



## PATIENT INFORMATION

Updated December 2005

### Menostar® (Men-ō-star)

(estradiol transdermal system)

Read this before you start using Menostar and read what you get each time you refill Menostar. There may be new information. This information does not take the place of talking to your health care provider about your medical condition or your treatment.

#### **What is the most important information I should know about Menostar (an osteoporosis preventative containing an estrogen hormone)?**

- Estrogens increase the chances of getting cancer of the uterus.

Report any unusual vaginal bleeding right away while you are taking estrogens. Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb). Your health care provider should check any unusual vaginal bleeding to find out the cause.

- Do not use estrogens with or without progestins to prevent heart disease, heart attacks, or strokes.

Using estrogens with or without progestins may increase your chances of getting heart attacks, strokes, breast cancer, or blood clots.

- Using estrogens with or without progestins may increase your risk of dementia.

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

#### **What is Menostar?**

Menostar is a medicine that contains an estrogen hormone.

#### **What is Menostar used for?**

Menostar is used after menopause to:

- **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. Very low doses of estrogen can help keep your bones from becoming weaker. You and your healthcare provider should talk regularly about whether you should continue with Menostar.

Weight-bearing exercise, like walking or running, and taking calcium and vitamin D supplements may also lower your chances of getting postmenopausal osteoporosis. It is important to talk about exercise and supplements with your healthcare provider before starting them.

#### **Who should not use Menostar?**

Do not start using Menostar if you:

- **have unusual vaginal bleeding**
- **currently have or have had certain cancers.** Estrogens may increase the chances of getting certain types of cancers, including cancer of the breast or uterus. If you have or had cancer, talk with your health care provider about whether you should use Menostar.
- **had a stroke or heart attack in the past year.**
- **currently have or have had blood clots.**
- **currently have or have had liver problems.**
- **are allergic to Menostar or any of its ingredients.** See the end of this leaflet for a list of ingredients in Menostar. If you are allergic to other estrogen patches, you will likely be allergic to Menostar.
- **think you may be pregnant**

#### **Tell your health care provider:**

- **if you are breastfeeding.** The hormone in Menostar can pass into your milk.
- **about all of your medical problems.** Your health care provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing), epilepsy (seizures), migraine, endometriosis, lupus, or problems with your heart, liver, thyroid, kidneys, or have high calcium levels in your blood.
- **about all the medicines you take,** including prescription and non-prescription medicines, vitamins, and herbal supplements. Do not use any estrogen pill, patch or injection with Menostar. Some medicines may affect how Menostar works. Menostar may also affect how your other medicines work.
- **if you are going to have surgery or will be on bed rest.** You may need to stop taking estrogens.

#### **How should I use Menostar?**

- Menostar is a patch that you wear on your skin. The estrogen in the Menostar patch passes through your skin. You must change your Menostar patch every 7 days (once a week). See the end of this leaflet for complete instructions for using Menostar.
- Estrogens should be used at the lowest dose possible for your treatment, only as long as needed. You and your healthcare provider should talk regularly about whether you still need treatment with Menostar.

#### **What are the possible side effects of estrogens?**

##### **Less common but serious side effects include:**

- Breast cancer
- Cancer of the uterus
- Stroke
- Heart attack
- Blood clots
- Dementia
- Gallbladder disease
- Ovarian cancer

##### **These are some of the warning signs of serious side effects:**

- Breast lumps
- Unusual vaginal bleeding
- Dizziness and faintness
- Changes in speech
- Severe headaches
- Chest pain
- Shortness of breath
- Pains in your legs
- Changes in vision
- Vomiting

Call your health care provider right away if you get any of these warning signs, or any other unusual symptom that concerns you.

##### **Common side effects include:**

- Headache
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach/abdominal cramps, bloating
- Nausea and vomiting
- Hair loss

##### **Other side effects include:**

- High blood pressure
- Liver problems
- High blood sugar
- Fluid retention

- Enlargement of benign tumors of the uterus (“fibroids”)
- Vaginal yeast infection

These are not all the possible side effects of Menostar. For more information, ask your healthcare provider or pharmacist.

