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**Patient Information**  
**AMABELZ™ (AM-ah-bells)**  
**(estradiol and norethindrone acetate tablets USP, for oral use)**

Read this Patient Information before you start using AMABELZ and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your menopausal symptoms or your treatment.

**What is the most important information I should know about Amabelz (a combination of estrogen and progestogen)?**

- Do not use estrogens with or without progestogens to prevent heart disease, heart attacks, strokes, or dementia (decline of brain function).
- Using estrogens with progestogens may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots.
- Using estrogens with progestogens may increase your chance of getting dementia, based on a study of women 65 years of age and older.
- Using estrogen-alone may increase your chance of getting cancer of the uterus (womb).
- Do not use estrogen-alone to prevent heart disease, heart attacks, strokes, or dementia (decline in brain function).
- Using estrogen-alone may increase your chances of getting strokes or blood clots.
- Using estrogen-alone may increase your chance of getting dementia, based on a study of women 65 years of age and older.
- Only one estrogen with progestogen product and dose have been shown to increase your chances of getting heart attacks, strokes, breast cancer, blood clots, and dementia. Only one estrogen-alone product and dose have been shown to increase your chances of getting strokes, blood clots, and dementia.

Because other products and doses have not been studied in the same way, it is not known how the use of AMABELZ will affect your chances of these conditions. You and your healthcare provider should talk regularly about whether you still need treatment with Amabelz.

**What is AMABELZ?**

AMABELZ is a prescription medicine that contains two kinds of hormones, an estrogen and a progestogen.

**What is AMABELZ used for?**

AMABELZ is used after menopause to:

- **Reduce moderate to severe hot flashes**  
Estrogens are hormones made by a woman's ovaries. The ovaries normally stop making estrogens when a woman is between 45 and 55 yrs old. This drop in body estrogen levels causes the "change of life" or menopause, the end of monthly menstrual periods. Sometimes both ovaries are removed during an operation before natural menopause takes place. The sudden drop in estrogen levels causes "surgical menopause."

When estrogen levels begin dropping, some women get very uncomfortable symptoms, such as feelings of warmth in the face, neck, and chest, or sudden, intense feelings of heat and

sweating (“hot flashes” or “hot flushes”). In some women, the symptoms are mild, and they will not need to use estrogens. In other women, symptoms can be more severe.

- **Treat moderate to severe menopausal changes in and around the vagina**  
You and your healthcare provider should talk regularly about whether you still need treatment with AMABELZ 1 mg/0.5 mg to treat these problems. If you use AMABELZ 1 mg/0.5 mg only to treat your menopausal changes in and around your vagina, talk with your healthcare provider about whether a topical vaginal product would be better for you.
- **Help reduce your chances of getting osteoporosis (thin weak bones)**  
Osteoporosis from menopause is a thinning of the bones that makes them weaker and easier to break. If you use AMABELZ to prevent osteoporosis due to menopause, talk with your healthcare provider about whether a different treatment or medicine without estrogens might be better for you.

You and your healthcare provider should talk regularly about whether you still need treatment with AMABELZ.

#### **Who should not use AMABELZ?**

**Do not use AMABELZ if you have had your uterus (womb) removed (hysterectomy).**

Amabelz contains a progestogen to decrease the chance of getting cancer of the uterus. If you do not have a uterus, you do not need a progestogen and you should not use AMABELZ.

#### **Do not start using AMABELZ if you:**

- **have unusual vaginal bleeding**  
Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.
- **have been diagnosed with a bleeding disorder**
- **currently have or have had certain cancers**  
Estrogens may increase the chance of getting certain types of cancers, including cancer of the breast or uterus (womb). If you have or have had cancer, talk with your healthcare provider about whether you should use AMABELZ.
- **had a stroke or heart attack**
- **currently have or have had blood clots**
- **currently have or have had liver problems**
- **are allergic to AMABELZ or any of the ingredients in it.**

See the list of ingredients in AMABELZ at the end of this leaflet.

**Before you use AMABELZ, tell your healthcare provider about all of your medical conditions, including if you:**

- **have any unusual vaginal bleeding**  
Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your healthcare provider should check any unusual vaginal bleeding to find out the cause.
- **have any other medical conditions that may become worse while you are using**

## **AMABELZ.**

Your healthcare provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing), epilepsy (seizures), diabetes, migraine, endometriosis, lupus, angioedema (swelling of face and tongue), problems with your heart, liver, thyroid, kidneys, or have high calcium levels in your blood.

- **are going to have surgery or will be on bed rest**  
Your healthcare provider will let you know if you need to stop using Amabelz.
- **are pregnant or think you may be pregnant**  
Amabelz is not for pregnant women.
- **are breast feeding**  
The hormones in AMABELZ can pass into your breast milk.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how AMABELZ works. AMABELZ may also affect how your other medicines work. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get new medicine.

