

Estraderm MX

Estradiol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about the menopause ("change of life"), hormone replacement therapy and Estraderm MX.

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

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will provide.

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

Keep this leaflet with the medicine.

You may need to read it again.

When you must not use Estraderm MX

Do not use Estraderm MX 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.

Talk regularly with your doctor about whether you still need treatment with Estraderm MX.

Treatment with oestrogens, with or without progestogens should be used at the lowest effective dose and for the shortest period of time.

What Estraderm MX is used for

Estraderm MX is a type of treatment called hormone replacement therapy (HRT). It is a stick-on patch that contains a hormone called estradiol.

Estraderm MX is used for the short-term relief of symptoms of the menopause. It can also be used to prevent thinning of the bones in women with a high risk of fractures due to osteoporosis who cannot use other treatments.

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

Estraderm MX is not suitable for birth control and it will not restore fertility.

How it works

Estradiol 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.

After the age of 40, and especially after the menopause, some women develop osteoporosis. This is a thinning of the bones that makes

them weaker and more likely to break, especially the bones of the spine, hip and wrist. Exercise, calcium and vitamin D can help reduce the risk of osteoporosis.

Estraderm MX 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.

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

Your doctor may have prescribed it for another purpose.

This medicine is available only with a doctor's prescription. It is not habit-forming.

Before you use Estraderm MX

When you must not use it

Do not use Estraderm MX if you have an allergy to:

- estradiol, the active ingredient, or to any of the other 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 in the future.

Do not use Estraderm MX 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
- blood clots in your blood vessels, now or in the past, or a condition or history of a condition that increases your tendency to get blood clots (such as thromboembolic disease, thrombophilia or thrombophlebitis). You may have had painful inflammation of the veins or blockage of a blood vessel in the legs (for example deep vein thrombosis), lungs, brain or heart
- endometriosis, which is a disorder where tissue grows outside of the uterus that may cause painful periods and abnormal bleeding
- untreated endometrial hyperplasia, which is where the lining of the uterus becomes thick, often causing heavy periods and vaginal bleeding
- abnormal vaginal bleeding that has not been investigated
- severe liver problems
- a condition called porphyria, which is a disease that results from a build up of chemicals related to red blood cell proteins

If you are not sure whether any of the above conditions apply to you, your doctor can advise you.

Do not use Estraderm MX if you are pregnant or breast-feeding.

It may affect your baby. If you become pregnant while taking Estraderm MC, you should stop treatment immediately.

If you still have a uterus (womb), do not use Estraderm MX unless you are also taking another medicine 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.

In that case, return it to your pharmacist.

Before you start to use it

Tell your doctor if you have:

- a family history of breast cancer
- a family history of ovarian or endometrial cancer
- a family history of, or have ever suffered from a stroke
- nodules, lumps or cysts in your breasts or any other benign breast condition (not cancer)
- 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
- a disease affecting the eardrum and hearing (otosclerosis)
- ever suffered from dementia, or have a family history of dementia
- gall bladder disease
- asthma
- a high level of triglycerides in the blood
- a disorder where the immune system can attack its own tissues called systemic lupus erythematosus (SLE)
- low levels of thyroid hormone

- 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)
- a skin condition that could be made worse by applying the patch
- severe allergic reactions
- hereditary angioedema or if you have had episodes of rapid swelling of the hands, feet, face, lips, eyes, tongue, throat (airway blockage) or digestive tract

Your doctor may want to take special precautions if you have any of the above conditions.

Your doctor will take a complete personal and family medical history and appropriate physical examinations before you start using Estraderm MX.

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.

Estraderm MX 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 (non-hormonal) 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 a pharmacy, supermarket or health food shop.

Some medicines and Estraderm MX may interfere with each other.

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, lamotrigine, phenobarbitol and carbamazepine
- phenylbutazone, a medicine for pain and inflammation
- some antibiotics, including rifampicin, erythromycin and rifabutin
- medicines for HIV infection, such as nevirapine, efavirenz, ritonavir and nelfinavir
- medicines for Hepatitis C virus, such as combination regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir as well as a regimen with glecaprevir/pibrentasvir
- ketoconazole (an antifungal medicine).

You may need to take different amounts of your medicines or to take different medicines while you are using Estraderm MX. Your doctor and pharmacist have more information.

If you have not told your doctor about any of these things, tell him/her before you start using this medicine.

How to use Estraderm MX

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

These instructions 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 Estraderm MX 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 Estraderm MX.

