

Estrofem[®] 1mg tablets

Estrofem[®] 2mg tablets

Oestradiol

Consumer Medicine Information

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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 using Estrofem against the benefits they expect it will have for you.

Ask your doctor or pharmacist if you have any concerns about using this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

Estrofem is available only by prescription at pharmacies.

What Estrofem[®] is used for

Estrofem, a hormone replacement therapy (HRT), is used for the short-term symptomatic treatment of women who have had their womb surgically removed (which is called hysterectomy) and who have signs and symptoms of oestrogen deficiency.

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 replaces the hormone called oestrogen which your body stops making after surgical or natural menopause.

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

The oestrogen in Estrofem relieves the symptoms caused by a lack of oestrogen.

If you have not had a hysterectomy your doctor may prescribe another medicine (a progesterone type medicine) 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 the combination of the two medicines please talk to your doctor.**

Your doctor may have prescribed Estrofem for another reason. Ask your doctor if you have any questions about why Estrofem has been prescribed for you.

Before you take Estrofem[®]

When you must not take it

Do not take Estrofem if:

- you are pregnant or suspect you may be pregnant
- you know or suspect you have a tumour which depends on hormones (eg cancer of the breast or the lining of the womb) or have ever had breast cancer
- you have porphyria (a rare disease of blood pigments)
- you have not had a hysterectomy and you have any unexplained vaginal bleeding
- you know that you are allergic to any of the ingredients in Estrofem
- you have or ever had any kind of blood clots
- you have pain in your calf and your leg is swelling
- it is after the expiry date (Expiry) printed on the pack
- the packaging is torn or shows signs of tampering

Before you start to take it

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 endometriosis (overstimulation of the lining of the womb).

Tell your doctor if:

- you have not had a hysterectomy, because another medicine may be more suitable for you
- you have previously taken oestrogen by itself for menopausal symptoms and have not had a hysterectomy. The long-term use of oestrogen without a progesterone can increase the risk of cancer of the lining of the womb
- you have a family history of blood clots
- you are to be hospitalised or undergoing surgery

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

- venous blood clots related to the use of oestrogen (eg while using an oral contraceptive pill)
- epilepsy, migraine, diabetes, asthma, liver disease, heart disease or high blood pressure (because you will need to be seen regularly by your doctor while you are taking Estrofem)
- fibroids of the womb or endometriosis and you have not had a hysterectomy. Fibroids may increase in size while taking Estrofem and symptoms of endometriosis may worsen.

If you have not told your doctor about any of the above, tell them before you take Estrofem.

Taking other medicines

Tell your doctor if you are taking or plan to take other medicines, including:

- other oestrogen medicines
- medicines for epilepsy, tuberculosis, sleeping problems or depression

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.

The effect of Estrofem can be reduced by other medicines.

How to take Estrofem[®]

How to take it

Read carefully the instructions included in this leaflet, in order to correctly use the calendar pack.

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. When you have finished each pack, start the next pack immediately.

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 bleeds, you should start using Estrofem on day 5.

Estrofem should not be taken by children, men, during pregnancy or while breast-feeding.

Duration of therapy: HRT should be prescribed at the lowest effective dose and for the shortest duration necessary. The continuation of the treatment should be re-evaluated annually. Women who have undergone a premature menopause (e.g. hysterectomy) may require longer term treatment.

If you forget to take it

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

If you forget to take a tablet at the usual time, take it as soon as you remember. If it is almost time for your next dose, throw away the tablet you missed and take your next dose when you are meant to.

If you take too much (overdose)

If you take more tablets than you have been prescribed, contact your doctor for advice.

Overdose may cause nausea and vomiting.

While you are taking Estrofem[®]

You can expect your symptoms to

improve within a few months 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 only recommended for women who have signs and symptoms of oestrogen deficiency due to surgical or natural menopause and who have had a hysterectomy performed. After hysterectomy you cannot get pregnant.

