AXYCIS™
(cisplatin) Injection

AVYXA



Ordering Information

To order AXYCIS™ (cisplatin) Injection, please contact one of the authorized specialty distributors below:

Institutions/Hospitals	50 mg /50 mL (1 mg/mL)
ASD Healthcare (Cencora)	10313933
Cardinal Health Specialty	6178925
McKesson Plasma & Biologics	3158847
Physician Offices	**50 mg /50 mL (1 mg/mL)**
BioCare	1004572
Cardinal Health Specialty	6178925
McKesson Specialty	5024010
Oncology Supply (Cencora)	10313943

Highlights[1]

- Supplied in multi-dose vials
- No reconstitution required and ready to dilute solution
- Ready to add to intravenous infusion solution with different options:
  - 2 liters of 5% Dextrose in 0.45% Sodium Chloride Injection, containing 37.5 g of mannitol
  - 2 liters of 5% Dextrose in 0.33% Sodium Chloride Injection, containing 37.5 g of mannitol
- Diluted infusion solution is stable for 24 hours when protected from light and for 12 hours under fluorescent light at 20°C to 25°C (68°F to 77°F)
- Partially used vials are stable for 28 days in the original carton at 20°C to 25°C (68°F to 77°F) when protected from light

J-CODE

J9999

Unique J-Code Expected July 2027

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

INDICATIONS AND IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

INDICATIONS

Advanced Testicular Cancer

AXYCIS™ is indicated for the treatment of advanced testicular cancer.

Advanced Ovarian Cancer

AXYCIS is indicated for the treatment of advanced ovarian cancer.

Advanced Bladder Cancer

AXYCIS is indicated for the treatment of advanced bladder cancer.

IMPORTANT SAFETY INFORMATION

WARNING: NEPHROTOXICITY, PERIPHERAL NEUROPATHY, NAUSEA AND VOMITING, AND MYELOSUPPRESSION.

- **Nephrotoxicity: AXYCIS can cause severe renal toxicity, including acute renal failure. Severe renal toxicities are dose-related and cumulative. Ensure adequate hydration and monitor renal function and electrolytes. Consider dose reductions or alternative treatments in patients with renal impairment.**
- **Peripheral Neuropathy: AXYCIS can cause dose-related peripheral neuropathy that becomes more severe with repeated courses of the drug.**
- **Nausea and Vomiting: AXYCIS can cause severe nausea and vomiting. Administer pre-treatment and post-treatment antiemetics as clinically indicated.**
- **Myelosuppression: AXYCIS can cause severe myelosuppression with fatalities due to infections. Monitor blood counts accordingly. Interruption of therapy may be required.**

CONTRAINDICATIONS

AXYCIS is contraindicated in patients with severe hypersensitivity to cisplatin.

WARNINGS AND PRECAUTIONS

Nephrotoxicity

AXYCIS can cause dose-related nephrotoxicity, including acute renal failure that becomes more prolonged and severe with repeated courses of the drug. Renal toxicity typically begins during the second week after a dose of AXYCIS. Patients with renal impairment, geriatric patients, patients who are taking other nephrotoxic drugs, or patients who are not well hydrated may be more susceptible to nephrotoxicity.

Ensure adequate hydration before, during, and after AXYCIS administration. Measure serum creatinine, blood urea nitrogen, creatinine clearance, and serum electrolytes including magnesium prior to initiating therapy, and as clinically indicated. Consider magnesium supplementation as clinically needed.

Consider alternative treatments or reduce the dose of AXYCIS for patients with renal impairment or who develop significant reductions in creatinine clearance during treatment with AXYCIS according to clinical treatment guidelines.

Peripheral Neuropathy

AXYCIS can cause dose-related peripheral neuropathy that becomes more severe with repeated courses of the drug. Neurologic symptoms can occur after a single dose. Neuropathy can also have a delayed onset from 3 to 8 weeks after the last dose of AXYCIS. Manifestations include paresthesias in a stocking-glove distribution, areflexia, and loss of proprioception and vibratory sensation. The neuropathy may progress further even after stopping treatment. Peripheral neuropathy may be irreversible in some patients.

Prolonged treatment, treatment with other platinum-containing therapies, or use in combination with other drugs that cause peripheral neuropathy may increase the incidence or severity of peripheral neuropathy. Geriatric patients may be more susceptible to peripheral neuropathy.

