ZEMDRI® (plazomicin) injection Billing and Coding Reference

As of October 1, 2019

INDICATIONS & USAGE

ZEMDRI is indicated in patients 18 years of age or older for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis caused by the following susceptible microorganism(s): *Escherichia coli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Enterobacter cloacae*.

As only limited clinical safety and efficacy data for ZEMDRI are currently available, reserve ZEMDRI for use in cUTI patients who have limited or no alternative treatment options.

To reduce the development of drug-resistant bacteria and maintain effectiveness of ZEMDRI and other antibacterial drugs, ZEMDRI should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible microorganisms.

IMPORTANT SAFETY INFORMATION

BOXED WARNINGS: NEPHROTOXICITY, OTOTOXICITY, NEUROMUSCULAR BLOCKADE AND FETAL HARM

- **Nephrotoxicity has been reported with ZEMDRI. The risk of nephrotoxicity is greater in patients with impaired renal function, the elderly, and in those receiving concomitant nephrotoxic medications. Assess creatinine clearance in all patients prior to initiating therapy and daily during therapy. Therapeutic Drug Monitoring (TDM) is recommended for complicated urinary tract infection (cUTI) patients with CLcr less than 90 mL/min to avoid potentially toxic levels.**
- **Ototoxicity, manifested as hearing loss, tinnitus, and/or vertigo, has been reported with ZEMDRI. Symptoms of aminoglycoside-associated ototoxicity may be irreversible and may not become evident until after completion of therapy. Aminoglycoside-associated ototoxicity has been observed primarily in patients with a family history of hearing loss, patients with renal impairment, and in patients receiving higher doses and/or longer durations of therapy than recommended.**
- **Aminoglycosides have been associated with neuromuscular blockade. During therapy with ZEMDRI, monitor for adverse reactions associated with neuromuscular blockade particularly in high-risk patients, such as patients with underlying neuromuscular disorders (including myasthenia gravis) or in patients concomitantly receiving neuromuscular blocking agents.**
- **Aminoglycosides, including ZEMDRI, can cause fetal harm when administered to a pregnant woman.**

Contraindications

ZEMDRI is contraindicated in patients with known hypersensitivity to any aminoglycoside.

