

KYXATA[®]
(carboplatin) Injection

BILLING AND CODING GUIDE

If you have additional billing and coding questions, please call your Field Reimbursement Manager or AVYXASSIST™ at 866-939-8927. Our Patient Access Specialists are available to assist Monday through Friday, 8 AM to 8 PM ET.

Please see Important Safety Information on pages 3 and 13-14 and full [Prescribing Information](#) for KYXATA including BOXED WARNING.



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The contents herein provide general coverage, coding, and payment information about KYXATA. The information within this guide was obtained from third-party sources and is made available for reference only. It is not exhaustive, is subject to change, and does not constitute billing, coding, or legal advice. Healthcare professionals are responsible for determining which code(s), charge(s), or modifier(s), if any, appropriately reflect a service or diagnosis. It is the healthcare professional's responsibility to determine medical necessity and provide adequate documentation. AVYXA® does not guarantee coverage or payment. Payment and coverage vary by payer. Questions about coding, coverage, and payment may be directed to the applicable third-party payer, reimbursement specialist, and/or legal counsel.

CMS: Centers for Medicare & Medicaid Services; CPT: Current Procedural Terminology; HCPCS: Healthcare Common Procedure Coding System; ICD: International Classification of Diseases; NDC: National Drug Code

Please see Important Safety Information on pages 3 and 13-14 and full [Prescribing Information](#) for KYXAT including BOXED WARNING.

INDICATIONS AND IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

INDICATIONS

Initial Treatment of Advanced Ovarian Carcinoma

KYXATA[®], as part of a combination regimen, is indicated for the initial treatment of adults with advanced ovarian carcinoma.

Recurrent Advanced Ovarian Carcinoma

KYXATA is indicated for treatment of adults with ovarian carcinoma recurrent after prior chemotherapy.

IMPORTANT SAFETY INFORMATION

WARNING: HYPERSENSITIVITY REACTIONS, INCLUDING ANAPHYLAXIS

- **Serious and life-threatening hypersensitivity reactions, including anaphylaxis, can occur with KYXATA within minutes of administration during any cycle.**
- **Immediately withhold KYXATA for severe hypersensitivity reactions and administer appropriate treatment for management of the hypersensitivity reaction.**

WARNING AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity, including anaphylaxis, can occur in patients treated with KYXATA. Hypersensitivity reactions occurred in 2% of patients treated with carboplatin and included rash, urticaria, erythema, pruritus, bronchospasm, and hypotension. These adverse reactions may occur within minutes of administration and during any cycle. There is an increased risk of allergic reactions, including anaphylaxis, in patients previously exposed to platinum-based therapy or after 6 cycles of carboplatin.

Monitor patients receiving KYXATA for hypersensitivity reactions. Ensure supportive equipment and medications are available to treat severe hypersensitivity reactions. Severe hypersensitivity reactions may require immediate discontinuation of KYXATA.

Myelosuppression

Myelosuppression (leukopenia, neutropenia, and thrombocytopenia) is dose-dependent, may be severe, and can cause fatal infections or hemorrhage in patients treated with KYXATA.

Grade 3-4 neutropenia occurred in 16% of the patients treated with carboplatin as a single agent. Grade 3-4 thrombocytopenia occurred in 25% of patients with ovarian cancer. Febrile neutropenia may occur. Blood product transfusions were required in 26% (44% of pretreated) of patients with ovarian cancer treated with carboplatin as a single agent. Infectious and hemorrhagic complications each occurred in 5% of the patients treated with carboplatin as a single agent. Fatal adverse reactions occurred in less than 1% of patients treated with carboplatin as a single agent.