How much to use

The patches come in three strengths. To reduce symptoms of the menopause, you will usually start with the Estraderm MX 50 patch. Your doctor will check your progress and may change you to a lower or higher strength, depending on your response to treatment. To prevent thinning of the bones, Estraderm MX 50 or 100 may be suitable.

How to use it

A leaflet in the carton contains pictures and information on how to apply the patch properly.

You will usually 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.

Estraderm MX can also be used in cycles of 3 weeks of patches and then 1 week with no treatment. Your doctor will advise you on the method that is best for you.

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

If you want to continue using HRT for longer than a few months, discuss the possible risks and benefits with your doctor. Depending on your medical history, your doctor will ensure you use the lowest dose for the shortest period of time.

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 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 will perform periodic check ups and 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 when to use or replace your patches, ask your pharmacist for some hints.

If you use too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think that an overdose has happened. Keep the telephone numbers for these places handy.

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

While you are using Estraderm MX

Things you must do

If you become pregnant while using Estraderm MX, 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 pelvis
- 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.

Tell your doctor that you are using Estraderm MX well in advance of any expected hospitalisation or surgery. If you go to hospital unexpectedly, tell the doctor who admits you that you are using it.

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 are about to be started on any new medicine, remind your doctor and pharmacist that you are using Estraderm MX.

Tell any other doctor, dentist or pharmacist who treats you that you are using Estraderm MX.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give it to anyone else, even if their symptoms seem similar to yours.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Estraderm MX.

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.

Do not be alarmed by these lists of possible side effects. You may not experience any of them. Ask your doctor or pharmacist to answer any questions you may have.

Stop using Estraderm and tell your doctor straight away if you experience:

- difficulty breathing or swallowing, tightness of the chest, shortness of breath or difficulty breathing, hives, general rash, swelling, itching, skin redness, dizziness, changes in level of consciousness, light-headedness, hypotension with or without mild generalised itching, vomiting, abdominal pain (possible signs of a severe allergic reaction)
- swelling of the face, lips, tongue, throat, the area around the eyes and/or extremities (possible signs of angioedema)

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- signs of allergy such as rash, itching or hives on the skin; swelling of the face, lips, tongue or other part of the body; shortness of breath, wheezing or troubled breathing
- signs that blood clots may have formed, 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 angioedema: swelling of the face, lips, tongue, throat, and/or extremities.

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

- irregular vaginal bleeding or spotting (if bleeding is heavy, check with your doctor as soon as possible)
- 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
- pain during sex or when urinating (passing water)
- palpitations (feeling of fast or irregular heartbeat)

- swelling of the lower legs, ankles, fingers or abdomen due to fluid retention
- nausea (feeling sick), abdominal cramps, bloating
- headache, migraine
- rise in blood pressure
- dizziness
- tiredness, nervousness, irritability, depression, reduced sex drive
- muscle or nerve pain, leg pain
- worsening of varicose veins
- ringing in the ears
- changes in weight
- reversible skin discolouration

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

Some people may have other side effects not yet known or mentioned in this leaflet. Some side effects can only be found when laboratory tests are done. Depending on the severity of the side effects, your doctor may decide for you to stop using Estraderm MX.

After using Estraderm MX

Storage

- Keep your medicine in the original container until it is time to use it.
- Store it in a cool dry place.
- Do not store Estraderm MX or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on windowsills.

Keep the patches where young children cannot reach them.

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

Disposal

Fold used patches in half with the sticky side inwards. Dispose of

them where children cannot reach them.

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 patches that are left over.

Product description

What it looks like

Estraderm MX patches come in four strengths: 25, 50, 75 and 100. They are thin, flat, square patches with rounded corners, sealed in individual pouches. Each carton contains 8 patches (enough for 4 weeks of treatment).

- Estraderm MX 25 patches are marked CG GRG
- Estraderm MX 50 patches are marked CG GSG
- Estraderm MX 75 patches are marked CG HKH
- Estraderm MX 100 patches are marked CG GTG

Estraderm MX patches are made up of three layers:

- a waterproof transparent backing film
- a sticky layer containing the active ingredient, estradiol (as hemihydrate)
- a protective liner (to be removed before use)

Ingredients

Estraderm MX patches release approximately 25, 50, 75 or 100 micrograms estradiol in 24 hours.

The following inactive ingredients are also used to make the patch:

- isopropyl palmitate
- acrylate
- methacrylate
- polyethylene terephthalate
- ethylene/vinylacetate copolymer

- silicone coating on the release liner

Sponsor

Estraderm MX is supplied in Australia by:

Juno Pharmaceuticals Pty Ltd
42 Kelso Street,
Cremorne,
VIC 3121.
www.junopharm.com.au

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