Additional Warnings and Precautions

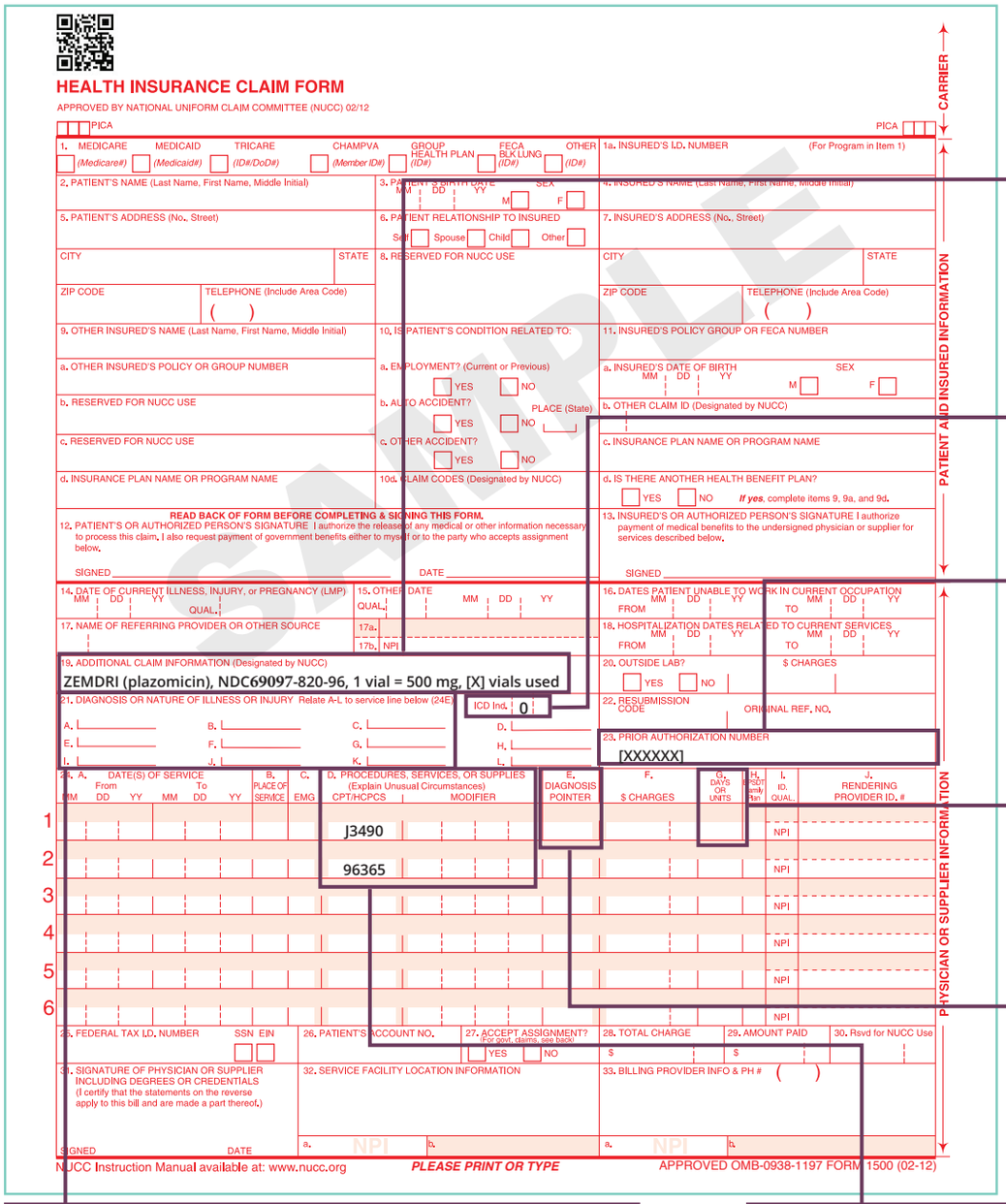
- **Nephrotoxicity:** Reported with the use of ZEMDRI. Most serum creatinine increases were ≤1 mg/dL above baseline and reversible. Assess CLcr in all patients prior to initiating therapy and daily during therapy with ZEMDRI, particularly i n those at increased risk of nephrotoxicity, such as those with renal impairment, the elderly and those receiving concomitant potentially nephrotoxic medications. In the setting of worsening renal function, the benefi t of continuing ZEMDRI should be assessed. Adjust the initial dosage regimen in cUTI patients with CLcr ≥15 mL/min and <60 mL/min. For subsequent doses, TDM is recommended for patients with CLcr ≥15 mL/min and <90 mL/min.
- **Ototoxicity:** Reported with ZEMDRI (manifested as hearing loss, tinnitus, and/or vertigo). Symptoms of aminoglycoside-associated ototoxicity may be irreversible and may not become evident until after completion of therapy. Aminoglycoside-associated ototoxicity has been observed primarily in patients with a family history of hearing loss (excluding age-related hearing loss), patients with renal impairment, and in patients receiving higher doses and/or for longer periods than recommended. Cases of ototoxicity with aminoglcosides have been observed in patients with certain variants in the mitochondrially encoded12S rRNA gene (*MT-RNR1*), particularly the m.1555A>G variant. Ototoxicity occurred in some patients even when their aminoglycoside serum levels were within the recommended range. In case of known maternal history of ototoxicity due to aminoglycoside use or a known mitochondrial DNA variant in the patient, consider alternative treatments other than aminoglycosides unless the increased risk of permanent hearing loss is outweighed by the severity of infection and lack of safe and effective alternative therapies. The benefit-risk of ZEMDRI therapy should be considered in these patients.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including **BOXED WARNINGS**.

