

Patient Information

MENOSTAR (Měn-ō-stär)

(estradiol transdermal system)

Read this Patient Information before you start using MENOSTAR 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 MENOSTAR (an estrogen hormone)?

- Using estrogen-alone may increase your chance of getting cancer of the uterus (womb).
- Report any unusual vaginal bleeding right away while you are using MENOSTAR. 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.
- 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 age 65 years of age and older.
- Do not use estrogens with progestogens to prevent heart disease, heart attacks, strokes or dementia.
- 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 age 65 years of age and older.
- Only one estrogen-alone product and dose have been shown to increase your chances of getting strokes, blood clots, and dementia. 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.

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

What is MENOSTAR?

MENOSTAR is a prescription medicine patch (transdermal system) that contains estradiol (an estrogen hormone).

What is MENOSTAR used for?

MENOSTAR is used after menopause to:

- **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 MENOSTAR only 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 Menostar.

Who should not use MENOSTAR?

Do not start using MENOSTAR 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 MENOSTAR.

- **had a stroke or heart attack**

- **currently have or have had blood clots**

- **currently have or have had liver problems**

- **are allergic to MENOSTAR or any of the ingredients in it.** See the list of ingredients in MENOSTAR at the end of this leaflet.

Before you use MENOSTAR, 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 MENOSTAR**

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), or 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 MENOSTAR.

- **are pregnant or think you may be pregnant**

MENOSTAR is not for pregnant women.

- **are breastfeeding**

The hormone in MENOSTAR 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 MENOSTAR works. MENOSTAR 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 MENOSTAR?

For detailed instructions, see the step-by-step instructions for using MENOSTAR at the end of this Patient Information.

- Use MENOSTAR exactly as your healthcare provider tells you to use it.
- MENOSTAR is for skin use only.
- Change your MENOSTAR patch 1 time each week or every 7 days.
- Apply your MENOSTAR patch to a clean, dry area on your lower abdomen or buttocks. This area must be clean, dry, and free of powder, oil or lotion for your patch to stick to your skin.
- Apply your MENOSTAR patch to a different area of your abdomen or your buttocks each time. Do not use the same application site 2 times in the same week.
- Do not apply MENOSTAR to your breasts.
- If you forget to apply a new MENOSTAR patch, apply a new patch as soon as possible.
- You and your healthcare provider should talk regularly (every 3 to 6 months) about the dose you are using and whether you still need treatment with MENOSTAR.

How to Change MENOSTAR.

- When changing MENOSTAR, peel off the used patch slowly from the skin.
- After removal of MENOSTAR if any adhesive residue remains on your skin, allow the area to dry for 15 minutes. Then, gently rub the area with an oil-based cream or lotion to remove the adhesive from your skin.
- Apply the new patch to a different area of your abdomen or buttocks. This area must be clean, dry, and free of powder, oil or lotion. Do not use the same site again for at least 1 week after removal of an old patch.

What are the possible side effects of MENOSTAR?

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 | • high levels of fat (triglyceride) in your blood |
| • stroke | • liver problems |
| • blood clots | • changes in your thyroid hormone levels |
| • breast cancer | • fluid retention |
| • cancer of the lining of the uterus (womb) | • cancer changes of endometriosis |
| • cancer of the ovary | • enlargement of benign tumors of the uterus ("fibroids") |
| • dementia | • worsening of swelling of face and tongue (angioedema) in women with a history of angioedema |
| • high or low blood calcium | |
| • gallbladder disease | |
| • visual abnormalities | |
| • high blood pressure | |

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 include:

- headache
- breast tenderness or pain
- irregular vaginal bleeding or spotting
- stomach or abdominal cramps, bloating
- nausea and vomiting
- hair loss
- fluid retention
- vaginal yeast infection
- redness and/or irritation at the patch placement site

These are not all the possible side effects of MENOSTAR. 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 FDA at 1-800-FDA-1088. You may report side effects to Bayer Healthcare Pharmaceuticals at 1-888-842-2937.

