

ESTROFEM[®]
Oestradiol (as hemihydrate) 1 mg or 2 mg
CONSUMER PRODUCT INFORMATION

What is in this leaflet

This leaflet answers some common questions about Estrofem. 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 taking Estrofem against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may need to read it again.

What is Estrofem used for?

A woman's last menstrual period is called the menopause and usually occurs between the ages of 45 and 55 years. Around the time of the menopause, the body slowly stops producing the two sex hormones called oestrogen and progesterone. Periods become irregular until they finally stop.

If a woman has surgical or natural menopause the production of these hormones is diminished or stopped.

Estrofem is a hormone replacement therapy (HRT) for women who have either had their wombs surgically removed (which is called hysterectomy) and have signs and symptoms of oestrogen deficiency. Estrofem replaces the hormone called oestrogen which your body stops making after surgical or natural menopause. The oestrogen in Estrofem relieves the symptoms caused by a lack of oestrogen.

The falling or reduced hormone levels cause many women to experience uncomfortable symptoms such as hot flushes, night sweats, sleeplessness, dry vagina, headaches, mood swings, lack of concentration or loss of energy.

Estrofem is used for the treatment of symptoms caused by a lack of oestrogen. However, your doctor may prescribe this medicine for another use. If you want more information, ask your doctor.

Before you take Estrofem

Your doctor should give you a complete physical examination and make a record of your family's medical history before you start taking Estrofem. The check-up should include a gynaecological examination, blood pressure test, and examination of the breasts and abdomen. If you have previously taken an oestrogen-only medicine, your doctor should examine you for a possible condition known as overstimulation of the lining of the womb.

Tell your doctor if:

- You have a history of blood clots or the presence of risk factors (see below)

- You have a history of oestrogen dependent tumours
- You have fibrocystic disease of the breast or any breast lumps
- You have migraine, diabetes, gall stones, severe kidney or liver disease, heart disease or high blood pressure because you will need to be seen regularly by your doctor while you are taking Estrofem
- You are taking, or plan to take, other medicines. See section '*Taking other Medicines*' for further information
- You have, or ever had, fibroids of the womb, endometriosis or endometrial hyperplasia (abnormal growth in the lining of the womb). Fibroids may increase in size while taking oestrogen, as in Estrofem, and symptoms of endometriosis may worsen
- Any bleeding following menopause

Some studies have suggested that hormone replacement therapy is associated with a higher relative risk of developing venous thromboembolism (the formation of a blood clot in the vessels of your legs or in your lungs). Tell your doctor before taking Estrofem if you have an increased risk for thrombosis (developing a blood clot) in your veins. The risk may be increased if you or anyone in your immediate family has ever had a thrombosis in the blood vessels of the legs or the lungs, if you are overweight, and possibly also if you have varicose veins.

Use of hormone replacement therapy for more than five years has been associated with an increase in the risk of breast cancer. The risk increases with the time of the treatment and decreases after the treatment has been stopped. Breast cancers found in women on hormone replacement therapy tend to be more limited than those not associated with hormone replacement therapy. For this reason your doctor may perform regular breast examinations and, when appropriate, may request a breast x-ray.

If you have not told your doctor about any of the above, tell them before you take Estrofem. If you have further questions about your Estrofem treatment, or are unsure of any of the above information, please see your doctor or pharmacist who will be able to assist you.

When you must not take Estrofem

Do not take Estrofem if:

- You are pregnant or suspect you may be
- You are breast feeding
- You know or suspect you have a tumour which depends on hormones (eg. cancer of the lining of the womb or breast) or have ever had breast cancer
- You have any unexplained vaginal bleeding
- You have or ever had blood clots in your legs or lungs
- You have acute or chronic liver disease or have previously had liver disease for which your liver tests have not yet returned to normal
- You are allergic to it or any of the ingredients listed at the end of this leaflet
- The packaging is torn or shows signs of tampering
- It is past the expiry date which is marked on the label on the calendar dial pack and on the carton. The medicine should not be used after the expiry date

Estrofem should not be taken by children or men.

Taking other medicines

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

How do I take Estrofem?

Please follow the illustrations telling you how to correctly use the calendar pack which are at the end of this leaflet.

Take one tablet a day, preferably at the same time each day, until all 28 tablets have been taken. Swallow each tablet whole with a glass of water. When you have finished each pack, start the next pack immediately.

If you are not on any other hormone replacement therapy you can start taking Estrofem on any day that is convenient. If you are going to change from another type of hormone replacement therapy, you should start using Estrofem at the end of the period-like bleed.

What if I forget to take a dose of Estrofem?

You can always see if you have taken your tablet by looking at the day on the calendar dial pack.

If it is almost time for your next tablet, skip the tablet you missed and take your next tablet when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally. You may have vaginal bleeding or spotting if you forget to take your tablets.

What if I take too much Estrofem (overdose)?

If you take more tablets than you have been prescribed, contact your doctor or the national poisons centre (0800 POISON or 0800 764766) for advice. Overdose may cause nausea and vomiting.