ZEMDRI®
(plazomicin) injection

CMS 1500 sample form for use by physician infusion clinic

This document is intended only as a potential reference for assistance when billing for ZEMDRI (plazomicin) injection.
You are responsible for determining all appropriate billing/coding information applicable to the treatment of your patients.


HEALTH INSURANCE CLAIM FORM

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

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

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

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)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

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

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

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.

SIGNED DATE

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

SIGNED

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 MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

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

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
ZEMDRI (plazomicin), NDC69097-820-96, 1 vial = 500 mg, [X] vials used

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. B. C. D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER
[XXXXXX]

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1				J3490						NPI	
2				96365						NPI	
3										NPI	
4										NPI	
5										NPI	
6										NPI	

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

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

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd 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.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

Box 19: Additional Information

Enter the appropriate drug identifying information as required by payer (eg, brand and generic drug name, NDC 11-digit format, dosage, number of vials used, method of administration).

Box 21: *ICD* Indicator

Indicate applicable *ICD* coding system (eg, "0" for *ICD-10-CM*).

Box 23: Prior Authorization

Enter the prior authorization number as obtained prior to services rendered, as appropriate.

Box 24G: Units

Enter the appropriate number of units of service. For example, J0291 has no specific unit value; therefore, a "1" is typically entered in this field. Some payers may provide alternate guidance.

Box 24E: Diagnosis Pointer

Enter the letter (A-J) that corresponds to the diagnosis in Box 21.

Box 21: Diagnosis

Enter the appropriate diagnosis code(s). Final codes depend on medical record documentation.

Box 24D: Procedures/Services/Supplies

Enter the appropriate CPT®/HCPCS codes and modifier.

- Drug: J0291 (drug code) for ZEMDRI
- Administration: 96365 for IV infusion

Note: Additional codes and modifiers may apply.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; *ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification*; IV, intravenous; NDC, National Drug Code.

IMPORTANT SAFETY INFORMATION

Additional Warnings and Precautions (continued)

- **Neuromuscular Blockade:** Aminoglycosides have been associated with exacerbation of muscle weakness in patients with underlying neuromuscular disorders, or delay in recovery of neuromuscular function in patients receiving concomitant neuromuscular blocking agents. During therapy with ZEMDRI, monitor for adverse reactions associated with neuromuscular blockade, particularly in high-risk patients, such as patients with underlying neuromuscular disorders (including myasthenia gravis) or those patients concomitantly receiving neuromuscular blocking agents.
- **Fetal Harm:** Aminoglycosides, including ZEMDRI, can cause fetal harm when administered to a pregnant woman. Patients who use ZEMDRI during pregnancy, or become pregnant while taking ZEMDRI should be apprised of the potential hazard to the fetus.