### What can I do to lower my chances of a serious side effect with Menostar?

- Talk with your healthcare provider regularly about whether you should continue using Menostar. If you have a uterus, talk to your healthcare provider about whether the addition of a progestin is right for you. In general, the addition of a progestin is recommended for women with a uterus to reduce the chance of getting cancer of the uterus.
- See your healthcare provider right away if you get vaginal bleeding while using Menostar.
- Have a 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, 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.

### General information about safe and effective use of Menostar.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use Menostar for conditions for which it was not prescribed. Do not give Menostar to other people, even if they have the same symptoms you have. It may harm them.

### Keep Menostar out of the reach of children.

This leaflet provides a summary of the most important information about Menostar. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about Menostar that is written for health professionals. You can get more information by calling the toll free number (1-888-237-5394) or visit [www.menostar-us.com](http://www.menostar-us.com).

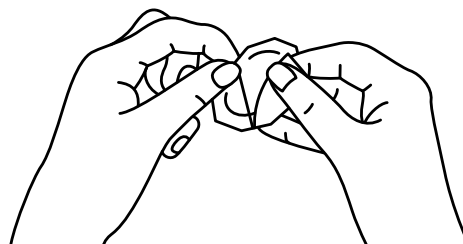
### What are the ingredients in Menostar?

The active ingredient of Menostar is estradiol. Menostar also contains acrylate copolymer adhesive, fatty acid esters, and polyethylene backing. Menostar does not contain latex.

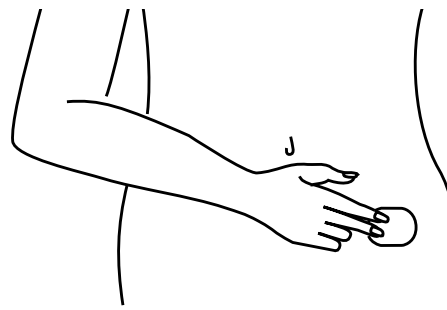
### Instructions for Use

#### How and where do I apply the Menostar patch?

- Talk to your healthcare provider or pharmacist if you have questions about applying the Menostar patch.
- 1 Menostar patch is applied and worn for 7 days (1 week). The Menostar patch is changed once a week.
- Each Menostar patch is individually sealed in a protective pouch. To open the pouch, hold it upright with the Menostar name facing you. Tear off the top of the pouch using the top tear notch. Tear off the side of the pouch using the side tear notch. Pull the pouch open. The Menostar patch is the see-through plastic film attached to the clear thicker plastic backing. There is a silver foil-sticker attached to the inside of the pouch. **Do not remove it from the pouch.** The sticker contains a moisture protectant. **Lift out the Menostar patch.** Notice that the patch is attached to a thicker, hard-plastic backing and that the patch itself is oval and see-through.



- Apply the sticky side of the Menostar patch to a clean, dry area of the lower stomach area below your belly button (see diagram below). **Do not apply the Menostar patch to your breasts.** The site selected should not be oily, damaged, or irritated. Avoid the waistline area, since tight clothing may rub and remove the patch. Also, do not put the patch on areas where sitting would rub it off or loosen it. Apply the patch right after opening the pouch and removing the protective liner. Press the patch firmly in place with your fingers for about 10 seconds. Make sure that it sticks all over, especially around the edges.



- The Menostar patch should be left in place for 7 days (one week). Change the Menostar patch every 7 days (once a week). Remove the used patch. Carefully fold it in half so that it sticks to itself and safely throwaway, away from children and pets. Place a new Menostar patch on a different clean, dry area of the lower stomach area below your belly button. The same skin site should not be used again for at least 1 week after removal of the patch.
- If the Menostar patch falls off, the same patch may be reapplied to another area of your lower stomach. Make sure that Menostar patch sticks well to your skin, especially around the edges. If the patch will not stick completely to your skin, remove it and safely throwaway. Apply a new patch on a different area of the lower stomach. Do not wear 2 Menostar patches at the same time.
- Bathing, swimming, or showering may affect and loosen the Menostar patch.

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