While you are using Estrofem

- You can expect your symptoms to improve within a few weeks of starting Estrofem
- Estrofem can be stopped at any time. You should discuss this with your doctor
- Estrofem is not a contraceptive and will not prevent pregnancy. Estrofem is recommended for women who have menopausal symptoms
- Tell your doctor if you will be hospitalised or undergoing surgery
- If you have further questions on your Estrofem treatment, or are unsure of any of the above information, please see your doctor or pharmacist who will be able to assist you

Things you must not do

- Do not give Estrofem to anyone else, even if they have the same condition or symptoms as you
- Do not use Estrofem to treat any other complaints unless your doctor tells you to
- Do not change the way you take Estrofem or lower the dosage, without checking with your doctor

Side Effects

All medicines can have unwanted effects. Most side effects associated with Estrofem are mild.

If while taking Estrofem, you experience any unwanted effects or symptoms which may be due to Estrofem (whether or not it is mentioned below) please tell your doctor or pharmacist as soon as possible. You may need medical treatment if you experience some of the unwanted effects.

When you start taking Estrofem your body has to adjust to new hormone levels. The most frequently reported unwanted effect during treatment is breast tenderness. Others include headache, abdominal pain, nausea, flatulence, breast enlargement, skin rash and itching, insomnia, depression, increase in size of uterine fibroids, venous thromboembolism and oedema. These unwanted effects are usually temporary and disappear.

Tell your doctor if

- You are not feeling well or find any unwanted effect too uncomfortable or unacceptable
- Any unwanted effect becomes worse
- Vaginal bleeding or spotting suddenly becomes heavier

Tell your doctor immediately if any of the following things happen.

- Severe pain or swelling in your legs
- Yellow colouring of the skin and eyes (jaundice)
- Sudden severe headache or migraine
- Problems with your eyesight
- Marked rise in blood pressure
- You know or suspect you are pregnant

Cancer of the breast, blood clots and changes in liver function have been reported with hormone replacement therapy.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Estrofem, especially if the unwanted effect is not mentioned in this package insert.

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

Storage

- Keep all medicines out of reach of children

- Estrofem should be kept in a cool dry place where the temperature stays below 25°C
- Do not put Estrofem in the refrigerator

Disposal

- If your doctor tells you to stop taking Estrofem, return any unused medicine to your pharmacist

Product Description

Estrofem comes in a calendar dial pack. Each pack holds 28 tablets. Each 1mg Estrofem tablet is red and round and marked 'NOVO 282' on one side. Each 2mg Estrofem tablet is blue and round and marked 'NOVO 280' on one side.

Each tablet contains 1 or 2 mg oestradiol (as hemihydrate) as the active ingredient. Oestradiol is identical to natural human oestrogen.

The tablets also contain lactose, maize starch, gelatin, talc, magnesium stearate, hypromellose, titanium dioxide. Estrofem is gluten-free.

Colours 1mg red - iron oxide red, propylene glycol
 2mg blue - indigo carmine, polyoxyethylene glycol 400

Other important information

- Estrofem is available only by prescription at pharmacies.
- The expiry date is marked on the label on the calendar dial pack and on the carton. The date, for example, 12.1998, refers to the twelfth month of 1998. The medicine should not be used after the expiry date.
- This medicine is for you only. Do not give it to someone else even if they seem to have the same symptoms as you.
- If your doctor tells you to stop taking Estrofem, return any unused medicine to your pharmacist.
- If you have further questions on your Estrofem treatment, or are unsure of any of the above information, please see your doctor or pharmacist who will be able to assist you.

Sponsor

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Novo Nordisk Pharmaceuticals Ltd
Auckland

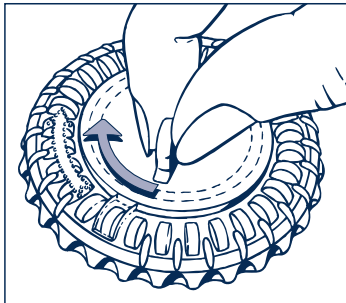
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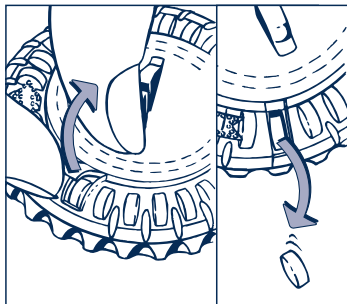
HOW TO USE Estrofem®

Follow these steps to use the calendar dial pack



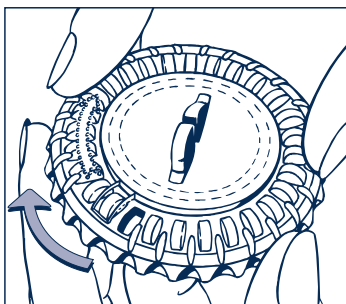
1. Set the day reminder:

Use a coin to turn the inner disc to set the day of the week opposite the little plastic tab.



2. How to take the first tablet:

Break the plastic tab and tip out the first tablet.



3. Every day:

Simply move the transparent dial clockwise one space as indicated by the arrow. Tip out the next tablet.

The transparent dial can only be turned after the tablet in the opening has been removed.