

ESTRADIOL TRANSDERMAL PATCHES (MYLAN)

Estradiol Transdermal Patches 0.025 mg/day, 0.05 mg/day, 0.075 mg/day, 0.1 mg/day

What is in this leaflet

Please read this leaflet carefully before you start using Estradiol Transdermal Patches.

This leaflet answers some common questions about Estradiol Transdermal Patches .

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Estradiol Transdermal Patches against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Estradiol Transdermal Patches is used for

Estradiol Transdermal Patches are a type of treatment called hormone replacement therapy (HRT). It is a stick-on patch that contains a hormone called Estradiol.

Estradiol Transdermal Patches is used for the short-term relief of symptoms of the menopause.

HRT is not used for the long-term maintenance of general health or to prevent heart disease or dementia.

Estradiol Transdermal Patches is not suitable for birth control and it will not restore fertility

Estradiol (also known as oestradiol) is a natural female sex hormone called an oestrogen. It is the same hormone that your ovaries were producing before the menopause.

The menopause occurs naturally in the course of a woman's life, usually between the ages of 45 and 55. It may happen sooner if the ovaries are removed by surgery (e.g. total hysterectomy).

After menopause, your body produces much less oestrogen than it did before. This can cause unpleasant symptoms such as a feeling of warmth in the face, neck and chest, "hot flushes" (sudden, intense feelings of heat and sweating throughout the body), sleep problems, irritability and depression. Some women also have problems with dryness of the vagina causing discomfort during or after sex. Oestrogens can be given to reduce or eliminate these symptoms.

Estradiol Transdermal Patches releases estradiol in a continuous and controlled way just as your ovaries were doing before. Because the medicine does not have to pass through your stomach and liver, it allows you to take a much lower dose of oestrogen than would be needed in a tablet and helps to avoid some unpleasant side effects.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use Estradiol Transdermal Patches

When you must not use it

Do not use Estradiol Transdermal Patches or other oestrogens, with or without a progestogen to prevent heart attacks, stroke or dementia.

A study called the Women's Health Initiative indicated increased risk of heart attack, stroke, breast cancer, and blood clots in the legs or lungs in women receiving treatment with a product containing conjugated oestrogens 0.625 mg and the progestogen medroxyprogesterone acetate (MPA).

The researchers stopped the study after 5 years when it was determined the risks were greater than the benefits in this group. The Women's Health Initiative Memory Study indicated increased risk of dementia in women aged 65-79 years taking conjugated oestrogens and MPA.

There are no comparable data currently available for other doses of conjugated oestrogens and MPA or other combinations of oestrogens and progestogens. Therefore, you should assume the risks will be similar for other medicines containing oestrogen and progestogen combinations.

Do not use Estradiol Transdermal Patches if you have an allergy to:

- any medicine containing Estradiol (also known as oestradiol)
- any of the ingredients listed at the end of this leaflet.

- Any other medicine containing oestrogen, including the birth control pill.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

If you had a severe skin reaction in the past, you could have a very serious reaction if you use any type of oestrogen (patch, tablet, cream, etc.) again.

Do not use Estradiol Transdermal Patches if you have:

- cancer of the breast or uterus (womb) or any other oestrogen dependent cancer, or you have had this condition in the past
- ever had blood clots in the veins or lungs. You may have had painful inflammation of the veins or blockage of a blood vessel in the legs, lungs, brain or heart
- a condition that increases the tendency for you to get blood clots
- abnormal vaginal bleeding that has not been investigated
- severe liver problems
- a condition called porphyria, this condition affects your liver.

Do not use this medicine if you are pregnant.

It may affect your developing baby if you use it during pregnancy.

Do not breast-feed if you are taking this medicine.

It may affect your baby.

If you still have a uterus (womb), do not use Estradiol Transdermal Patches unless you are also taking another drug called a progestogen.