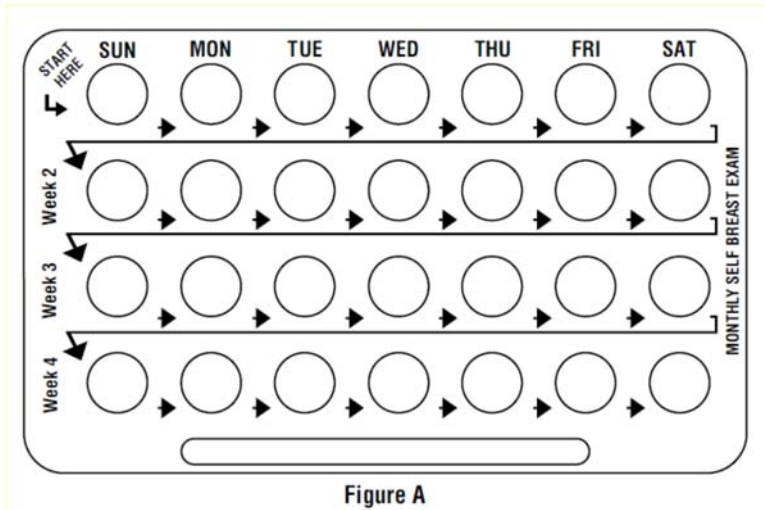
### **How should I use AMABELZ?**

- Use AMABELZ exactly as your healthcare provider tells you to use it.
- Take 1 tablet at the same time each day.
- You and your healthcare provider should talk regularly (every 3 to 6 months) about your dose and whether you still need treatment with AMABELZ.

### **Follow the instructions below to use your Amabelz Blister Pack:**

#### **1. Set The Day Reminder**

- Each blister has been preprinted with the days of the week, starting with Sunday, to facilitate a Sunday-Start regimen.
- Six different day label strips of the week have been provided with this pack in order to accommodate beginning any day of the week.
- Pick the day label strip that starts with the current day of the week. Place this day label strip over the area that has the days of the week (starting with Sunday) pre-printed on the blister (Refer figure below).



## 2. How to take the first tablet.

- Remove tablet “1” by pushing down on the tablet. The tablet will come out through a hole in the back of the strip.
- The patient should wait 24 hours to take the next tablet. Moving across each row of the blister, continue taking tablet daily until all tablets have been taken.
- When your blister is empty, you will start a new blister on the day after tablet “28.” The first tablet in every refill will always be taken on the same day of the week, no matter when the patient takes the next tablet.

## What are the possible side effects of AMABELZ?

Side effects are grouped by how serious they are and how often they happen when you are treated.

### Serious, but less common side effects include:

- heart attack
- stroke
- blood clots
- breast cancer
- cancer of the lining of the uterus (womb)
- cancer of the ovary
- dementia
- high or low blood calcium levels
- gallbladder disease
- visual abnormalities
- high blood pressure
- high levels of fat (triglycerides) in your blood
- liver problems
- changes in your thyroid hormone levels
- fluid retention
- cancer changes of endometriosis
- enlargement of benign tumors of the uterus (“fibroids”)

- worsening swelling of face and tongue (angioedema) in women who have a history of angioedema
- changes in laboratory tests results such as bleeding times and high blood sugar levels

**Call your healthcare provider right away if you get any of the following warning signs or any other unusual symptoms that concern you:**

- new breast lumps
- unusual vaginal bleeding
- changes in vision or speech
- sudden new severe headaches
- severe pains in your chest or legs with or without shortness of breath, weakness and fatigue

**Common side effects of AMABELZ include:**

- irregular vaginal bleeding or spotting
- nausea
- stomach or abdominal cramps, bloating
- headache
- vomiting
- back pain
- breast pain
- diarrhea
- fluid retention
- vaginal yeast infection

These are not all the possible side effects of AMABELZ. For more information, ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effects that bother you or do not go away.

You may report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561 or to FDA at 1-800-FDA-1088.

**What can I do to lower my chances of a serious side effect with AMABELZ?**

- Talk with your healthcare provider regularly about whether you should continue using AMABELZ.
- If you have a uterus, talk with your healthcare provider about whether AMABELZ is right for you.
- In general, the addition of a progestogen is generally recommended for a woman with a uterus to reduce the chance of getting cancer of the uterus (womb).
- See your healthcare provider right away if you get vaginal bleeding while using AMABELZ.
- Have a pelvic exam, breast exam and mammogram (breast X-ray) every year unless your healthcare provider tells you something else.
- If members of your family have had breast cancer or if you have ever had breast lumps or an abnormal mammogram (breast x-ray), you may need to have breast exams more often.
- If you have high blood pressure, high cholesterol (fat in the blood), diabetes, are overweight, or if you use tobacco, you may have higher chances for getting heart disease.

- Ask your healthcare provider for ways to lower your chances for getting heart disease

**How should I store AMABELZ?**

- Store AMABELZ at room temperature between 68°F to 77°F (20°C to 25°C).
- Store AMABELZ in a dry place protected from light.

**KEEP Amabelz and all medicines out of the reach of children.**

**General information about the safe and effective use of AMABELZ.**

Medicines are sometimes prescribed for purposes other than those listed in Patient Information leaflets. Do not use AMABELZ for conditions for which it was not prescribed. Do not give AMABELZ to other people, even if they have the same symptoms you have. It may harm them.

You can ask your healthcare provider or pharmacist for information about AMABELZ that is written for health professionals.

For more information, you can call our toll free number 1-800-399-2561 or you can visit the Lupin website at [www.lupinpharmaceuticals.com](http://www.lupinpharmaceuticals.com).

**What are the ingredients in AMABELZ?**

**Active ingredients:** estradiol and norethindrone acetate

**Inactive Ingredients:** copovidone, hypromellose, lactose monohydrate, magnesium stearate, starch (corn) and triacetin.

Amabelz 1 mg/0.5 mg or Amabelz 0.5 mg/0.1 mg is supplied in a blister pack enclosed in a pouch with the desiccants containing 28 tablets.

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

Amabelz™ is a trademark of Lupin Pharmaceuticals, Inc.

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