ESTROFEM®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Estrofem® ?

Estrofem® contains the active ingredient estradiol hemihydrate. Estrofem® is a hormone replacement therapy (HRT) used for the short-term treatment of low estrogen levels in women.

For more information, see Section 1. Why am I using Estrofem® ? in the full CMI.

2. What should I know before I use Estrofem® ?

Do not use Estrofem® if you have ever had an allergic reaction to estradiol or any of the ingredients listed at the end of the CMI.

Talk to your doctor about your medical history and your family's medical history, and if you take any other medicines, before starting Estrofem® . Do not use if pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Estrofem® ? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Estrofem® and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Estrofem®

- Estrofem® must be taken once a day, at about the same time each day.
- It is supplied in a 28-day calendar dial pack.

More instructions can be found in Section 4. How do I use Estrofem® ? in the full CMI.

5. What should I know while using Estrofem® ?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Estrofem® . • Keep all of your doctor's appointments so that you can be carefully monitored.
Things you should not do	• Do not stop using this medicine suddenly. • Do not change the way you take Estrofem® .
Driving or using machines	• There is no specific information on driving or using machines while you are taking Estrofem® .
Drinking alcohol	• There is no specific information of the effect of drinking alcohol while you are taking Estrofem® .
Looking after your medicine	• Keep Estrofem® in a cool, dark place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using Estrofem® ? in the full CMI.

6. Are there any side effects?

Serious side effects may include the potential for blood clots (in veins, lungs or brain), severe allergic reaction (anaphylaxis), sudden onset headache or migraine, changes to breasts suggestive of breast cancer, unexpected vaginal bleeding.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

ESTROFEM®

Active ingredient: *estradiol hemihydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Estrofem®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Estrofem®.**

Where to find information in this leaflet:

1. Why am I using Estrofem®?

Estrofem® contains the active ingredient estradiol hemihydrate.

Estrofem® is a hormone replacement therapy (HRT).

It is used for the short-term treatment of estrogen-deficiency (low levels of estrogen) in women who have had a hysterectomy (removal of the uterus) or who have signs and symptoms of low estrogen levels, such as hot flushes, night sweats, sleeplessness, dry vagina, urinary problems, headaches, mood swings, lack of concentration, loss of energy.

If you have not had a hysterectomy, your doctor may prescribe another medicine (called a 'progestogen') to be taken with Estrofem® for 10-14 days of your 28-day cycle. It is very important to take both medications exactly the way your doctor has prescribed.

If you have any questions about Estrofem®, either taken alone or in combination with another medicine, please talk to your doctor.

2. What should I know before I use Estrofem®?

Medical history and regular check-ups

The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

Before you start (or restart) HRT, your doctor must ask about your own and your family´s medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Note: Estrofem® is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years' old, you may still need to use additional contraception to prevent pregnancy.

Warnings

Do not use Estrofem® if:

- you are pregnant or suspect you may be pregnant, or you are breast-feeding
- you have, have had or suspect having breast cancer
- you have, have had or suspect having cancer of the uterus lining (endometrial cancer), or any other estrogen dependent cancer
- you have any unexplained vaginal bleeding
- you have excessive thickening of the uterus lining (endometrial hyperplasia) that is not being treated
- you have or have ever had a blood clot in a vein (venous thromboembolism), such as in the legs (e.g. deep vein thrombosis), or the lungs (pulmonary embolism)
- you have a blood clotting disorder (such as protein C, protein S or antithrombin deficiency)
- you have or previously have had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina
- you have or have ever had a liver disease, and your blood test results have not returned to normal
- you have a rare blood problem called 'porphyria' which is passed down in families (inherited)
- you have kidney disease
- you are allergic to estradiol or any of the ingredients listed at the end of this leaflet.

  Always check the ingredients to make sure you can use this medicine.

Estrofem® should not be used in children or by males.

