Patient Information
IXEMPRA® Kit (ĭk-'sĕm-pră)
(ixabepilone)
for injection, for intravenous use

What is the most important information I should know about IXEMPRA?

Your healthcare provider should do blood tests to check your liver function:

- before you begin receiving IXEMPRA
- as needed while you are receiving IXEMPRA

If blood tests show that you have liver problems, do not receive injections of IXEMPRA along with the medicine capecitabine. Taking these two medicines together if you have liver problems increases your chance of serious problems. These include: serious infection and death due to a very low white blood cell count (neutropenia).

What is IXEMPRA?

IXEMPRA is used alone **or** with another cancer medicine called capecitabine to treat locally advanced breast cancer or breast cancer that has spread to other parts of the body (metastatic), when certain other medicines have not worked or no longer work.

It is not known if IXEMPRA is safe and effective in children.

Do not receive IXEMPRA if you:

- have low white blood cell or platelet counts. Your healthcare provider will check your blood counts.
- are allergic to a medicine, such as TAXOL® that contains Cremophor® EL or polyoxyethylated castor oil.
- are also taking a cancer medicine called capecitabine and you have liver problems. **See "What is the most important information I should know about IXEMPRA?"**

Before you receive IXEMPRA, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have heart problems or a history of heart problems
- have had an allergic reaction to IXEMPRA. You will receive medicines before each injection of IXEMPRA to decrease the chance of an allergic reaction. **See "How will I receive IXEMPRA?"**
- are pregnant or plan to become pregnant. IXEMPRA can harm your unborn baby. Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with IXEMPRA.
  - If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with IXEMPRA.
  - **Females** who are able to become pregnant should use effective birth control during treatment with IXEMPRA and for 7 months after the last dose.
  - **Males** with female partners who are able to become pregnant should use effective birth control during treatment with IXEMPRA and for 4 months after the last dose.
- are breastfeeding or plan to breastfeed. It is not known if IXEMPRA passes into breast milk. Do not breastfeed during treatment with IXEMPRA and for 2 weeks after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

IXEMPRA and certain other medicines may affect each other causing side effects. IXEMPRA may affect the way other medicines work, and other medicines may affect how IXEMPRA works.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider.

How will I receive IXEMPRA?

- IXEMPRA is given by an injection directly into your vein (intravenous infusion).
- IXEMPRA is usually given 1 time every 3 weeks.
- Each treatment with IXEMPRA will take about 3 hours.
- Your healthcare provider will decide how much IXEMPRA you will receive and how often you will receive it.
- To lower the chance of allergic reaction, you will receive other medicines about 1 hour before each treatment with IXEMPRA. **See "What are the possible side effects of IXEMPRA?"**
- If you have an allergic reaction to IXEMPRA, you will receive a steroid medicine before future doses of IXEMPRA. You may also need to receive your doses of IXEMPRA more slowly.

What should I avoid while receiving IXEMPRA?

- IXEMPRA contains alcohol. If you are dizzy or drowsy, avoid activities that may be dangerous, such as driving or operating machinery.
- Do not drink grapefruit juice during treatment with IXEMPRA. Drinking grapefruit juice may cause you to have too much IXEMPRA in your blood and lead to side effects.

What are the possible side effects of IXEMPRA?
IXEMPRA may cause serious side effects including:

- **Numbness, tingling, or burning in the hands or feet can occur during treatment with IXEMPRA peripheral neuropathy (PN).** These symptoms may be new or get worse during treatment with IXEMPRA. If you have diabetes, you may have a higher risk for severe neuropathy. These symptoms often occur early during treatment with IXEMPRA. Tell your healthcare provider if you have any of these symptoms. Your dose of IXEMPRA may need to be decreased, stopped until your symptoms get better, or totally stopped.
- **Low blood cell counts especially low white blood counts (neutropenia).** Low white blood cell counts are common with IXEMPRA treatment, but can sometimes be severe and have led to death**.** White blood cells help protect the body from infections caused by bacteria. If you get a fever or infection when your white blood cells are very low, you can become seriously ill and die. You may need treatment in the hospital with antibiotic medicines. Your healthcare provider will monitor your white blood cell count often with blood tests. Tell your healthcare provider right away or go to the nearest hospital emergency room if you have a fever (temperature above 100.5° F) or other signs of infection, such as chills, cough, burning or pain when you urinate, any time between treatments with IXEMPRA.
- **Allergic reactions.** Severe allergic reactions can happen with IXEMPRA and may cause death in some cases. Allergic reactions are most likely to happen while IXEMPRA is being injected into your vein. Tell your healthcare provider right away if you get any of the following signs and symptoms of an allergic reaction:
  - itching, hives (raised itchy welts), rash
  - flushed face
  - sudden swelling of face, throat or tongue
  - chest tightness, trouble breathing
  - feel dizzy or faint
  - feel your heart beating (palpitations)
- **Heart problems.** IXEMPRA might cause decreased blood flow to the heart, problems with heart function, and abnormal heart beat. This is seen more often in patients who also take capecitabine. **Tell your healthcare provider right away if you have any of the following symptoms:**
  - chest pain
  - difficulty breathing
  - feel your heart beating (palpitations)
  - unusual weight gain

The most common side effects with IXEMPRA when used alone or with capecitabine may include:

- tiredness
- loss of appetite
- disorders of toenails and fingernails
- hair loss
- fever
- decreased red blood cell count (anemia)
- joint and muscle pain
- headache
- decreased platelet count (thrombocytopenia)
- nausea, vomiting, diarrhea, constipation, and abdominal pain
- sores on the lip, in the mouth and esophagus
- tender, red palms and soles of feet (hand-foot syndrome) that looks like a sunburn; the skin may become dry and peel. There may also be numbness and tingling.

IXEMPRA may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of IXEMPRA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of IXEMPRA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. If you would like more information about IXEMPRA, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about IXEMPRA that is written for health professionals.

What are the ingredients in IXEMPRA?

Active ingredient: ixabepilone

Inactive ingredients: The DILUENT for IXEMPRA contains purified polyoxyethylated castor oil and dehydrated alcohol.

IXEMPRA® (ixabepilone) for injection Manufactured by: Baxter Oncology GmbH, 33790 Halle/Westfalen, Germany
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For more information about IXEMPRA, call 1-844-586-8953.

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 01/2022