STERIMAX
2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4
Tel.: 905-890-0661 800-881-3550 • Fax: 905-890-0508 877-546-7667 • Web: www.sterimaxinc.com

**IMPORTANT PRESCRIBING INFORMATION**

August 21, 2026

**Subject: Temporary Importation of Ifosfamide for Injection with non-U.S. Labeling to Address Drug Shortage**

Dear Healthcare Professional:

Due to the current critical shortage of Ifosfamide for Injection products in the United States (U.S.) market, SteriMax USA Inc. (SteriMax), is coordinating with the U.S. Food and Drug Administration (FDA) to temporarily import unapproved Ifosfamide for Injection, 1g/vial currently marketed in China. FDA has not approved imported Ifosfamide for Injection from Qilu Pharmaceuticals Co. Ltd in the United States. The imported Ifosfamide for Injection is manufactured at an FDA-inspected facility.

At this time, no other entity except SteriMax USA Inc., NJ or its distributor GlobalRX, NC is authorized by the FDA to **import or distribute** imported Ifosfamide for Injection in the United States.

Effective immediately, GlobalRX **will distribute** the following presentations of imported Ifosfamide for Injection to address the critical shortage:

| **Imported Ifosfamide for Injection** | | | | |
|---|---|---|---|---|
| **Product Name** | **Quantity** | **Batch/Lot Details** | **Expiry Date** | **NDC** |
| Ifosfamide for Injection, 1g per vial | Five vials per carton | FA2B6007A | June 21, 2029 | 21586-021-02 |
| | | FA2B6008BA | June 25, 2029 | **Labeled:** 21586-0211-2 |

**The barcode on the imported product carton label may not register accurately on the 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. In addition, the packaging of the imported product does not include serialization information. Imported Ifosfamide for Injection does not meet the Drug Supply Chain Security Act (DSCSA) requirements for the Interoperable Exchange of Information for Tracing of Human, Finished Prescription Drugs.

**It is important to note the following:**

- The imported product should be stored under refrigeration at 2°C to 8°C, protected from light, and sealed. These storage instructions differ from the FDA-approved product. The storage conditions are supported by stability and compatibility studies.
- Reconstitution and administration instructions differ between the imported product label and the FDA-approved IFEX labeling. The FDA-approved IFEX labeling provides specific reconstitution volumes, final concentration, further dilution options, and stability instructions; the imported package insert directs reconstitution with sterile water for injection, further dilution with 500 to

STERIMAX
2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4

1000 mL of 0.9% Sodium Chloride Injection or 5% Dextrose Injection, and slow intravenous infusion over at least 30 minutes. Refer to the Product Comparison Table for details.

- The Chinese vial label and carton are over labeled with English labels, as shown in the Product Comparison Table below. Healthcare professionals should use the English over labels, English translation, and Product Comparison Table to verify the product name, strength, storage, handling, reconstitution, and administration information before use.
- The imported product contains excipients, glycine and mannitol, whereas FDA-approved IFEX contains no excipients.
- In addition, the imported package insert lists different drug interaction information than the FDA-approved IFEX labeling; healthcare professionals should review the Product Comparison Table and FDA-approved IFEX prescribing information before prescribing, preparing, or administering imported Ifosfamide for Injection.

Ifosfamide for Injection is available only by prescription in the U.S. Please refer to the package insert provided here for the FDA-approved Ifosfamide for Injection drug product for full prescribing information.

**Finally, please ensure that your staff and others in your institution who may be involved in the administration of Ifosfamide for Injection receive a copy of this letter and review the information.**

If you have any questions about the information contained in this letter, any quality related problems, or questions on the use of imported Ifosfamide for Injection, please contact SteriMax USA Inc. at 1-877-373-4657.

To place an order, please contact GlobalRX at info@globalrx.com or (919) 245-8418.

Healthcare providers should report adverse events associated with the use of imported Ifosfamide for Injection to SteriMax USA Inc. at 1-877-373-4657 and/or by e-mail pv@sterimaxinc.com

Adverse events, medication errors, 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 pre-addressed form or submit by fax to 1-800-FDA -0178.