CMS 1450 sample form for use by hospital outpatient department

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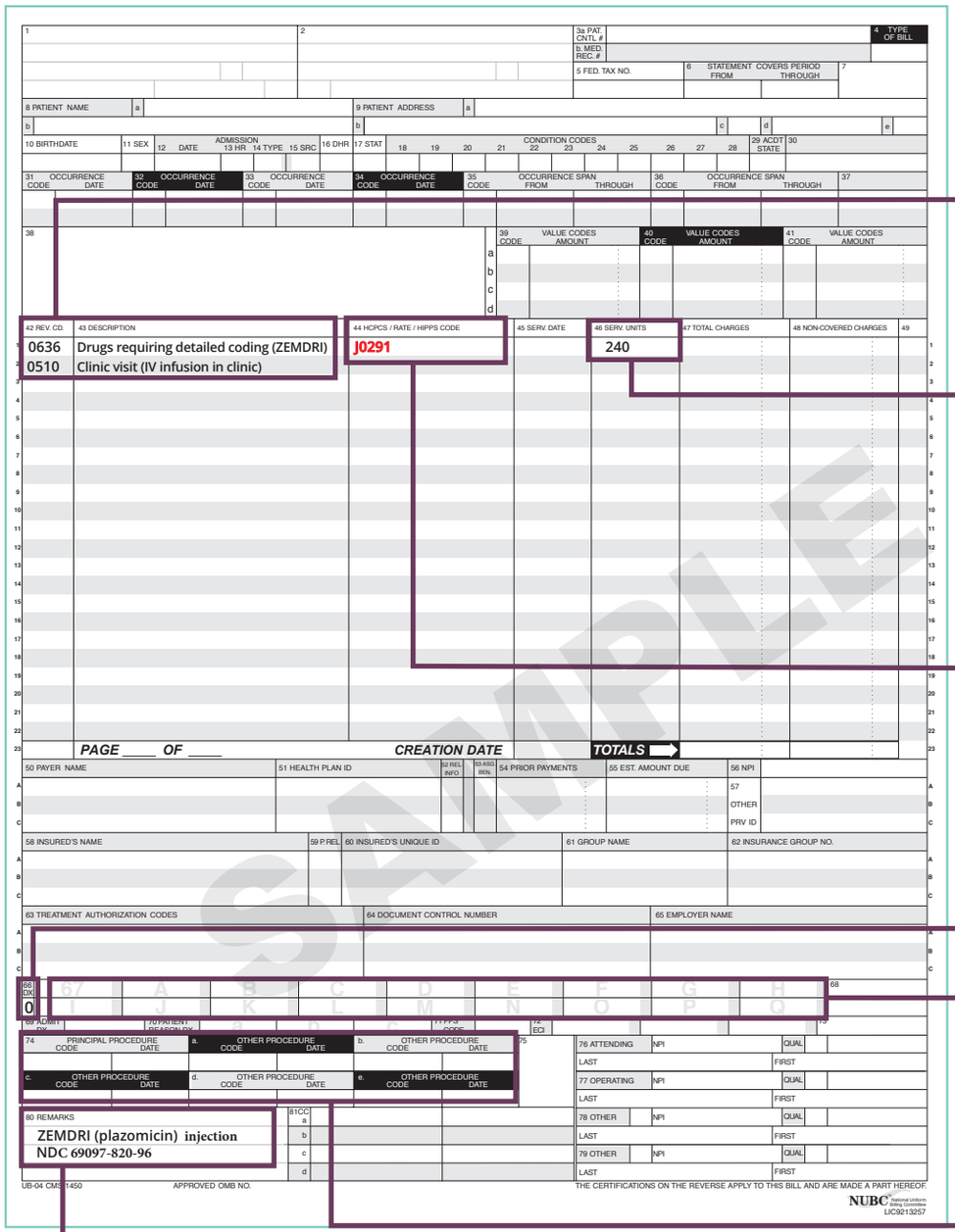

Fields 42-43:

Enter the appropriate revenue code and description corresponding to the HCPCS code in Field 44.

- 0636 for ZEMDRI
- 0510 for IV infusion administered in the clinic

Note: Other revenue codes may apply.

Field 46:

Enter the appropriate number of units of service; eg, J0291: 1 unit equals 5 mg. If dosing a patient daily with 1,200 mg, the units would be 240 units (1,200 mg ÷ 5 mg = 240 units)

Field 44:

Enter the appropriate CPT®/HCPCS codes and modifiers.

- Drug: J0291 injection, plazomicin, 5 mg (effective 10/1/2019 for HOPD)
- Administration: 96365 for drug administration

Note: Other HCPCS codes may apply for non-Medicare payers.

Field 66:

Identify the *ICD* diagnosis code (eg, enter "0" for *ICD-10-CM*).

Fields 67 and 67A-67Q:

Enter the appropriate diagnosis codes. Final codes depend on medical record documentation.

Note: Other diagnosis codes may apply.