Check with your doctor if you:

- have not had a hysterectomy, in case another medicine may be more suitable for you
- have previously taken estrogen by itself for menopausal symptoms and have not had a hysterectomy. The long-term use of estrogen without a progesterone can increase the risk of cancer of the lining of the womb
- have premature menopause
- have fibroids inside your uterus
- a growth of the uterus lining outside your uterus (endometriosis)
- have a history of excessive growth of the uterus lining (endometrial hyperplasia)
- have an increased risk of developing blood clots (see *Blood clots in a vein (venous thromboembolism)*)
- are to be hospitalised or undergoing surgery, particularly where you are or will be off your feet for a long time. You may need to stop taking Kliovance® for several weeks before your operation, to reduce the risk of a blood clot

- have an increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- have high blood pressure
- have a liver disorder, such as a benign liver tumour
- have diabetes
- have or have had gallstones
- have migraines or severe headaches
- have systemic lupus erythematosus (SLE)
- have epilepsy
- have asthma
- have otosclerosis (hearing loss caused by changes to the bones in your ear)
- have very high levels of fat in your blood (triglycerides)
- have fluid retention due to heart or kidney problems
- have a condition where your thyroid gland fails to produce enough thyroid hormone (hypothyroidism) and you are treated with thyroid hormone replacement therapy
- have a hereditary condition causing recurrent episodes of severe swelling (hereditary angioedema) or if you have had episodes of rapid swelling of the hands, face, feet, lips, eyes, tongue, throat (airway blockage) or digestive tract
- have a lactose intolerance
- have any other medical conditions
- take any medicines for any other condition.

Cancer risk

Endometrial hyperplasia and cancer

Taking estrogen-only HRT will increase the risk of excessive thickening of the lining of the uterus (endometrial hyperplasia) and cancer of the uterus lining (endometrial cancer).

Taking a progestogen in addition to the estrogen for at least 10 days of each 28-day cycle reduces this extra risk.

Your doctor will prescribe a progestogen separately if you still have your uterus.

If you have had your uterus removed (a hysterectomy), discuss with your doctor whether you can safely take this product without a progestogen.

For women aged 50 to 65 who still have a uterus and who take estrogen-only HRT, between 10 and 60 women in 1,000 will be diagnosed with endometrial cancer, depending on the dose and for how long it is taken.

Irregular bleeding

You will have a bleed once a month (so-called withdrawal bleed) while taking Estrofem®.

See your doctor as soon as possible if you have not had a hysterectomy and you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which:

- carries on for more than the first 6 months, or
- starts after you have been taking Estrofem® more than 6 months, or
- carries on after you have stopped taking Estrofem®.

Breast cancer

Evidence shows that taking combined estrogen-progestogen or estrogen-only hormone replacement therapy (HRT) increases the risk of breast cancer. The extra risk depends on how long you use HRT. The additional risk becomes clear within 3 years of use. After stopping HRT the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.

Risk with 5 years of use

For women aged 50 who start taking estrogen-progestogen HRT for 5 years, it is estimated that 21 cases of breast cancer in 1000 users are diagnosed, compared with 13 to 17 cases per 1000 in those who do not take HRT.

Risk with 10 years of use

For women aged 50 who start taking estrogen-progestogen HRT for 10 years, it is estimated at 48 cases of breast cancer in 1,000 users are diagnosed, compared with 27 cases per 1,000 in those who did not take HRT.

Ovarian cancer

Ovarian cancer is rare - much rarer than breast cancer. The use of estrogen-only or combined estrogen-progestogen HRT has been associated with a slightly increased risk of ovarian cancer.

Blood clots in a vein (venous thromboembolism)

The risk of blood clots in the veins is about 1.3- to 3-times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

Inform your doctor if any of these risks apply to you:

- you are unable to walk for a long time because of major surgery, injury or illness
- you have had one or more miscarriages
- you are overweight or obese (BMI >30 kg/m^2)
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ
- you have systemic lupus erythematosus (SLE)
- you have cancer.

Heart disease (heart attack)

There is no evidence that HRT will prevent a heart attack.

Women over the age of 60 years who use estrogen-progestogen HRT are slightly more likely to develop heart disease than those not taking any HRT.

Stroke

The risk of experiencing stroke is about 1.5-times higher in HRT users than in non-users. The number of extra cases of stroke due to use of HRT increases with age.

