

Drug Name	IXEMPRA
Brand Name:	Ixempra
Generic Class	Ixabepilone
Active Ingredients(s)	IXABEPOLONE Ixempra Kit (ixabepilone) for injection
Distributed by:	Bristol-Myers Squibb Company
FDA approval date	October 16, 2007
Class of Drug	Antineoplastic agent
Mechanism of Action	Microtubule inhibitor
MSDS on file	No
Sales Representative	
Nurse Educator	
Insurance In-Service	Yes, 9 AM on Monday, October 22 <sup>nd</sup>
Nurse In-Service	Yes, 8 AM on Friday, November 9 <sup>th</sup>
Do we have the PI on file (electronic format)	Yes
NDC	<b><u>NDC 0015-1910-12</u></b> Ixempra kit containing 1 vial of Ixempra for injection, 15 mg and 1 vial of diluent for Ixempra, 8 mL <b><u>NDC 0015-1911-13</u></b> Ixempra kit containing 1 vial of Ixempra for injection, 45 mg and 1 vial of diluent for Ixempra, 23.5 mL
Dosing	Ixempra 40 mg/m <sup>2</sup> IV over 3hours q 3 weeks (1.5–2.0 m <sup>2</sup> dose range expected 60–120 mg) <i>Xeloda dose 1,000 mg/m<sup>2</sup> twice daily for 2 weeks followed by 1 week of rest</i>
Cycles	Ixempra and capecitabine median of 4 cycles Ixempra alone median of 5 cycles
J CODE	J9999 (unlisted antineoplastic agent)

Compendia Listing

N/A at this time

Indications

**Ixempra (combination)**, a microtubule inhibitor, in combination with capecitabine is indicated for the treatment of metastatic or locally advanced breast cancer in patients after failure of an anthracycline and a taxane or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated. Anthracycline resistance is defined as progression while on therapy or within 6 months in the adjuvant setting or 3 months in the metastatic setting. Taxane resistance is defined as progression while on therapy or within 12 months in the adjuvant setting or 4 months in the metastatic setting.

**Ixempra (alone)** as monotherapy is indicated for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine.

ICD-9

174 to 174.9

**Black box warning**

Yes, Ixempra in combination with capecitabine must **not** be given to patients with AST or ALT > 2.5 x ULN or bilirubin >1 x ULN due to increased risk of toxicity and neutropenia-related death.

See page 7, #4 for additional contraindications, warnings, and precautions.

Billing Units

Not available at this time (guessing 15 mg)

ASP

Not available at this time

Is drug available from wholesaler?

Shipment 10/24

Vial sizes	15 mg and 45 mg
SDV OR MDV	SDV
Cost	15 mg Ixempra kit \$921.96 45 mg Ixempra kit \$2,765.89

**Product support**

Product hotline # Destination Access BMSO (800) 861-0048 Fax (888) 776-2370

Letter of medical necessity y/n Yes – electronic format + hard copy

Insurance Verification y/n Yes Provided

If yes, do we have information on file Yes

Drug replacement for insured pt y/n **Yes** / after 2 levels of appeal and claim denied. Will actually reimburse provider @ invoice cost if criteria are met. Must be US citizen or proof of legal status/ drug must have been administered in US, total yearly household adjusted gross income < \$75,000. (W2, Social Security letter, pay stubs, tax return) + patient has diagnosis 174 to 174.9

Indigent program (no insurance) y/n Yes

If yes, do we have information on file Yes ~ same criteria as above for free drug

Co-pay assistance program y/n Yes ~ patient will be referred to Foundations

Chemotherapy teaching material

For nurse? Not available at this time x for Package Insert

For patient? Not available at this time x for Package Insert

For patients with insurance, registration prior to therapy with Destination Access is not required/product hotline will assist anytime during the treatment.

**Drug supplied**

Solution, powder, special kit? “Powder.” Each Ixempra kit is shipped with diluent.

Refrigeration: Yes, Ixempra kit must be stored in refrigerator in the original package to protect from light.

\*Notify front desk when ordering

Mixing? Solution/anything special? After constituting with the diluent, the concentration of ixabepilone is 2 mg/mL. The constituted solution must be further diluted with

1. Lactated Ringer's injection supplied in DEHP {di-(2-ethylhexyl) phthalate} free bags.

2. The final infusion solution must be administered through an in-line filter with microporous membrane of 0.2 to 1.2 microns.

*\*DEHP-free infusion containers and administration sets must be used.*

Stability After constituting ixabepilone for injection, the constituted solution should be further diluted with lactated Ringer's injection as soon as possible but may be stored in the vial (not the syringe) for a maximum of 1 hour at room temperature and room light. Once diluted with lactated Ringer's injection, USP the solution is stable at room temperature and room light for a maximum of 6 hours.

### **Pre-administration instructions**

Lab Complete CBC and liver functions

### **Pre meds**

Nausea index > 20% adverse events of N/V (page 11 of PI)

Benadryl 50 mg orally or equivalent

Zantac 150–300 mg orally or equivalent

Patients with hypersensitivity reaction will require premeds with

Dexamethasone 20 mg IV, 30 minutes prior (or)

Dexamethasone 20 mg orally, 60 minutes prior

### **Drug administration**

Drug administration instructions

Total infusion time?	3 hours/No pre or post observation necessary
Any precautions? (light sensitive)	Not necessary during infusion
Ambulatory pump	No
Stationary pump	Not necessary. 90 cc per hour
Special tubing?	Yes – 0.2 to 1.2 micron tubing in-line filter
Special solution? solution	DEHP-free bag (empty). Use 250 mL of lactated Ringer's solution

### **Post-infusion precautions**

Grade of neutropenia?	Yes (page 15 of PI) 20% require GSF on combo, 17% Ixempra alone. <b><i>Factor in Neulasta or Neupogen on authorization and regimen cost.</i></b>
Anemia?	Yes (page 15 of PI). <b><i>Factor in ESA authorization and regimen cost because the patients bone marrow has been compromised by prior therapy.</i></b>
Other side effects	<b><u>Peripheral neuropathy</u></b> (page 8 of PI) 67% of patients on combo of Ixempra with capecitabine reported treatment-related peripheral neuropathy and 63% of patients on Ixempra alone reported peripheral neuropathy. See page 3, Table, 1 for Dose Adjusted Guidelines if necessary.
Authorization department	<ol style="list-style-type: none"><li>1. Ixempra</li><li>2. 3-hour chemotherapy infusion</li><li>3. Neulasta or Neupogen (may need)</li></ol>

4. ESA (may need)
5. Benadryl
6. Zantac
7. Up to 1-hour non-chemotherapy infusion
8. Solutions/supplies

**Things to review with nurses and doctors:**

Will this drug replace a drug you currently stock? If so, consider adjusting your inventory min/max par levels for inventory control

Do you need to search your data base to consider this new drug for other patients?