We remain at your disposal to answer any questions you may have about our product; and provide more information if needed.

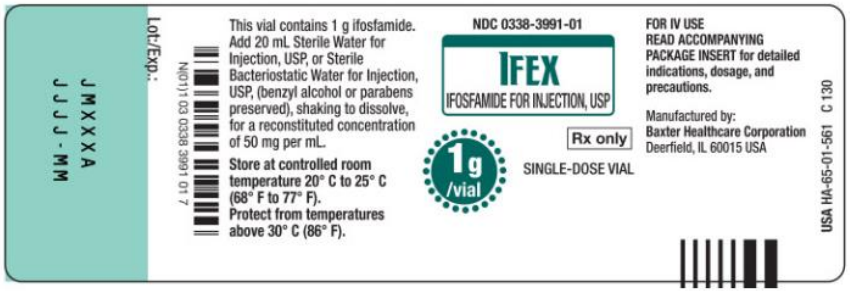
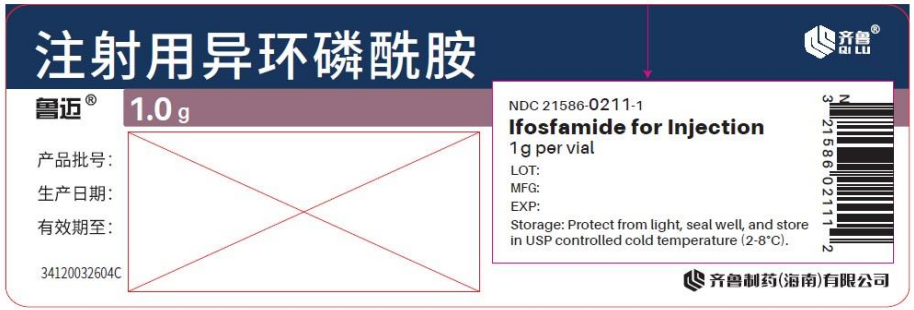
Sincerely,

Signed by Ritesh Acharya
Ritesh Acharya | I approve this document
Aug 21, 2026 | 12:07:45 PM EDT
F3EB2DA650A245FFB37A01A72CC340C7

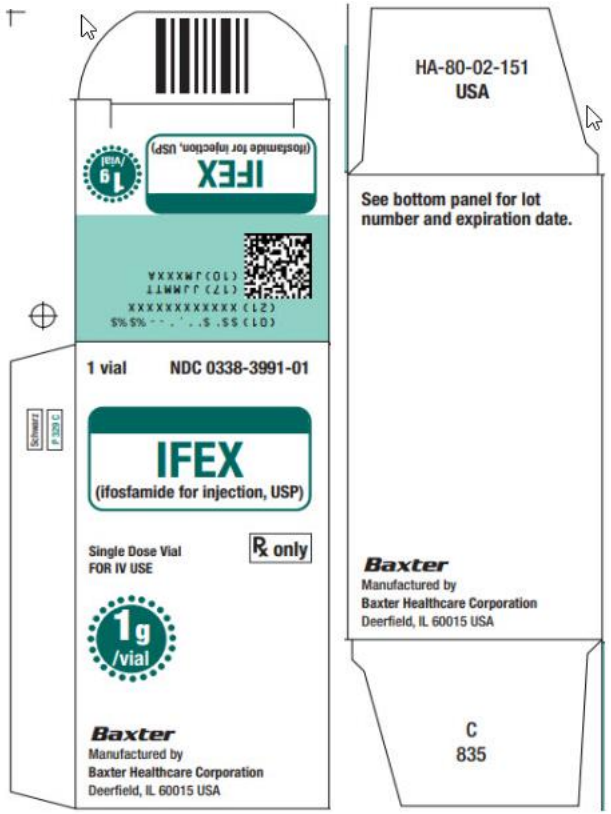
Ritesh Acharya
Chief Scientific Officer
SteriMax Inc.