Other things that can increase the risk of stroke include:

- high blood pressure
- smoking
- drinking too much alcohol
- an irregular heartbeat.

Other conditions

HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65.

Tell your doctor or the laboratory staff that you are taking Estrofem® if you need a blood test. This is because this medicine can affect the results of some tests.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not use Estrofem® in you are pregnant or suspect you are pregnant.

Do not use Estrofem® if you are breastfeeding breastfeeding.

3. What if I am taking other medicines?

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

Some medicines may interfere with Estrofem® and how it works including:

- some medicines to help you sleep, including barbiturates
- some medicines for epilepsy e.g. phenytoin and carbamazepine
- some antibiotics and other anti-infective medicines e.g. rifampicin, rifabutin, nevirapine, efavirenz
- some anti-infectives such as ritonavir and nelfinavir, when used at the same time as steroid hormones
- St. John's Wort – used to treat depression or low mood

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Estrofem® .

4. How do I use Estrofem®

How much to take

- Take one tablet a day, preferably at the same time each day until all 28 tablets have been taken.
- Swallow each tablet with a glass of water.
- Once you have finished all 28 tablets in a pack, start the new pack continuing the treatment without interruption.

When to take Estrofem®

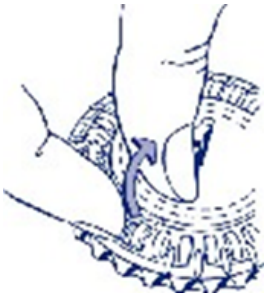
- Your doctor will tell you when to start taking the tablets.
- Carefully follow all instructions provided.
- Use Estrofem® until your doctor tells you to stop.
- If you are **not** on any other hormone replacement therapy and you have had a hysterectomy you can start taking Estrofem® on any day that is convenient.
- If you are still experiencing periods, you should start using Estrofem® on day 5 of your cycle.

How to take Estrofem®

How to use the calendar dial pack:

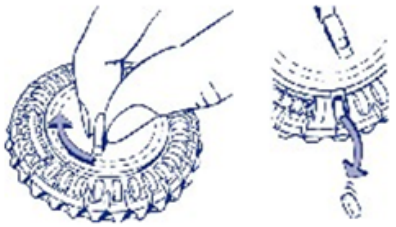
1. **Set the day reminder.**

Turn the inner disk to set the day of the week opposite the little plastic tab.



2. **Take the first day's tablet.**

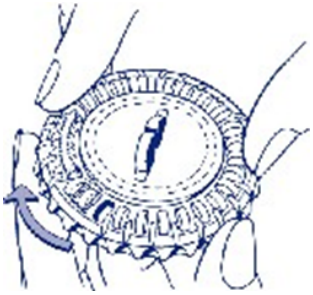
Break the plastic tab and tip out the first tablet.



3. **Move the dial every day.**

On the next day, simply move the transparent dial clockwise 1 space as indicated by the arrow. Tip out the next tablet.

Remember to take only 1 tablet once a day.



You can only turn the transparent dial after the tablet in the opening has been removed.

If you forget to use Estrofem®

Estrofem® should be taken regularly at the same time each day. If you miss your dose at the usual time, take it when you remember if it is within 12 hours.

If it has been longer than 12 hours, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed. Throw away the tablet you missed.

If you still have your uterus, you may have vaginal bleeding or spotting if you forget to take your tablets.

If you take too much Estrofem®

If you think that you or anyone else have taken too many Estrofem® tablets, you may need medical attention.

You should:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Estrofem®?

Things you should do

- **Regularly check your breasts.**
  See your doctor if you notice changes such as:
  - o dimpling of the skin
  - o changes to the nipple
  - o any lumps you can feel.

Go for regular breast screening and pap smear tests.

- Once you've started on HRT, you should see your doctor for regular check-ups (at least once a year). At these check-ups, your doctor may discuss with you the benefits and risks of continuing to take HRT.
- If you need to have surgery, tell your surgeon you are taking HRT, and specifically Estrofem®. You may need to stop taking your tablets a few weeks prior to your surgery.
- If you have stopped therapy, ask your doctor when you can start taking Estrofem® again.
- Note that there is only limited experience of treating women older than 65 years with Estrofem®.