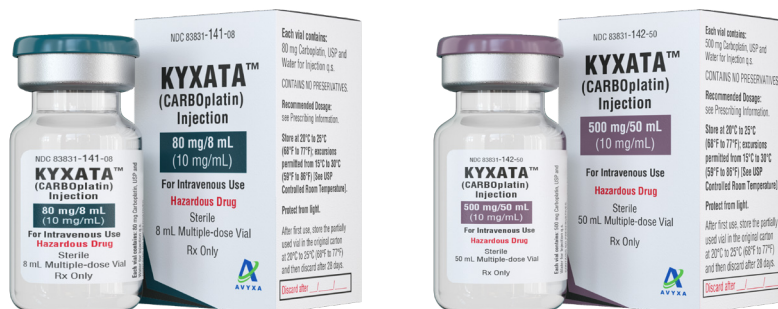
Patients with impaired kidney function are at increased risk of severe myelosuppression and may require dosage modifications.

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

KYXATA[®] (carboplatin) Injection

Ordering Information

To order KYXATA (carboplatin) Injection, please contact one of these authorized specialty distributors and use the appropriate order number:



80 mg/8 mL
NDC: 83831-0141-08

500 mg/50 mL
NDC: 83831-0142-50

Institutions/Hospitals	80 mg/8 mL	500 mg/50 mL
Cardinal Health Specialty	6051080	6051098
CENCORA - ASD Healthcare	10302720	10302740
McKesson Plasma & Biologics	Not Available	3057718
Physician Offices	80 mg/8 mL	500 mg/50 mL
Cardinal Health Specialty	6051080	6051098
Oncology Supply	10302702	10302730
McKesson Specialty Health	Not Available	5021021

Highlights¹

- Supplied in multi-dose vials
- No reconstitution required and ready to dilute solution
- Ready to add to intravenous infusion solution with different options:
 - 5% Dextrose Injection, USP
 - 0.9% Sodium Chloride Injection, USP
- Diluted infusion solution is stable for a maximum of 8 hours
- Partially used vials are stable for up to 28 days at 20°C to 25°C (68°F to 77°F)
- Not made with natural rubber



Effective April 1, 2026

Please see Important Safety Information on pages 3 and 13-14 and full [Prescribing Information](#) for KYXATA including **BOXED WARNING**.

AVYXASSIST™

Simplifying patient access, providing comprehensive support

AVYXASSIST can offer support to qualifying patients in need. The program provides the following services.*

- Benefit verification
- Prior authorization requirements
- Appeals support
- Claims support
- Referrals to 501(c)(3) foundations
- Free product assistance
- Bridge supply
- Product replacement
- Copay assistance

*For eligibility requirements, please contact a Patient Access Specialist. Terms and conditions apply.

To enroll, please choose one of the following options.

Call 866-939-8927
Monday through Friday
8 AM to 8 PM ET



CALL NOW

Click on the link
below to begin
online enrollment



ENROLL
NOW

Download, print, and fax
a completed enrollment
form to 833-852-3420



DOWNLOAD
NOW

Commercially eligible
patients prescribed an
AVYXA product may pay
as little as

\$0 per dose*

AVYXASSIST™		ELIGIBLE PATIENTS MAY PAY AS LITTLE AS \$0
BIN	025706	
PCN	IFX	
GROUP #	00000000	
MEMBER #	0000000000	
<small>Patients with questions, please call 866-939-8927</small>		

Our dedicated AVYXASSIST Patient Access Specialists work collaboratively with you to explore tailored affordability solutions. AVYXA aims to facilitate financial accessibility for eligible patients in need.



ENROLL
NOW

Copay Program Details for Eligible Patients

In some cases, the patient out-of-pocket cost for their AVYXA product could be as low as \$0.*

- Up to \$25,000 **per product** in annual benefits

*Please visit avyxassist.com/copay-assistance-program to see full Terms and Conditions.

Additional Assistance

Patients without insurance or who do not qualify for copay assistance through AVYXASSIST may qualify for free product assistance. Call an AVYXASSIST Patient Access Specialist to learn more.