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 with your healthcare provider about whether MENOSTAR 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 MENOSTAR.
- 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, 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 of getting heart disease. Ask your healthcare provider for ways to lower your chances of getting heart disease.

How should I store and throw away used MENOSTAR?

- Store MENOSTAR at room temperature 68°F to 77°F (20°C to 25°C).
- Do not store MENOSTAR patches outside of their pouches. Apply immediately upon removal from the protective pouch.
- Used patches still contain estrogen. To throw away the patch, fold the sticky side of the patch together, place it in a sturdy child-proof container, and place this container in the trash. Used patches should not be flushed in the toilet.

Keep MENOSTAR and all medicines out of the reach of children.

General information about the 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.

You can ask your healthcare provider or pharmacist for information about MENOSTAR that is written for health professionals. For more information, go to www.menostar-us.com or call Bayer Healthcare Pharmaceuticals Inc. at 1-888-842-2937.

What are the ingredients in MENOSTAR?

Active ingredient: estradiol

Inactive ingredients: acrylate copolymer adhesive, fatty acid esters, and polyethylene backing.

Instructions for Use
MENOSTAR (Měn-ō-stär)
(estradiol transdermal system)

Read this Patient Information before you start using MENOSTAR 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.

You will need the following supplies: See Figure A



Figure A

Step 1: Pick the days you will change your MENOSTAR.

- You will need to change your patch 1 time each week or every 7 days.

Step 2. Remove the MENOSTAR patch from the pouch.

- Remove the patch from its protective pouch by tearing at the notch (do not use scissors). **See Figure B**
- **Do not** remove your patch from the protective pouch until you are ready to apply it.

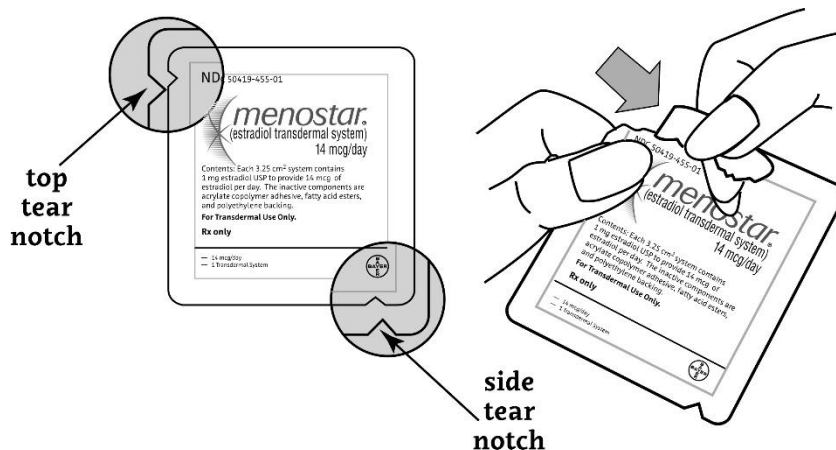


Figure B

Step 3. Remove the adhesive liner. See Figure C

- You will see that MENOSTAR is an oval shaped clear patch that is attached to a thick, hard-plastic adhesive liner and covered by a clear, plastic film. **See Figure C**
- To apply your patch you must first remove the protective, clear plastic film that is attached to the clear thicker plastic backing. **See Figure D**

- There is a silver foil-sticker attached to the inside of the pouch. **Do not** remove the silver foil sticker from the pouch. **See Figure E**