STERIMAX
2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4

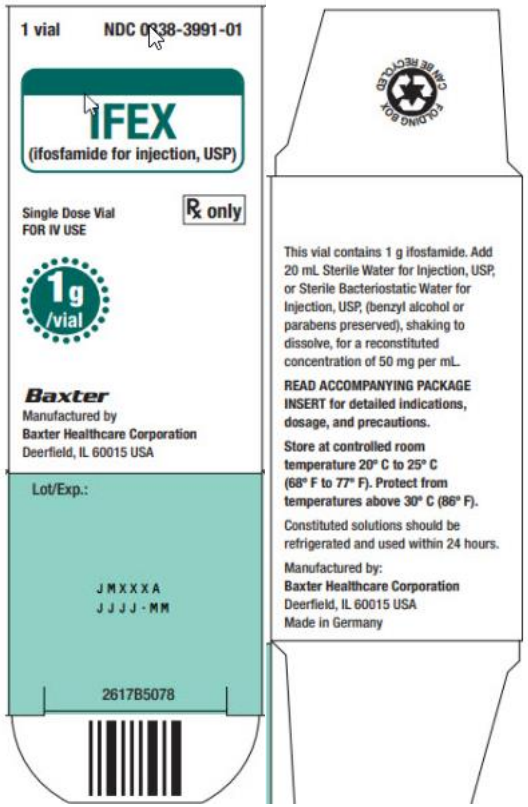
# Product Comparison Table

| | US FDA Approved Product | Imported Product |
|---|---|---|
| **Vial Container Label – 1 gram** |  | **Chinese Label:**<br>  <br>**Chinese Label with English over label:**<br>  |

STERIMAX
2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4

| | US FDA Approved Product | Imported Product |
|---|---|---|
| Carton – 1 gram |  | **Chinese Label:**<br>  |

STERIMAX
2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4

| | US FDA Approved Product | Imported Product |
|---|---|---|
| |  | **Chinese label with English over label:**<br>  |
| **Product Name** | IFEX (Ifosfamide) for Injection, USP | Ifosfamide for Injection |
| **Strength** | **1 g per vial** | **1 g** |
| **Pack Size** | **1 vial per carton** | **5 vials per carton** |
| **Language of Label** | **English** | **Chinese** |
| **English Overlabeling** | Not applicable; the FDA-approved IFEX vial and carton labeling are in English. | The Chinese vial label and carton will be overlabeled with English labels for use in the United States. |
| **Route of Administration** | **Intravenous** | **Intravenous** |