Call 866-939-8927 or Fax 833-852-3420 | Monday through Friday, 8:00 AM to 8:00 PM ET

KYXATA® Billing and Coding Information

The information provided is for informational purposes only and represents no statement, promise, or guarantee by AVYXA concerning reimbursement, payment, or charges. The information provided is not intended to increase or maximize reimbursement by any payer. Healthcare professionals are responsible for selecting appropriate codes used to file a claim. Codes should be based on the patient's diagnosis and the items and services furnished by the healthcare professional. All codes should be verified between the healthcare professional and the payer. AVYXA does not recommend using any particular diagnosis code in billing situations for KYXATA (carboplatin) Injection. The codes below are for reference only; coding as submitted is the sole responsibility of the prescribing physician.

NDCs

National Drug Codes (NDC) are unique product identifiers used for drugs and biologicals. The Centers for Medicare & Medicaid Services (CMS) and private payors often require an NDC as part of the billing claim form. If the NDC Package code is less than 11 digits 5-4-2 format, the code must be padded with leading zeros, as shown below.²

KYXATA NDC ¹	Strength	Package	NDC Unit
83831-0141-08	80 mg/8 mL (10 mg/mL)	1 multiple-dose vial in 1 carton	mL
83831-0142-50	500 mg/50 mL (10 mg/mL)	1 multiple-dose vial in 1 carton	mL

HCPCS Code³

HCPCS Level II codes are used to identify most drugs and biologics administered in the office. Correct coding requires reporting the most specific code to describe the service accurately.

KYXATA J-Code	Description
J9278	Injection, carboplatin (Avyxa), 1 mg

Note: While there are several HCPCS codes associated with carboplatin products, KYXATA is assigned a unique HCPCS code (J9278). Please ensure the HCPCS code used matches the specific product purchased and administered.

J-Code Billing Unit⁶

- For this product, KYXATA J9278 is billed as 1mg. With the example below, it would be 623 billed J-Code units
- J-code billing units define the specific quantity of a drug represented by one HCPCS code, necessitating accurate, often per-unit calculations based on the total dose administered. Miscalculating units (e.g., 100 mg vs. 10 mg/unit) causes significant claim denials.

- KYXATA is billed by 1mg.

KYXATA[†] is a platinum-based drug indicated in adults:

- As part of a combination regimen, for the initial treatment of advanced ovarian carcinoma.
- As a single-agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy.¹

Please see Important Safety Information on pages 3 and 13-14 and full [Prescribing Information](#) for KYXATA including **BOXED WARNING**.

CPT Drug Administration Codes

CPT codes are used to bill drug administration services in the physician’s office and other outpatient settings.⁷ The recommended dosage of KYXATA® depends on body surface area and whether it is used alone or as a part of a combination regimen. Please code based on the start and stop times listed in the patient’s medical chart.¹

KYXATA is supplied as a multiple-dose vial.¹ Medicare will not pay for drug waste on multiple-dose vials, so the JW and JZ modifiers are not applicable in the billing of KYXATA.⁸

CPT Code	Description ⁹	Place of Service (POS) ¹⁰
96413	Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug	<ul style="list-style-type: none"> Physician Office (11) Off-Campus Outpatient Hospital (19) On-Campus Outpatient Hospital (22)
96417	Chemotherapy administration, intravenous infusion technique, each additional sequential infusion (different substance/drug), up to 1 hour	

CPT codes, descriptions, and other data are copyright 2025 American Medical Association. All Rights Reserved. Applicable FARS/ HHSARS apply. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Revenue Codes

Claim Item	Revenue Code ¹¹	Description	Place of Service (POS) ¹⁰
KYXATA	0636	Drugs Requiring Detailed Coding	<ul style="list-style-type: none"> Off-Campus Outpatient Hospital (19)
Drug Administration	0335	Chemotherapy Administration – IV	<ul style="list-style-type: none"> On-Campus Outpatient Hospital (22)

ICD Diagnosis Codes

KYXATA is a platinum-based drug indicated in adults:

- As part of a combination regimen, for the initial treatment of advanced ovarian carcinoma.
- As a single-agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy¹¹

It is best practice to code the most specific ICD-10-CM Code within the indication to justify medical

International Classification of Disease, 10th Edition, Clinical Modification Codes for KYXATA Injection	
Indication	ICD-10-CM Codes
Ovarian Cancer ¹²	C56.1, C56.2, C56.3, C56.9

ICD Diagnosis Codes by Indication

ICD-10-CM coding for KYXATA® Injection varies greatly by payer. Please check with each payer to ascertain the best coding for the KYXATA Injection according to their policy.

Ovarian Cancer: ICD-10-CM Diagnosis Coding ¹²	
ICD-10 Code	Descriptor
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary

FL 45

(Electronic Claim Form = Loop 2400, Segment DTP/472/03):

Enter the date of service.

FL 46

(Electronic Claim Form = Loop 2400, SV205):

Enter the units for the HCPCS code billed. Enter the number of service units for each item.

FL 63

(Electronic Claim Form = Loop 2300, REF/G1/02):

Enter treatment authorization code.

FL 67A-Q

(Electronic Claim Form Loop 2300, H101-2 (H101-1=BK):

Enter a diagnosis code for the drug documented in the medical record. Be as specific as possible.

The code listed here is an example: **C56.1 Malignant neoplasm of right ovary.** Ensure the diagnosis code listed matches the line-item for **KYXATA®**.

Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.Com. Palmetto GBA, Accessed September 16, 2025. https://www.palmettogba.com/pal-%20metto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf

CPT Codes are a registered trademark of the American Medical Association (AMA), All Rights Reserved.

THIS INFORMATION IS PROVIDED FOR EDUCATIONAL PURPOSES ONLY AND IS NOT A GUARANTEE OF COVERAGE. IT IS THE SOLE RESPONSIBILITY OF THE HEALTH CARE PROVIDER TO SELECT THE PROPER CODES AND ENSURE THE ACCURACY OF ALL STATEMENTS USED IN SEEKING COVERAGE AND REIMBURSEMENT FOR AN INDIVIDUAL PATIENT.

Sample CMS 1500 Claim Form^{3,5,6,9,10,12}

Item 21

(Electronic Claim Form = Loop 2300, Segment H101-2 through H112=2):

Enter the patient's diagnosis from the patient's medical record.

An example code for this drug is **C56.1 Malignant neoplasm of right ovary.**

Use Item 21 B-L fields for secondary diagnoses.

Item 23

(Electronic Claim Form = Loop 2300, REF02):

Enter prior authorization number if one exists.


Item 24A-B

(Electronic Claim Form: Item 24A (Electronic Claims = Loop 2400, DTP02; Item 24 B (Loop 2300/2400, Segment CLM05-1/SV105)

In the non-shaded area, enter the appropriate date of service and place of service code. Example: Physician Office = 11.

If required, in the shaded area, enter the N4 indicator first, then the 11-digit NDC code.

In the third space, list the unit measurement code, and last, the quantity.