Monitor for signs and symptoms of peripheral neuropathy. Withhold, reduce, or discontinue AXYCIS depending on the severity and persistence of peripheral neuropathy as clinically indicated.

Nausea and Vomiting

AXYCIS is a highly emetogenic antineoplastic agent. Administer pre-treatment and post-treatment antiemetics as clinically indicated. Without antiemetic therapy, marked nausea and vomiting occur in almost all patients treated with cisplatin and may be so severe that the drug must be discontinued. Nausea and vomiting may begin within 1 to 4 hours after treatment and last up to 72 hours. Maximal intensity occurs 48 to 72 hours after administration. Various degrees of vomiting, nausea, and/or anorexia may persist for up to 1 week after treatment. Delayed nausea and vomiting (begins or persists 24 hours or more after chemotherapy) has occurred in patients attaining complete emetic control on the day of cisplatin therapy. Consider the use of additional antiemetics following infusion.

Monitor and manage patients with antiemetics or fluid replacement, as clinically indicated. Consider withholding or delaying AXYCIS if nausea or vomiting is severe or intolerable and is not responsive to antiemetics.

Myelosuppression

AXYCIS can cause myelosuppression. Myelosuppression occurs in 25% to 30% of patients treated with cisplatin, including febrile neutropenia and infection, and can be fatal. Fatalities due to infection (secondary to myelosuppression) have been reported. Geriatric patients may be more susceptible to myelosuppression.

Patients with impaired kidney function are at increased risk of severe myelosuppression and may require dosage modifications.

Monitor complete blood counts prior to each cycle and as clinically indicated. If myelosuppression occurs, modify AXYCIS dosage when required.

Hypersensitivity Reactions

AXYCIS can cause severe hypersensitivity reactions, including anaphylaxis and death. Hypersensitivity reactions included facial edema, wheezing, tachycardia, and hypotension. These adverse reactions may occur within minutes of administration and during any cycle.

Monitor patients receiving AXYCIS for hypersensitivity reactions. Ensure supportive equipment and medications are available to treat severe hypersensitivity reactions. Severe hypersensitivity reactions require immediate discontinuation of AXYCIS and aggressive therapy. Do not rechallenge patients with a history of severe hypersensitivity reactions with AXYCIS. Cross-reactivity between platinum-based antineoplastic agents has been reported. Cases of severe hypersensitivity reactions have recurred after rechallenging patients with a different platinum agent.

Ototoxicity

AXYCIS can cause ototoxicity, which is cumulative and may be severe. Monitor for signs and symptoms of ototoxicity and consider audiometric and vestibular function monitoring.

Ototoxicity is manifested by tinnitus, hearing loss in the high frequency range (4,000 to 8,000 Hz) and/or decreased ability to hear normal conversational tones, and vestibular toxicity. Ototoxicity can occur during or after treatment and can be unilateral or bilateral. Deafness after the initial dose of cisplatin has been reported.

Ototoxic effects can be more severe and detrimental in pediatric patients, particularly in patients less than 5 years of age. The prevalence of hearing loss in pediatric patients is estimated to be 40-60%. Additional risk factors for ototoxicity include simultaneous cranial irradiation, treatment with other ototoxic drugs and renal impairment. Consider audiometric and vestibular testing in all pediatric patients receiving cisplatin. Genetic factors (e.g. variants in the thiopurine S-methyltransferase [TPMT] gene) may also contribute to the cisplatin-induced ototoxicity; this association has not been consistent across populations and study designs.

Consider permanent discontinuation of AXYCIS for patients who develop ototoxicity.

Ocular Toxicity

AXYCIS can cause ocular toxicity including optic neuritis, papilledema, and cortical blindness. Blurred vision and altered color perception have been reported after the use of regimens with higher doses and dose frequencies of

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

IMPORTANT SAFETY INFORMATION (continued)

AXYCIS™ (cisplatin) Injection

cisplatin. The altered color perception manifests as a loss of color discrimination, particularly in the blue-yellow axis and irregular retinal pigmentation of the macular area on fundoscopic exam. Improvement and/or total recovery usually occurs after discontinuing AXYCIS but can be delayed.

Monitor for signs and symptoms of ocular toxicity. Promptly refer patients to an eye care provider for any new or worsening ocular signs and symptoms. Interrupt, reduce the dose, or permanently discontinue AXYCIS based on severity.

Secondary Malignancies

Secondary acute leukemia has occurred with use of cisplatin.