Women who still have a uterus must take both oestrogen and progestogen as part of HRT. This is

because oestrogen stimulates the growth of the lining of the uterus (called the endometrium). Before menopause this lining is removed during your period through the action of a natural progestogen. After menopause, taking oestrogen on its own as HRT may lead to irregular bleeding and to a disorder called endometrial hyperplasia. Your doctor will prescribe a progestogen to protect the lining of the uterus from the effects of oestrogen.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- a family history of breast cancer
- nodules, lumps or cysts in your breasts or any other benign breast condition (not cancer)
- endometriosis (a disorder of the uterus that may cause painful periods and abnormal bleeding)
- fibroids or other benign tumours of the uterus (not cancer)
- had one or more pregnancies where you lost the baby before birth
- high blood pressure
- heart disease
- kidney or liver problems
- diabetes
- epilepsy
- migraine or other severe headaches
- gall bladder disease
- asthma

- hearing loss due to a problem with the bones in the ear called otosclerosis
- a high level of triglycerides in the blood
- a disorder called systemic lupus erythematosus (SLE)
- a bone disease causing high calcium levels in the blood
- very low calcium levels in the blood
- had a problem in the past with jaundice (a liver problem) or itching skin when you took an oestrogen (e.g. the birth control pill or HRT) or during pregnancy
- a skin condition that could be made worse by applying the patch
- hypothyroidism (a condition in which your thyroid gland fails to produce enough thyroid hormone and for which you are treated with thyroid hormone replacement therapy). Your doctor will then have to monitor your thyroid hormone levels regularly
- severe allergic reactions
- hereditary angioedema or episodes of rapid swelling of the hands, feet, face, lips, eyes, tongue, throat (airway blockage) or digestive tract

If you have not told your doctor about any of the above, tell them before you start Estradiol Transdermal Patches.

Tell your doctor if you are likely to have an increased risk of developing blood clots in your blood vessels. The risk increases as you get older and it may also be increased if:

- anyone in your immediate family has ever had blood

- clots in the blood vessels of the legs or lungs
- you are overweight
- you have varicose veins
- you have a disorder called systemic lupus erythematosus (SLE)

Taking other medicines

Tell your doctor if you are taking birth control pills. Estradiol Transdermal Patches is not a contraceptive. Since pregnancy may be possible early in the menopause while you are still having menstrual periods, you should ask your doctor to suggest another (nonhormonal) method of birth control.

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

You should also tell any health professional who is prescribing a new medication for you that you are using Estradiol Transdermal Patches.

Some medicines may interfere with Estradiol Transdermal Patches. These include:

- herbal medicines containing St. John's Wort
- some medicines to help you sleep, including barbiturates and meprobamate
- some medicines for epilepsy, including phenytoin, phenobarbitone and carbamazepine
- phenylbutazone, a medicine for pain and inflammation
- some antibiotics and other anti-infective medicines, including rifampicin, ketoconazole, erythromycin, rifabutin, nevirapine, efavirenz, ritonavir and nelfinavir

These medicines may be affected by Estradiol Transdermal Patches or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

If you have not told your doctor about any of the above, tell them before you start Estradiol Transdermal Patches.

How to use Estradiol Transdermal Patches

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

When to start it

If you are not already using HRT, you can start Estradiol Transdermal Patches at a convenient time for you. If you are already using a different type of HRT, your doctor can advise you when to switch to Estradiol Transdermal Patches.

How much to use

Estradiol Transdermal Patches patches come in four strengths. You will usually start with the Estradiol 0.025 mg/day Transdermal Patches patch. Your doctor will check your progress and may change you to a different strength, depending on your response to treatment.

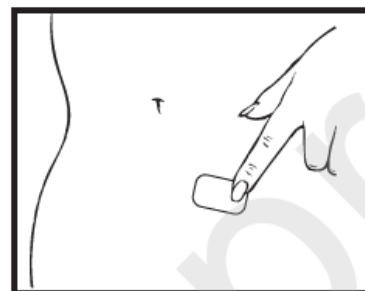
How to use it

- Determine your schedule for your twice a week application**
 - Decide upon which 2 days you will change your patch.
 - Your estradiol transdermal patch individual carton contains a calendar card printed on its inner flap. Mark the 2-day schedule you plan to follow on your carton's inner flap.
 - Be consistent.

