

August 2026, 14th

IMPORTANT DRUG INFORMATION

Subject: Temporary importation of non-FDA-approved Zanosar[®] (Streptozocin powder for concentrate for solution for infusion) to address shortage

Dear Healthcare Professional,

Due to a critical shortage of Zanosar[®] 1g (streptozocin sterile powder) in the United States, Esteve Pharmaceuticals S.A.S (Esteve), in coordination with the U.S. Food and Drug Administration (FDA) intends to temporarily import non-FDA-approved Zanosar[®] (Streptozocin powder for concentrate for solution for infusion, dosage of 1g for single-use per vial) (NDC 68118-500-01) for U.S. patient use. The imported Zanosar[®] (Streptozocin powder for concentrate for solution for infusion) is labeled in English and currently marketed in the European Union and United Kingdom.

Important Product Information:

- Storage requirement for the imported Zanosar[®] (Streptozocin powder for concentrate for solution for infusion) is 2°C to 8°C in a refrigerator.

Main characteristics of the Imported Product:

	Imported Product
Pharmaceutical form	Powder for concentrate for solution for infusion
Marketing Authorization number	PL 40308/0001 NDC 68118-500-01

	Imported Product
Carton labeling	Zanosar® 1g Powder for concentrate for solution for infusion Streptozocin Zanosar® 1g Powder for concentrate for solution for infusion Streptozocin UK Only 1 vial cytotoxic STATEMENT OF ACTIVE SUBSTANCE Streptozocin 1g LIST OF EXCIPIENTS Citric acid anhydrous Sodium hydroxide for pH adjustment METHOD AND ROUTE OF ADMINISTRATION Read the package leaflet before use. For reconstitution conditions, see package leaflet. After reconstitution, each mL contains 100 mg of streptozocin and 22 mg of citric acid. Intravenous use. Single use only. KEEP OUT OF THE SIGHT AND REACH OF CHILDREN. The preparation of injectable solutions of cytotoxic agents should be done by specialist and trained personnel (see package leaflet for detailed precautions). The reconstituted solution should be immediately diluted and the product should be used immediately. Read the leaflet for further information. SPECIAL STORAGE CONDITIONS Before opening, store in a refrigerator (2°C-8°C). Keep the vial in the original package in order to protect from light. Storage after opening: Reconstitution and dilution: Read the leaflet for further information. SPECIAL PRECAUTIONS FOR DISPOSAL Any waste material should be disposed of in appropriate conditions, in accordance with local requirements. Medicinal product subject to restricted medical prescription. MARKETING AUTHORISATION NP PL 40300/0001 MARKETING AUTHORISATION HOLDER ESTEVE PHARMACEUTICALS S.A.S. Immeuble Cap Sud 106, avenue Max-Dormoy 92120 Montrouge - France EXP. DATE: ZANOL_HUE_1706_19090002_V03 0001010107 Réserve de vernis
Container label	Zanosar® 1g Streptozocin ESTEVE Powder for concentrate for solution for infusion Intravenous use For single use only Cytotoxic BATCH - EXP ZANOL_HUE_1706_19090002_V03
Shelf life	36 months
Indication	Zanosar is indicated for the systemic treatment of adult patients with inoperable, advanced or metastatic, progressive and/or symptomatic, well-differentiated, G1 or G2 neuroendocrine tumours of pancreatic origin, in combination with 5-Fluorouracil.
Administration	Zanosar should be administered intravenously by infusion. The duration of infusion should be between 30 minutes and 4 hours. The administration of Zanosar requires hyperhydration. This medicinal product is vesicant in nature and as such should be administered with caution through a free-flowing line. In case of extravasation, administration should be stopped immediately. Healthcare professionals should take appropriate protection measures. The initial aim is to minimize the volume of extravasated product into the surrounding tissues and to aspirate as much as possible product from the canula with a syringe. Cold packs should be applied and appropriate medical monitoring should be performed.
Instruction for reconstitution	Each 20 mL vial of Zanosar must be reconstituted with 9.5 mL of sodium chloride 9 mg/mL (0.9%) solution for injection.

	Imported Product
Reconstituted solution storage conditions	The reconstituted solution should be immediately diluted. The chemical and physical in-use stability of the resulting solution has been demonstrated for 24 hours below 25°C in polyethylene Ecoflac® type bag containing a sodium chloride 9 mg/ml (0.9%) solution for injection.

The barcode on the imported product label may not register accurately on U.S. scanning systems. Institutions should manually input the imported product information into their systems and confirm that the barcode, if scanned, provides correct information. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

The packaging of the imported product does not include serialization information. Esteve's Zanosar® (Streptozocin powder for concentrate for solution for infusion) does not meet the Drug Supply Chain Security Act (DSCSA) requirements for the Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs.

Esteve's Zanosar® (Streptozocin powder for concentrate for solution for infusion) is available only by prescription in the U.S. However, the imported product does not have the statement "Rx only" on its labeling.

Reporting Quality Problems or Adverse Events:

Any quality problems or claims may be reported also by email to contact-france@esteve.com.

Any adverse events or any event related to safety associated with use of the imported Zanosar® (Streptozocin powder for concentrate for solution for infusion) should be reported by email to safetyreporting@esteve.com.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the preaddressed form or submit by fax to 1-800-FDA-0178 (1-800-332-0178).

If you have any questions about the information contained in this letter, please contact us at: ESTEVE medical inquiries department at contact-france@esteve.com.

Yours faithfully,
14-08-2026

Neus Gascón, MD

Head of Drug Safety and Pharmacovigilance/ EUQPPV

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