Field 74:

Enter the appropriate NTAP *ICD-10-PCS* code

Field 80:

Enter the appropriate drug identifying information as required by payer (eg, brand and generic name, NDC 11-digit format, dosage, method of administration).

Note: Additional information may also be sent via electronic attachment or other format as allowed by the payer.

IMPORTANT SAFETY INFORMATION

Additional Warnings and Precautions (continued)

- **Hypersensitivity Reactions:** Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving aminoglycoside antibacterial drugs. Before therapy with ZEMDRI is instituted, careful inquiry about previous hypersensitivity reactions to other aminoglycosides should be made. Discontinue ZEMDRI if an allergic reaction occurs.

Please see additional Important Safety Information throughout and accompanying full Prescribing Information, including **BOXED WARNINGS**.

ZEMDRI®
(plazomicin) injection

Coding Related to Administration of ZEMDRI

Current coding for services[a]

Site of service	Type of code	Code	Description
Hospital Outpatient Department Place of service code 19 or 22[b]	CPT® Code (procedure code)	96365	IV infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	HCPCS Level II Code	**J0291** Effective 10/1/2019	**Injection, plazomicin, 5 mg**
Physician Office Infusion Center Place of service code 11[b]	CPT® Code (procedure code)	96365	IV infusion for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
	HCPCS Level II Code	**J0291** Effective 10/1/2019	**Injection, plazomicin, 5 mg**
Home Health Place of service code 12[b]	HCPCS Level II Code	S9500	Home infusion therapy, antibiotic, antiviral, or antifungal therapy; once every 24 hours; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately) per diem
Hospital Inpatient Department Place of service code 21[b]	*ICD-10-PCS*	XW033G4	New technology, anatomical regions, introduction, peripheral vein, percutaneous, plazomicin anti-infective, new technology group 4
	ICD-10-PCS	XW043G4	New technology, anatomical regions, introduction, central vein, percutaneous, plazomicin anti-infective, new technology group 4

[a]This table is provided for informational purposes only. Correct coding is the responsibility of the provider submitting the claim for the item or service. Please check with the payer to verify codes and specific billing requirements. Cipla Therapeutics, a division of Cipla USA, Inc. cannot and does not guarantee success in obtaining third-party insurance payments. Providers are encouraged to contact their third-party payers for specific information on their coverage, coding, and payment policies.

[b]Place of service link: https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set.html.

Regarding Use of This Resource - Informational Only - No Guarantee of Coverage or Reimbursement

This document is presented for informational purposes only and is not intended to provide reimbursement or legal advice, nor does it promise or guarantee coverage, levels of reimbursement, payment, or charge. Similarly, all CPT® and HCPCS codes are supplied for informational purposes only and represent no statement, promise, or guarantee by Cipla Therapeutics, a division of Cipla USA, Inc., that these codes will be appropriate or that reimbursement will be made.

IMPORTANT SAFETY INFORMATION

Additional Warnings and Precautions (continued)

- ***Clostridium difficile*-Associated Diarrhea (CDAD):** Reported for nearly all systemic antibacterial drugs and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial drugs alters the normal flora of the colon and may permit overgrowth of *C. difficile*. Careful medical history is necessary. If CDAD is suspected or confirmed, antibacterial drugs not directed against *C. difficile* may need to be discontinued.
- **Development of Drug-Resistant Bacteria:** Prescribing ZEMDRI in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

The most common adverse reactions (≥1% of patients treated with ZEMDRI) are decreased renal function, diarrhea, hypertension, headache, nausea, vomiting and hypotension.

Please see accompanying full Prescribing Information, including **BOXED WARNINGS**, for additional Important Safety Information.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Cipla Therapeutics at (866) 604-3268 or drugsafety@cipla.com

Cipla THERAPEUTICS Division of Cipla USA, Inc.

US-PLZ-05/23-0003

ZEMDRI® (plazomicin) injection