- If you forget to change your patch on the correct date, apply a new one as soon as you remember.
- No matter what day this happens, stick to the schedule you have marked on the inner flap of your carton (your calendar card).

2. Where to apply Estradiol Transdermal Patches

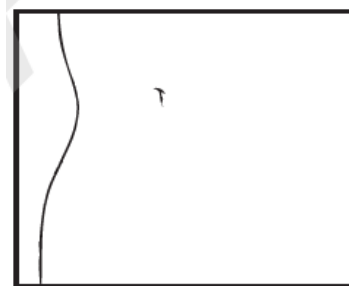
- Apply patch to a dry area of the skin of the trunk of the body, including the lower abdomen, or buttocks. Avoid the waistline, since clothing may cause the patch to rub off.
- Do not apply patch to breasts.
- When changing your patch, based on your twice a week schedule, apply your patch to a different site. Do not apply a new patch to that same area for at least 1 week.



3. Before your Apply Estradiol Transdermal Patches

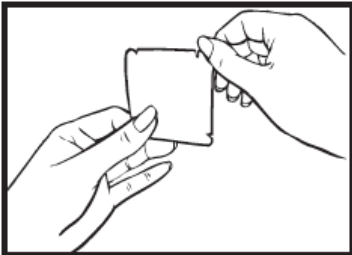
Make sure your skin is:

- Clean (Freshly washed), dry and cool.
- Free of any powder, oil, moisturizer or lotion.
- Free of cuts or irritations (rashes or other skin problems).

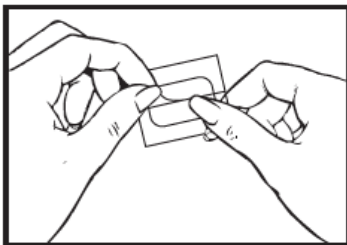


4. How to apply Estradiol Transdermal Patches

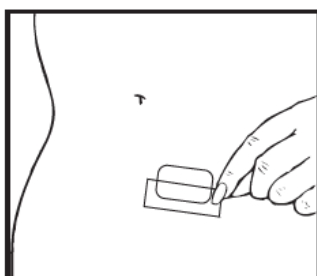
- Each patch is individually sealed in a protective pouch.
- Tear open the pouch at the tear notch (do not use scissors).
- Remove the patch.



- **Apply the patch immediately after removing the pouch.**
- Holding the patch with the rigid oversized protective liner facing you, remove **half** of the protective liner, which covers the sticky surface of the patch.

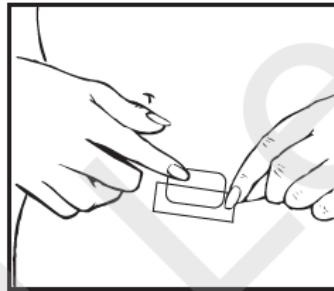


- **Avoid touching the sticky side of the patch with your fingers.**
- Using the other half of the rigid protective liner as a handle, apply the sticky side of the patch to the selected area of the abdomen or buttocks.

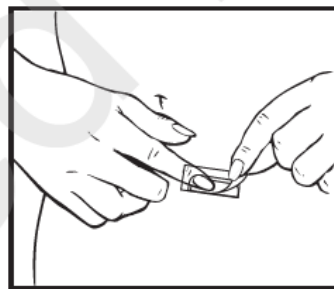


- Press the sticky side of the patch firmly into place.

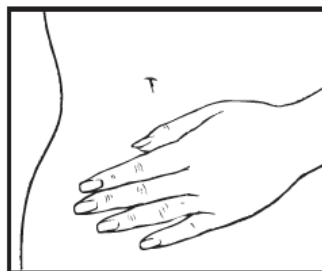
- Smooth it down.
- While still holding the sticky side down, fold back the other half of the patch.



