

Patient Information
EXEMESTANE (ek"e mes'tane)
TABLETS

What are exemestane tablets?

Exemestane tablets are used in women who are past menopause for the treatment of:

- **Early breast cancer** (cancer that has not spread outside the breast) in women who:
 - o have cancer that needs the female hormone estrogen to grow, **and**
 - o have had other treatments for breast cancer, **and**
 - o have taken tamoxifen for 2 to 3 years, **and**
 - o are switching to exemestane tablets to complete 5 years in a row of hormonal therapy.
- **Advanced breast cancer** (cancer that has spread) after treatment with tamoxifen, and it did not work or is no longer working.

It is not known if exemestane tablets are safe and effective in children.

Do not take exemestane tablets if you are allergic to exemestane tablets or any of the ingredients in exemestane tablets. See the end of this leaflet for a complete list of ingredients in exemestane tablets.

Before you take exemestane tablets, tell your doctor about all your medical conditions, including if you:

- are still having menstrual periods (are not past menopause). Exemestane tablets are only for women who are past menopause.
- have weak or brittle bones (osteoporosis)
- are pregnant or plan to become pregnant. Taking exemestane tablets during pregnancy or within 1 month of becoming pregnant can harm your unborn baby.
 - o Females who are able to become pregnant should have a pregnancy test within 7 days before starting treatment with exemestane tablets.

- o Females who are able to become pregnant should use effective birth control (contraceptive) during treatment with exemestane tablets and for 1 month after your last dose of exemestane tablets. Tell your doctor right away if you become pregnant or think you may be pregnant.
- are breastfeeding or plan to breastfeed. It is not known if exemestane tablets pass into your breast milk. Do not breast-feed during treatment with exemestane tablets and for 1 month after your last dose of exemestane tablets.
- Have liver or kidney problems.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Especially tell your doctor if you take medicines that contain estrogen, including other hormone replacement therapy or birth control pills or patches. Exemestane tablets should not be taken with medicines that contain estrogen as they could affect how well exemestane tablets work.

How should I take exemestane tablets?

- Take exemestane tablets exactly as your doctor tells you.
- Take exemestane tablets 1 time each day after a meal.
- If you take too many exemestane tablets, call your doctor right away or go to nearest hospital emergency room.

What are the possible side effects of exemestane tablets?

Exemestane tablets may cause serious side effects, including:

- **Bone loss.** Exemestane tablets decrease the amount of estrogen in your body which may reduce your bone mineral density (BMD) over time. This may increase your risk for bone fractures or weak and brittle bones

(osteoporosis). Your doctor may check your bones during treatment with exemestane tablets if you have osteoporosis or at risk for osteoporosis.

The most common side effects of exemestane tablets in women with early breast cancer include:

- hot flashes
- feeling tired
- joint pain
- headache
- trouble sleeping
- increased sweating

The most common side effects of exemestane tablets in women with advanced breast cancer include:

- hot flashes
- nausea
- feeling tired
- increased sweating
- increased appetite

Your doctor will do blood tests to check your vitamin D level before starting treatment with exemestane tablets. Exemestane tablets may cause decreased fertility in males and females. Talk to your doctor if you have concerns about fertility.

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

How should I store exemestane tablets?

- Store exemestane tablets at room temperature 68°F to 77°F (20°C to 25°C).
- Keep exemestane tablets and all medicines out of the reach of children.

General information about the safe and effective use of exemestane tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use exemestane tablets for a condition for which it was not prescribed. Do not give exemestane

tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or doctor for information about exemestane tablets that is written for health professionals.

What is in exemestane tablets?

Active ingredient: exemestane

Inactive ingredients: colloidal silicon dioxide, crospovidone, hydroxypropyl methylcellulose, magnesium stearate, mannitol, microcrystalline cellulose, polysorbate 80, sodium starch glycolate. The tablet coating contains: hypromellose, propylene glycol, and titanium dioxide.

For more information, go to www.bpirx.com or call 1-800-367-3395.

Manufactured by:

MSN Laboratories Private Limited
Telangana – 509 228,
INDIA

Distributed by:

Breckenridge Pharmaceutical, Inc.
Berlin, CT 06037

This Patient Information has been approved by the U.S. Food and Drug Administration

Issued: 07/2019