

# Estraderm®

estradiol

25, 50 and 100mcg/24hrs Transdermal Patches

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## Consumer Medicine Information

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### What is in this leaflet

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

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.medsafe.govt.nz](http://www.medsafe.govt.nz)**

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 Estraderm against the benefits they expect it will provide.

**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.

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### What Estraderm is used for

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

Estraderm helps to relieve the discomfort so many women feel during and after the menopause. It also helps

to prevent thinning of the bones which causes fractures.

### How it works

Estradiol is a natural female sex hormone called an estrogen. 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 estrogen 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 urine control or with dryness of the vagina causing discomfort during or after sex. Estrogens 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. The risk of osteoporosis is increased by lack of estrogen. Estrogens can be given to reduce this risk.

Estraderm 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 estrogen 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 Estraderm 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.

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

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## Before you use Estraderm

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### When you must not use it

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

- estradiol, the active ingredient in Estraderm, or to any of the other ingredients listed at the end of this leaflet
- any other medicine containing estrogen, 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 estrogen (patch, tablet, cream, etc.) again in the future.

**Do not use Estraderm if you have:**

- cancer of the breast or uterus (womb) or any other estrogen dependent cancer, or you have had this condition in the past
- blood clots in your blood vessels, now or in the past. 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

- endometriosis (a disorder of the uterus that may cause painful periods and abnormal bleeding)
- abnormal vaginal bleeding that has not been investigated
- severe liver disease
- a condition called porphyria

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

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

It may affect your baby.

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

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

**Do not use Estraderm 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
- 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
- gall bladder disease

- asthma
- a high level of triglycerides in the blood
- had a problem in the past with jaundice (a liver problem) or itching skin when you took an estrogen (e.g. the birth control pill or HRT)
- a skin condition that could be made worse by applying the patch

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

**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 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 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 and carbamazepine
- phenylbutazone, a medicine for pain and inflammation
- some antibiotics and other anti-infective medicines, including

rifampicin, rifabutin, nevirapine, efavirenz, ritonavir and nelfinavir

You may need to take different amounts of your medicines or to take different medicines while you are using Estraderm. 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.**

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## How to use Estraderm

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**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 any type of HRT, you can start Estraderm at a convenient time for you. If you are already using a different type of HRT, your doctor can advise you when to start Estraderm.

**How much to use**

For all therapeutic indications, the lowest effective dose should be used and consideration should be given to the shortest duration of use.

Estraderm patches come in three strengths. To reduce symptoms of the menopause, you will usually start with the lowest strength. 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 50 or 100 are 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. A new patch is applied twice weekly (every 3 or 4 days). There are 8 patches in the carton, enough for a 4-week cycle.

Estraderm 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. The Medicines Adverse reactions Committee advises that combined HRT should not be used for longer than 3 – 4 years.

### ***How long to use it***

Although some women have no symptoms of the menopause or only mild ones, and may not need extra hormones, other women may need to use HRT for as long as 2 or 3 years to control their symptoms.

**If you want to continue using HRT for several years, you should discuss the possible risks and benefits with your doctor.**

Women who use HRT for long periods (i.e. 5 years or more) may have a small increased risk of developing breast cancer, heart disease, stroke and blood clots on the lungs. 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. 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 when to use or replace your patches, ask your pharmacist for some hints.**

### ***If you use too much (Overdose)***

**Immediately telephone your doctor or National Poisons Information Centre (telephone 0800 POISON, 0800 764766) or go to the Accident and Emergency Department at your nearest hospital, if you think that an overdose has happened. Keep the telephone numbers for these places handy.**

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

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### **While you are using Estraderm**

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#### ***Things you must do***

**If you become pregnant while using Estraderm, 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.

**Tell your doctor that you are using Estraderm 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.**

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

### ***Things you must not do***

**Do not use Estraderm to treat any other complaints unless your doctor tells you to.**

**Do not give this medicine to anyone else, even if their symptoms seem to be the same as yours.**

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### **Side effects**

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

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, hives, general rash, swelling, itching, dizziness, vomiting, abdominal pain (possible signs of a severe allergic reaction) or
- swelling of the face, lips, tongue, throat, 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 of angioedema: swelling of the face, lips, tongue, throat, and/or extremities.
- 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.

### **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
- 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
- muscle or nerve pain, leg pain
- worsening of varicose veins
- ringing in the ears
- changes in weight
- reversible skin discolouration
- blurred vision
- dementia

### **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.

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## **After using Estraderm**

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### **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 or any other medicine in the bathroom or near a sink.
- Do not leave it in the car or on window sills.

### **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.**

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## **Product description**

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### **What it looks like**

Estraderm patches come in three strengths: 25, 50 and 100. They are round or oblong transparent patches sealed in individual pouches. Each carton contains 8 patches (enough for 4 weeks of treatment).

- Estraderm 25 patches are marked CG DWD
- Estraderm 50 patches are marked CG EFE

- Estraderm 100 patches are marked CG FBF.

Estraderm patches are made up of five layers:

- a waterproof transparent backing film
- a drug reservoir containing the active ingredient, estradiol
- a membrane which controls the release of estradiol into the skin
- an adhesive (sticky) layer
- a protective liner (to be removed before use)

### **Ingredients**

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

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

- ethanol
- hydroxypropylcellulose
- polyethylene terephthalate
- ethylene/vinylacetate copolymer
- liquid paraffin
- polyisobutylene
- silicone coating on the release liner

### **Sponsor**

Estraderm is supplied in New Zealand by:  
NOVARTIS New Zealand Limited  
Novartis New Zealand Limited  
Private Bag 65904  
Mairangi Bay  
Auckland  
Building G, 5 Orbit Drive  
Rosedale  
Auckland 0632  
Telephone: 0800 652 422  
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