hypersensitivity, stop the infusion and administer volume expanders, corticosteroids, antihistamines, and pressor agents as appropriate. Permanently discontinue AVOPEF in patients who experience a severe hypersensitivity reaction. Hypotension due to rapid intravenous injection has also occurred. To reduce the risk of hypotension due to an infusion-related reaction, administer AVOPEF by intravenous infusion over 30 to 60 minutes.

Extravasation Resulting in Tissue Necrosis

Extravasation of etoposide can result in swelling, pain, cellulitis, and tissue necrosis.

Secondary Leukemia

Secondary leukemia has occurred with use of etoposide.

Risk of Increased AVOPEF Toxicity with Low Serum Albumin

Etoposide is highly protein-bound. Patients with low serum albumin may have increased concentrations of unbound etoposide and may be at an increased risk for etoposide associated adverse reactions. Monitor for increased adverse reactions during treatment with AVOPEF in patients with low serum albumin.

Alcohol Content

The alcohol content in a dose of AVOPEF may affect the central nervous system and should be taken into account for patients in whom alcohol intake should be avoided or minimized. Consideration should be given to the alcohol content in AVOPEF on the ability to drive or use machines immediately after the infusion. Each administration of AVOPEF at 100 mg/m² delivers 1.5 g/m² of ethanol. For a patient with a BSA of 2.0 m² this would deliver 3.0 grams of ethanol. Other etoposide products may have a different amount of alcohol or no alcohol.

Embryo-Fetal Toxicity

AVOPEF can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise female patients of reproductive potential to use effective contraception during treatment with AVOPEF and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with AVOPEF and for 4 months after the last dose.

ADVERSE REACTIONS

The most common adverse reactions are myelosuppression, hypersensitivity, nausea/vomiting, and alopecia.

DRUG INTERACTIONS

Effect of Other Drugs on AVOPEF

CYP3A Inhibitors: Avoid concomitant use of strong CYP3A inhibitors. Etoposide is a CYP3A4 substrate. Strong CYP3A inhibitors may increase etoposide exposure, which may increase the risk of AVOPEF-associated adverse reactions.

CYP3A Inducers: Avoid concomitant use of strong CYP3A inducers. Etoposide is a CYP3A4 substrate. Strong CYP3A inducers may reduce etoposide exposure, which may decrease the effectiveness of AVOPEF.

Effect of AVOPEF on Other Drugs

Vitamin K Antagonists: Monitor INR more frequently and modify the dosage of the vitamin K antagonists as appropriate. Co-administration of AVOPEF with warfarin can result in elevated international normalized ratio (INR).

IMPORTANT SAFETY INFORMATION (continued)



USE IN SPECIFIC POPULATIONS

Pregnancy

AVOPEF can cause fetal harm when administered to a pregnant woman. AVOPEF contains alcohol which can interfere with neurobehavioral development. Additionally, published studies have demonstrated that alcohol is associated with fetal harm including central nervous system abnormalities, behavioral disorders and impaired intellectual development. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise female patients of reproductive potential to use effective contraception during treatment with AVOPEF and for 6 months after the last dose.

Lactation

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

Females and Males of Reproductive Potential

Pregnancy Testing: Verify the pregnancy status of female patients of reproductive potential prior to initiating AVOPEF.

Contraception: Advise females of reproductive potential to use effective contraception during treatment with AVOPEF and for 6 months after the last dose. Due to the potential for genotoxicity, advise males with female partners of reproductive potential to use effective contraception during treatment with AVOPEF and for 4 months after the last dose.

Infertility: In females of reproductive potential, AVOPEF may cause infertility and result in amenorrhea. Premature menopause can occur with AVOPEF. Recovery of menses and ovulation is related to age at treatment. In male patients, AVOPEF may result in oligospermia, azoospermia, and permanent loss of fertility. Sperm counts have been reported to return to normal levels in some men, and in some cases, have occurred several years after the end of therapy.

Geriatric Use

Reported clinical experience demonstrated that patients 65 years and older experienced more myelosuppression, anorexia, mucositis, dehydration, somnolence, elevated blood urea nitrogen (BUN), infectious complications and alopecia compared to younger patients. In general, dosage selection for an older patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

Renal Impairment

Reduce the dose of AVOPEF in patients with creatinine clearance (CL_{cr}) of 15 to 50 mL/min. No dosage modification is recommended for patients with CL_{cr} > 50 mL/min.

DOSAGE AND ADMINISTRATION GUIDELINES

It is very important that the dosage, preparation and administration instructions provided in the full prescribing information are strictly followed to reduce the risk of severe adverse reactions.

Do not administer AVOPEF by rapid intravenous injection. To reduce the risk of infusion-related reactions including hypotension, administer diluted AVOPEF intravenously over 30 to 60 minutes. A longer duration of administration may be used if there is a large volume of fluid to be infused.

Before each AVOPEF administration and at appropriate intervals during and after therapy, monitor complete blood counts with differential and serum albumin.

If severe reactions occur, reduce the dosage or discontinue AVOPEF and take appropriate corrective measures according to the clinical judgment of the healthcare provider.

Please see AVOPEF 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. AVOPEF (etoposide) injection. Prescribing information. Revised 06/2026.



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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.

Please see Important Safety Information including **Boxed Warning**, on page 2-3 and full [Prescribing Information](#) for AVOPEF.