STERIMAX
2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4

<table>
<tr><th></th><th>US FDA Approved Product</th><th>Imported Product</th></tr>
<tr><td>Ingredients</td><td>1 gram vial<br>IFEX (ifosfamide for injection, USP) single-dose vials for constitution and administration by intravenous infusion each contain 1 gram of sterile ifosfamide.<br>There are no excipients in the formulation.</td><td>The main ingredient of this product is ifosfamide.<br>Excipients include glycine and mannitol.</td></tr>
<tr><td>Drug Interactions</td><td>FDA-approved IFEX labeling identifies:<br><br>Inducers of CYP3A4<br>CYP3A4 inducers may increase the metabolism of ifosfamide to its active alkylating metabolites. CYP3A4 inducers may increase the formation of the neurotoxic/nephrotoxic ifosfamide metabolite, chloroacetaldehyde. Closely monitor patients taking ifosfamide with CYP3A4 inducers for toxicities and consider dose adjustment.<br><br>Inhibitors of CYP3A4<br>CYP3A4 inhibitors may decrease the metabolism of ifosfamide to its active alkylating metabolites, perhaps decreasing the effectiveness of ifosfamide treatment.</td><td>The English translation of the imported Ifosfamide package insert lists the following interactions:<br>(1) Prior administration of cisplatin exacerbate ifosfamide-induced myelosuppression, neurotoxicity, and nephrotoxicity.<br>(2) Concomitant use with anticoagulants cause bleeding.<br>(3) Concomitant use with hypoglycemic agents potentiate hypoglycemic effects.<br>(4) Dose reduction should be considered as appropriate when used in combination with other cytotoxic agents.<br>(5) Administration of live vaccines (e.g., rotavirus vaccine) during therapy increases the risk of infection from the live vaccine; live vaccines should not be administered to patients receiving immunosuppressive chemotherapy.<br>(6) Concomitant radiotherapy exacerbate radiation-induced cutaneous reactions.</td></tr>
<tr><td>Reconstitution and Administration</td><td>Prepare IFEX for intravenous use by adding Sterile Water for Injection, USP or Bacteriostatic Water for Injection, USP to the vial and shaking to dissolve. Before administration, the substance must be completely dissolved. Use the quantity of diluents shown in Table 1 below to reconstitute the product:<br><br>Table 1: IFEX Quantities for Dilution and Final Concentrations
<table>
<tr><th>Dosage Strength</th><th>Quantity of Diluent</th><th>Final Concentration</th></tr>
<tr><td>1 gram</td><td>20 mL</td><td>50 mg per mL</td></tr>
<tr><td>3 grams</td><td>60 mL</td><td>50 mg per mL</td></tr>
</table>
Solutions of ifosfamide may be diluted further to achieve concentrations of 0.6 to 20 mg/mL in the following fluids:<br>• 5% Dextrose Injection, USP<br>• 0.9% Sodium Chloride Injection, USP<br>• Lactated Ringer’s Injections, USP<br>• Sterile Water for Injection, USP</td><td>The imported package insert states that the product should be reconstituted in 20 mL of sterile water for injection, then further diluted with 500 to 1000 mL of 0.9% Sodium Chloride Injection or 5% Dextrose Injection, to achieve concentration of 0.6 to 20 mg/mL and administered by slow intravenous infusion over at least 30 minutes. Single-drug therapy: 1.2 to 2.5 g/m$^2$ per day for 5 consecutive days as one cycle. Combination therapy: 1.2 to 2.0 g/m$^2$ per day for 5 consecutive days as one cycle. The next cycle should be initiated after an interval of 3 to 4 weeks or once hematologic toxicity has recovered (platelet count100,000/μL and white blood cell count 4,000/μL). To prevent bladder toxicity, adequate hydration is required, with a daily fluid intake of 2 L via oral or intravenous route. A protective agent against hemorrhagic cystitis, such as Mesna, should be co-administered. Mesna dissolved in normal saline should be given intravenously concurrently with ifosfamide administration and again at 4 and 8 hours post-administration. The usual dose of Mesna is 20% of the total daily dose of ifosfamide. Dosage adjustment for patients with hepatic or renal impairment has not been established.</td></tr>
</table>

STERIMAX
2770 Portland Drive, Oakville, Ontario, Canada L6H 6R4

| | US FDA Approved Product | Imported Product |
|---|---|---|
| | Administer IFEX with extensive hydration consisting of at least 2 liters of oral or intravenous fluid per day to reduce the incidence or severity of bladder toxicity.<br>Administer IFEX with mesna to reduce the incidence or severity of hemorrhagic cystitis. | |
| **Storage and Stability** | **Product Vial:**<br>Store at controlled room temperature **20°C to 25°C (68°F to 77°F).**<br>Protect from temperatures above 30°C (86°F).<br><br>**Reconstituted Solution:**<br>Refrigerate constituted or constituted and further diluted solutions of IFEX and use **within 24 hours.**<br>Benzyl-alcohol-containing solutions can reduce the stability of ifosfamide | **Product Vial:**<br>Store at **2°C to 8°C.**<br>Protect from light, seal, discard unused portion.<br><br>**Reconstituted Solution:**<br>Reconstituted solution is **stable for 24 hours at 20°C to 25°C at a concentration of 50 mg/mL in the original container**.<br><br>Reconstituted and diluted solutions are **stable for 48 hours in PVC and polypropylene bags at 20°C to 25°C**, **protected from light**. |