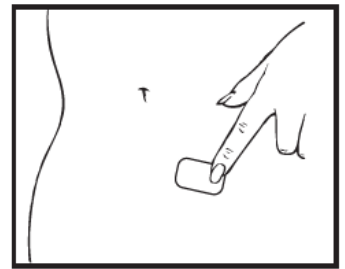
- Grasp an edge of the remaining protective liner and gently pull it off.
- **Avoid touching the sticky side of the patch with your fingers.**



- Press the entire patch firmly into place with the palm of the hand.
- Continue to apply pressure, with the palm of the hand over the patch, for approximately 10 seconds.



- Make sure that the patch is properly adhered to your skin.
- Go over the edges with your finger to ensure good contact around the patch.



Note:

- Showering will not cause your patch to fall off
- If your patch falls off reapply it. If you cannot reapply the patch, apply a new patch to another area and continue to follow your original placement schedule.
- If you stop using your estradiol transdermal patch or forget to apply a new patch as scheduled, you may have spotting, or bleeding, and recurrence of symptoms.

5. 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 with a sturdy child-proof container, and place the container in the trash. Used patches should not be flushed in the toilet.

You will have a patch on all the time. You will apply a new patch twice weekly (every 3 or 4 days). There are 8 patches in the carton, enough for a 4- week cycle.

If you have not had a hysterectomy (operation to remove the uterus), you must take another type of hormone called a progestogen as well as using the patches. A progestogen helps to protect the lining of the uterus. If you have not been asked to take a progestogen, talk to your doctor.

How long to use it

Continue using your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep using your medicine even if you feel well.

If you want to continue using HRT for longer than a few months, discuss the possible risks and benefits with your doctor.

You may have an increased risk of developing breast cancer, heart disease, stroke, blood clots on the lungs and dementia. On the other hand, the risk of hip fractures and bowel cancer may be reduced. If you have had a hysterectomy but still have your ovaries, there may also be a small increase in the risk of developing cancer of the ovaries. Women taking oestrogens (also known as estrogens) alone, or in combination with progestogens, may have a higher risk of ovarian cancer that may appear within 5 years of use and slowly diminishes over time after discontinuation. Your doctor can discuss these risks and benefits with you, taking into account your particular circumstances.

If you forget to use it

Apply a new patch as soon as you remember, and then go back to your usual schedule.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

While you are using Estradiol Transdermal Patches

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Estradiol Transdermal Patches.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine. It may affect other medicines used during surgery.

The risk of developing blood clots in your blood vessels may be temporarily increased as a result of an operation, serious injury or having to stay in bed for a prolonged period. If possible, this medicine should be stopped at least 4 weeks before surgery and it should not be restarted until you are fully mobile

If you become pregnant while using this medicine, tell your doctor immediately. It should not be used while you are pregnant.

See your doctor at least once a year for a check-up. Some women will need to go more often. Your doctor will:

- check your breasts and order a mammogram at regular intervals
- check your uterus and cervix and do a pap smear at regular intervals
- check your blood pressure and cholesterol level.

Check your breasts each month and report any changes promptly to your doctor. Your doctor or nurse can show you how to check your breasts properly.

If you are about to have any blood tests, tell your doctor that you are using this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use Estradiol Transdermal Patches to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Estradiol Transdermal Patches affects you.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you use too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have used too much Estradiol Transdermal Patches. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Because of the way this medicine is used, an intentional overdose is unlikely. Swallowing a patch may cause nausea and vomiting.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Estradiol Transdermal Patches. This medicine helps most people but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- irregular vagina bleeding or spotting (if bleeding is heavy, check with your doctor as soon as possible). Some people may have some irregular bleeding or spotting during the first few months of treatment. The bleeding usually becomes lighter and less frequent over time, and eventually stops. If you have heavy bleeding or continue to have bleeding or spotting after a few months of treatment, tell your doctor so that the treatment can be re-evaluated if necessary.
- tender, painful or swollen breasts
- period-like pain
- redness, irritation or itching under the patch (signs of application site reaction includes bleeding, bruising, burning, discomfort, dryness, skin boils, oedema, erythema, inflammation, irritation, pain, tiny solid skin bumps, rash, skin discolouration, skin pigmentation, swelling, hives, and blisters)
- itching or inflammation of the vagina or discharge of vaginal fluid
- swelling of the lower legs, ankles, fingers or abdomen due to fluid retention
- nausea (feeling sick), vomiting, abdominal cramps, bloating
- headache, migraine
- dizziness
- depression
- eye irritation when wearing contact lenses
- uncontrollable jerky movements
- changes in weight
- spotty darkening of the skin, especially on the face
- changes in hair growth (either hair loss or excessive hairiness)