Call your doctor straight away if you:

- Become pregnant while taking Estrofem®.

Remind any doctor, dentist or pharmacist you visit that you are on HRT and specifically taking Estrofem®.

Things you should not do

- Do not stop using this medicine suddenly
- Do not change the way you are taking Estrofem®
- Do not give Estrofem® to anyone else, even if you think they may have the same condition as you
- Do not take Estrofem® if you are breastfeeding.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Estrofem® affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight, where the temperature stays below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep the calendar pack in the outer carton in order to protect from light.

Do not put Estrofem® in the refrigerator.

- **Keep it where young children cannot reach it.**

When to discard your medicine

Discard all medicine if it is after the expiry date printed on the pack. The expiry date refers to the last day of that month.

Do not use your medicine if the packaging is torn or shows signs of tampering.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When you start on Estrofem® your body will need to adjust to new hormone levels.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Breast and gynaecological: • breast tenderness, enlargement or pain • vaginal bleeding or spotting suddenly becoming heavier • fungal infection of the vagina (thrush). **Blood vessel-related:** • inflammation of a vein. **Gut-related** • abdominal (stomach) pain • indigestion • feeling sick (nausea), vomiting	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• diarrhoea, bloating, flatulence • gall bladder problems, gall stones. **Head and brain:** • you think you may be suffering from depression (low mood) • changes in libido • problems getting to sleep • headache, migraine • dizziness • epilepsy. **Other:** • any side effect becomes worse • Estrofem® does not treat your symptoms effectively • you are not feeling well or find any side effect too uncomfortable or unacceptable • skin rash or itching • skin reactions • changes in hair growth • leg cramps • weight change • swelling due to fluid retention (oedema) • visual disturbances.	

Serious side effects

Serious side effects	What to do
Breast and gynaecological: • you can see or feel a lump in your breast, or you notice dimpling of the skin or changes in the nipple • you know or suspect you are pregnant. **Blood vessel-related:** • a pain in your chest that spreads to your arm or neck • difficulty breathing • severe pain in your calf and your leg is swelling • any kind of blood clots you notice. **Head and brain:** • migraine or sudden severe headache, when you have not previously had migraines • problems with your eyesight which develop suddenly.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
Severe allergic reaction (anaphylaxis): • skin rashes over a large part of the body • shortness of breath, wheezing • swelling of the face, lips or tongue • fast pulse • sweating. **Other:** • yellow colouring of the skin and eyes (jaundice) • large rise in blood pressure (you may have a headache, feel tired or dizzy).	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Estrofem® 1 mg tablet contains

Active ingredient (main ingredient)	estradiol hemihydrate 1 mg
Other ingredients (inactive ingredients)	hyprolose hypromellose iron oxide red lactose monohydrate magnesium stearate maize starch propylene glycol purified talc titanium dioxide
Potential allergens	lactose monohydrate

What Estrofem® 2 mg tablet contains

Active ingredient (main ingredient)	estradiol hemihydrate 2 mg
Other ingredients (inactive ingredients)	hyprolose hypromellose indigo carmine lactose monohydrate macrogol 400 magnesium stearate maize starch purified talc titanium dioxide
Potential allergens	lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What Estrofem® looks like

Estrofem® is supplied in a calendar dial pack. Each pack holds 28 tablets.

Estrofem® 1 mg tablets are red, film-coated, round, biconvex, and marked 'NOVO 282' on one side.

AUST R 188520

Estrofem® 2 mg tablets are blue, film-coated, round, biconvex, and marked 'NOVO 280' on one side.

AUST R 188521

Who distributes Estrofem®

Novo Nordisk Pharmaceuticals Pty Ltd

Level 10

118 Mount Street

North Sydney NSW 2060

Australia

Estrofem® is registered trademark of Novo Nordisk Health Care AG.

Further information

For further information call Novo Nordisk Medical Information on 1800 668 626.

Always check the following websites to ensure you are reading the most recent version of the Consumer Medicine Information:

- www.novonordisk.com.au
- www.ebs.tga.gov.au

This leaflet was prepared in December 2025.