Embryo-Fetal Toxicity

Based on human data, AXYCIS 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 females of reproductive potential to use effective contraception during treatment and for 14 months after the last dose of AXYCIS. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 11 months after the last dose of AXYCIS.

Injection Site Reactions

Injection site reactions can occur during the administration of AXYCIS. Local soft tissue toxicity has been reported following extravasation of AXYCIS. Severity of the local tissue toxicity appears to be related to the concentration of the AXYCIS solution. Infusion of solutions with a cisplatin concentration greater than 0.5 mg/mL may result in tissue cellulitis, fibrosis, necrosis, pain, edema, and erythema.

Monitor patients for extravasation and advise patients to seek medical care for progression of symptoms.

ADVERSE REACTIONS

Common adverse reactions are nephrotoxicity, peripheral neuropathy, nausea and vomiting, myelosuppression, and ototoxicity.

DRUG INTERACTIONS

Drugs that Cause Nephrotoxicity

Avoid concomitant use with other products known to cause nephrotoxicity.

Cisplatin can cause nephrotoxicity. Concomitant use of AXYCIS with other products that cause nephrotoxicity may result in a greater risk of nephrotoxicity.

USE IN SPECIFIC POPULATIONS

Pregnancy

Based on human data from published literature, AXYCIS can cause fetal harm when administered to pregnant women. Data demonstrates transplacental transfer of cisplatin. Exposure of pregnant women to cisplatin-containing chemotherapy has been associated with oligohydramnios, intrauterine growth restriction, and preterm birth. Cases of neonatal acute respiratory distress syndrome, cytopenias, and hearing loss have been reported.

Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Lactation

Limited data from published literature report the presence of cisplatin in human milk in low amounts. Because of the potential for serious adverse reactions from cisplatin in a breastfed child and because of the potential for tumorigenicity shown for cisplatin, advise lactating women not to breastfeed during treatment with AXYCIS.

Females and Males of Reproductive Potential

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

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to initiation of AXYCIS.

Contraception

Advise females of reproductive potential to use effective contraception during treatment and for 14 months following the last dose of AXYCIS. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 11 months after the last dose of AXYCIS.

Infertility

The use of cisplatin in females has been associated with cumulative dose-dependent ovarian failure, premature menopause, and reduced fertility. The use of cisplatin in males has been associated with a cumulative dose-dependent impairment of spermatogenesis (oligospermia, azoospermia; possibly irreversible) and reduced fertility.

Pediatric Use

The safety and effectiveness of AXYCIS in pediatric patients have not been established.

Ototoxic effects may be more severe and detrimental in pediatric patients receiving cisplatin, particularly in patients less than 5 years of age. Consider audiometric and vestibular function monitoring in all patients receiving AXYCIS. The prevalence of hearing loss in pediatric patients is particularly high and is estimated to be 40% to 60%. Earlier detection of hearing loss can limit the potential impact of hearing impairment on a pediatric patient's cognitive and social development.

Geriatric Use

Reported clinical experience suggests that geriatric patients may be more susceptible to nephrotoxicity, myelosuppression, and infectious complications than are younger patients.

OVERDOSAGE

The signs and symptoms of overdose are similar to known adverse reactions of cisplatin but may be more severe. Acute overdosage with AXYCIS may result in renal failure, hepatic failure, hearing loss, ocular toxicity, myelosuppression, nausea and vomiting, and neuritis. In addition, death can occur following overdosage.

Important measures include renal protection by intravenous hydration with or without the use of an osmotic diuretic. Hemodialysis is not effective because of the high degree of protein binding of cisplatin. Plasmapheresis has been used to treat cases of cisplatin overdosage, but the optimal treatment regimen has not been established.

Closely monitor patients suspected of receiving an overdose, including signs and symptoms of the adverse reactions and administer appropriate supportive treatment.

Consider contacting the Poison Help line (1-800-222-1222) or a medical toxicologist for additional overdose management recommendations.

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.

Please see AXYCIS 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. AXYCIS™ (cisplatin) Injection, Full Prescribing Information. Revised 10/2026.

AXYCIS™
(cisplatin) Injection



50 mg /50 mL (1 mg/mL)
NDC: 83831-0158-01

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.

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

AVYXA

© Copyright 2026 AVYXA Pharma, LLC I All Rights Reserved
US-AXY-0002-1 I October 2026