- increase or decrease in sex drive

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- signs of allergy such as itching, hives, breathlessness or difficult breathing, wheezing or coughing, light-headedness, dizziness, changes in levels of consciousness, skin reddening, swelling of the face, lips, tongue, around the eyes or other part of the body; shortness of breath, wheezing or troubled breathing
- signs or symptoms of blood clots, such as sudden severe headache, sudden loss of coordination, blurred vision or sudden loss of vision, slurred speech, numbness or tingling in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing blood
- pain or tenderness in the abdomen, which may be accompanied by fever, loss of appetite, nausea and vomiting
- a yellow colour to the skin or eyes, itching, dark coloured urine or light coloured bowel motions
- signs of a skin reaction, such as redness, swelling, painful sores or lumps, areas of skin that bleed or weep fluid
- signs or symptoms of a heart attack, chest pain, dizziness, nausea, shortness of breath, irregular pulse.
- signs or symptoms of a stroke: collapse, numbness or weakness of the arms and the legs, headache, dizziness and confusion, visual disturbance, difficulty swallowing, slurred speech and loss of speech

The above list includes very serious side effects. You may need urgent

medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

Some side effects (e.g. increase in blood sugar level) can only be found when laboratory tests are done.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Estradiol Transdermal Patches

Storage

Keep your medicine in the original container until it is time to use them.

Keep your patches in a cool dry place where the temperature stays between 20°C & 25°C.

Do not store Estradiol Transdermal Patches or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Fold the sticky side of the patch together, place it with a sturdy child-proof container, and place the container in the trash. Used patches should not be flushed in the toilet. Used patches still contain some estradiol which could harm a child

If your doctor tells you to stop using this medicine or the expiry

date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

0.025 mg/day – Each rectangular patch with rounded corners consists of an opaque, white to cream adhesive layer, matte film backing randomly printed with 'Estradiol 0.025 mg/day' in brown ink, and a clear release liner. The patch is contained in a square, flat, notched, pouch.

0.05 mg/day – Each rectangular patch with rounded corners consists of an opaque, white to cream adhesive layer, matte film backing randomly printed with 'Estradiol 0.05 mg/day' in brown ink, and a clear release liner. The patch is contained in a square, flat, notched, pouch.

0.075 mg/day – Each rectangular patch with rounded corners consists of an opaque, white to cream adhesive layer, matte film backing randomly printed with 'Estradiol 0.075 mg/day' in brown ink, and a clear release liner. The patch is contained in a square, flat, notched, pouch.

0.1 mg/day – Each rectangular patch with rounded corners consists of an opaque, white to cream adhesive layer, matte film backing randomly printed with 'Estradiol 0.1 mg/day' in brown ink, and a clear release liner. The patch is contained in a square, flat, notched, pouch.

Ingredients

Active ingredient(s):

Estradiol Transdermal Patches release approximately 0.025, 0.05, 0.075 or 0.1 mg of Estradiol per day as the active ingredient.

Inactive ingredient(s):

Estradiol Transdermal Patches also contain:

Backing layer:

- A translucent polyolefin film printed with brown ink

Adhesive containing Estradiol:

- Silicon adhesive
- Acrylic adhesive
- Dipropylene glycol
- Povidone
- Oleyl alcohol

Release liner:

- A transparent fluoropolymer (or fluorosilicone) coated polyester

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Estradiol Transdermal Patches are supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Eilerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

15 June 2023.
(Based on datasheet dated 15 June 2023)