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE <input type="checkbox"/> PICA <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA BOX (LUNG) <input type="checkbox"/> OTHER <input type="checkbox"/>		1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)		3. PATIENT'S BIRTH DATE (MM DD YY) SEX (M F)	
5. PATIENT'S ADDRESS (No., Street)		6. PATIENT RELATIONSHIP TO INSURED (Self Spouse Child Other)	
CITY STATE		7. INSURED'S ADDRESS (No., Street)	
ZIP CODE TELEPHONE (include Area Code)		8. RESERVED FOR NUCC USE	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		10. IS PATIENT'S CONDITION RELATED TO:	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. EMPLOYMENT? (Current or Previous) YES NO	
b. RESERVED FOR NUCC USE		b. AUTO ACCIDENT? PLACE (State) YES NO	
c. RESERVED FOR NUCC USE		c. OTHER ACCIDENT? YES NO	
d. INSURANCE PLAN NAME OR PROGRAM NAME		10d. CLAIM CODES (Designated by NUCC)	
11. INSURED'S POLICY GROUP OR FECA NUMBER		11. INSURED'S DATE OF BIRTH (MM DD YY) SEX (M F)	
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.)		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)	
14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (MM DD YY) QUAL		15. OTHER DATE (MM DD YY) QUAL	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE (17a. I7a. NPI 17b. NPI)		16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM TO) (MM DD YY MM DD YY)	
19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)		18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM TO) (MM DD YY MM DD YY)	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24B)) (ICD Ind.)		20. OUTSIDE LAB? \$ CHARGES (YES NO)	
A B C D E F G H I J K L		22. RESUBMISSION CODE ORIGINAL REF. NO.	
24. A. DATE(S) OF SERVICE (From To) (DD YY MM DD YY) B. PLACE OF SERVICE (EMG) C. D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) (CPT/HCPCS) MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. PAYS OR UNITS H. I. EXPRT (Rpt) I. ID. QUAL		23. PRIOR AUTHORIZATION NUMBER	
25. FEDERAL TAX I.D. NUMBER SSN EIN		26. PATIENT'S ACCOUNT NO.	
27. ACCEPT ASSIGNMENT? (For OPTARIS, see box) YES NO		28. TOTAL CHARGE \$ 29. AMOUNT PAID \$ 30. Rev'd for NUCC Use	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)		32. SERVICE FACILITY LOCATION INFORMATION	
SIGNED DATE		a. NPI b. NPI	
33. BILLING PROVIDER INFO & PH # ()		33. BILLING PROVIDER INFO & PH # ()	

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

Item 21

Item 24A-B

Item 23

Item 24D

(Electronic Claim Form = Loop 2400, Segment SV101):

Enter the appropriate HCPCS code: **J9278 Injection, carboplatin (Avyxa), 1mg**

For administration, enter the appropriate code or codes for intravenous administration. As an example, chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug requires CPT code 96413.*

Item 24E

(Electronic Claim Form = Loop 2400, Segment SV107):

Specify the diagnosis letter that corresponds with the drug and drug administration code(s) in Item 21.

Item 24G

(Electronic Claim Form = Loop 2400, SV104):

Enter the number of J-Code service units for KYXATA®. It will be the number of milligrams administered to the patient.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/82

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BENEFIT (LUNG) OTHER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.)

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) MM DD YY QUAL

15. OTHER DATE MM DD YY QUAL

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. NPI 17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? \$ CHARGES YES NO

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E) ICD Ind.)

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE FROM MM DD YY TO MM DD YY B. PROCEDURE(S), SERVICE(S), OR SUPPLIES (CPT/HCPCS) MODIFIER E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OR UNITS H. ICD IDENTIFY I. ID. QUAL J. RENDERING PROVIDER ID. #

25. FEDERAL TAX I.D. NUMBER SSN EBN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For gov. claims, see back) YES NO

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Paid for NUCC Use 1 NPI

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREE(S) OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH # ()

SIGNED DATE a. NPI b. NPI

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED CMS-0935-1197 FORM 1500 (02-12)

*CPT Code 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug. Initial infusion times may vary.

Electronic Claims Reference: ASC 837I Version 5010A2 Institutional Health Care Claim to the CMS-1450 Claim Form Crosswalk. Palmettogba.Com. Palmetto GBA, Accessed September 16, 2025. https://www.palmettogba.com/pal-%20metto/providers.nsf/files/EDI_837I_v5010A2_crosswalk.pdf

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IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS

Nausea and Vomiting

KYXATA® can induce emesis, which can be more severe in patients previously receiving emetogenic therapy, and is dose-dependent. Administer pre-treatment and post-treatment antiemetics as clinically indicated.

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

Peripheral Neuropathy

Peripheral neuropathy, including paresthesia, can occur in patients treated with KYXATA.