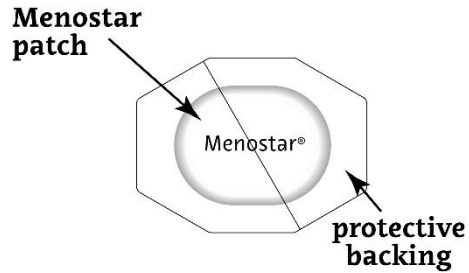


Figure C

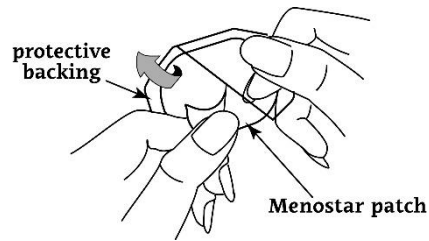


Figure D

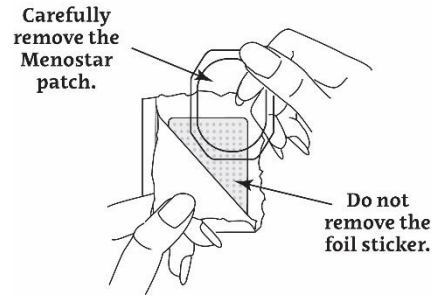


Figure E

Step 4. Placing the patch on your skin.

- Apply the sticky side of the patch to 1 of the areas of skin shown below. **See Figure F and Figure G**
- Do not** touch the sticky side of the patch with your fingers.

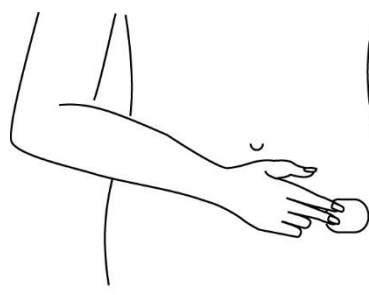


Figure F

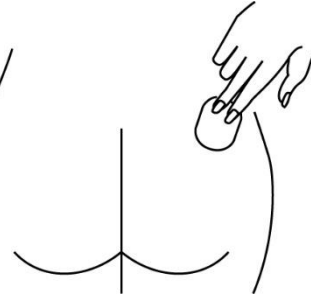


Figure G

Note:

- Avoid the waistline, since clothing and belts may cause the patch to be rubbed off.
- Do not** apply MENOSTAR to your breasts.
- Only apply MENOSTAR to skin that is clean, dry, and free of any powder, oil, or lotion.
- Do not apply the patch to injured, burned, or irritated skin, or areas with skin conditions (such as birth marks, tattoos, or that is very hairy).

Step 5. Press the patch firmly onto your skin.

- Press the patch firmly in place with your fingers for at least 10 seconds.
- Rub the edges of the patch to make sure that it will stick to your skin. (**See Figure H**)

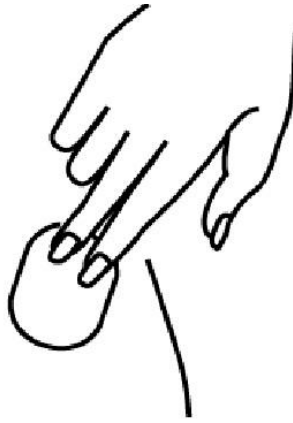


Figure H

Note:

- Contact with water while you are swimming, using a sauna, bathing, or showering may cause the patch to fall off.
- If your patch falls off reapply it. If you cannot reapply the patch, apply a new patch to another area (See Figure F and Figure G) and continue to follow your original application schedule.
- If you stop using your MENOSTAR patch or forget to apply a new patch as scheduled, you may have spotting, or bleeding, or your symptoms may come back.

Step 6: Throwing away your used patch.

- When it is time to change your patch, remove the old patch before you apply a new patch.
- To throw away the patch, fold the sticky side of the patch together, place it in a sturdy child-proof container, and place this container in the trash. Used patches should not be flushed in the toilet.

This Patient Information and Instructions for Use have been approved by the U.S Food and Drug Administration.

Revised: 9/2021

© 2013, Bayer HealthCare Pharmaceuticals Inc. All rights reserved.

Northridge, CA 91324

Manufactured for Bayer HealthCare Pharmaceuticals Inc.

Whippany, NJ 07981