Peripheral neuropathy occurred in 4% of patients receiving carboplatin as a single agent (6% of pretreated patients with ovarian cancer). Peripheral neuropathy occurred in 10% of patients older than 65 who were previously treated with carboplatin.

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.

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

Embryo-Fetal Toxicity

Based on findings in animals and its mechanism of action, KYXATA can cause fetal harm when administered to a pregnant woman. Administration of carboplatin to pregnant rats caused adverse developmental outcomes, including embryo-fetal lethality and structural abnormalities.

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 with KYXATA and for 6 months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with KYXATA and for 3 months after the last dose.

ADVERSE REACTIONS

Most common adverse reactions, including laboratory abnormalities, in patients with advanced ovarian cancer who received KYXATA in combination with cyclophosphamide ($\geq 30\%$) are leukopenia, neutropenia, nausea and vomiting, anemia, thrombocytopenia, hypomagnesemia, other gastrointestinal adverse reactions, alopecia, asthenia, and pain.

Most common adverse reactions, including laboratory abnormalities, in patients with recurrent ovarian cancer who received KYXATA as a single agent ($\geq 30\%$) are nausea and vomiting, anemia, neutropenia, thrombocytopenia, hyponatremia, hypomagnesemia, hyperphosphatasemia, and hypocalcemia.

DRUG INTERACTIONS

Use with Aminoglycosides: Avoid concomitant use of aminoglycosides with KYXATA. Concomitant use of KYXATA with aminoglycosides increased renal toxicity and ototoxicity.

USE IN SPECIFIC POPULATIONS

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

Lactation: Advise women not to breastfeed during treatment with KYXATA and for 1 week after the last dose.

Females and Males of Reproductive Potential: Advise females of reproductive potential to use effective contraception during treatment with KYXATA and for 6 months after the last dose; and advise male patients with female partners of reproductive potential to use effective contraception during treatment with KYXATA and for 3 months after the last dose.

Please see Important Safety Information on pages 3 and 13-14 and full [Prescribing Information](#) for KYXATA including **BOXED WARNING**.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Geriatric Use: Elderly patients treated with carboplatin were more likely to develop severe thrombocytopenia or peripheral neuropathy than younger patients. Consider renal function when selecting the KYXATA® dose for older adults since they often have decreased renal function. To minimize the risk of toxicity in older adults, calculate the dose based on AUC.

Renal Impairment: Reduce the dose for patients with creatinine clearance (CL_{cr}) of 16 to 59 mL/min who will be administered a dose based on body surface area. A recommended dose of KYXATA has not been established for patients with a $CL_{cr} < 16$ 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.

Administer KYXATA in a setting where cardiopulmonary resuscitation medication and equipment are available.

Premedicate patients with antiemetics prior to each infusion of KYXATA for the prevention of nausea and vomiting. Continue antiemetics following infusion as needed.

Do not use needles or intravenous infusion sets containing aluminum; aluminum reacts with carboplatin causing precipitate formation and a loss of potency.

OVERDOSAGE

There is no known antidote for KYXATA overdose. The anticipated complications of overdose would be secondary to bone marrow suppression and/or hepatic toxicity. Patients receiving overdoses of carboplatin experienced severe liver function test abnormalities. Loss of vision, which can be complete for light and colors, has been reported after the use of carboplatin at doses higher than the recommended approved dosage for KYXATA. Vision recovers totally or to a significant extent after discontinuation of carboplatin. Clinically significant hearing loss has been reported to occur in pediatric patients when carboplatin was administered at higher than approved recommended doses for KYXATA and in combination with other ototoxic agents. KYXATA is removed by dialysis.

Closely monitor patients suspected of receiving an overdose, including for the adverse reactions described above, and administer appropriate supportive treatment.

Please see KYXATA 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.

References:

1. KYXATA™ Prescribing Information. AVYXA™ Pharma. Revised September 2025.
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