At your routine check-up, your doctor may reassess your continued need for Estrofem. Alternative HRT treatment may be given if troublesome symptoms remain.

If you have any concerns about taking Estrofem, ask your doctor or pharmacist. If your doctor tells you to stop taking Estrofem, return any unused medicine to your pharmacist.

Things you must not do

This medicine is for you only. **Do not give it to someone else even if they seem to have the same symptoms as you.**

Do not take 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 side effects. Sometimes they are serious, most of the time they are not.

Tell your doctor or pharmacist if you experience any side effects while you are taking Estrofem (whether or not they are mentioned below).

You may need medical treatment if you experience some of the side effects.

When you start taking Estrofem your body has to adjust to new hormone levels. You may experience the following side

effects:

stomach or bowel problems such as:

- nausea
- bloating

skin or hair problems such as:

- skin rash or itching
- changes in hair growth

other changes or problems such as:

- headache, migraine
- breast tenderness
- asthma
- gallbladder problems

These side effects are usually temporary and disappear.

Tell your doctor if:

- you are not feeling well or find any side effect too uncomfortable or unacceptable
- any side effect becomes worse
- you have not had a hysterectomy and vaginal bleeding or spotting suddenly becomes heavier

Tell your doctor immediately if any of the following conditions occur (because you may be told to stop taking Estrofem):

- pain in your calf and your leg is swelling
- any kind of blood clots
- yellow colouring of the skin and eyes (jaundice)
- migraine or sudden severe headache
- problems with your eyesight
- marked rise in blood pressure
- if you have not had a hysterectomy – vaginal bleeding or spotting occurring after you have been period-free for some time
- you know or suspect you are pregnant

Breast cancer, ovarian cancer, blood clots, dementia and changes in liver function have been reported with hormone replacement therapy.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storage

Keep all medicines out of reach of children.

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

Product Description

What Estrofem[®] looks like

Estrofem comes in a calendar dial pack. Each pack holds 28 round tablets.

Estrofem 1mg tablets are red and marked 'NOVO 282' on one side. Estrofem 2mg tablets are blue and marked 'NOVO 280' on one side.

Ingredients

Each Estrofem 1mg tablet contains 1mg oestradiol (as hemihydrate) as the active ingredient and iron oxide red CI77491 as a colouring agent.

Each Estrofem 2mg tablet contains 2mg oestradiol (as hemihydrate) as the active ingredient and indigo carmine CI73015 as a colouring agent.

Oestradiol is identical to natural human oestrogen.

The tablets also contain lactose, maize starch, gelatin, talc, magnesium stearate, hypromellose, titanium dioxide, macrogol 400 and propylene glycol.

Estrofem is gluten-free.

Manufacturer

Estrofem is made in Denmark and supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

A.B.N. 40 002 879 996
Level 3
21 Solent Circuit
Baulkham Hills NSW 2153

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Estrofem 2mg AUST R 61910

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For further information call the NovoCare[®] Customer Care Centre on 1800 668 626.

www.novonordisk.com.au

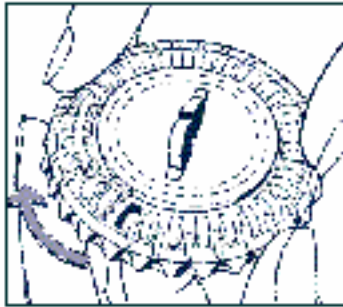
Estrofem[®]

Oestradiol

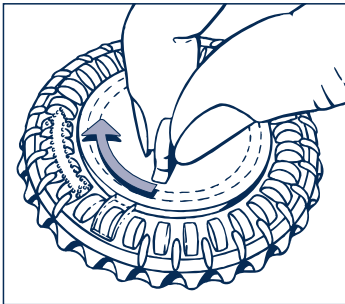
Directions for Use

Follow these steps to use the calendar dial pack.

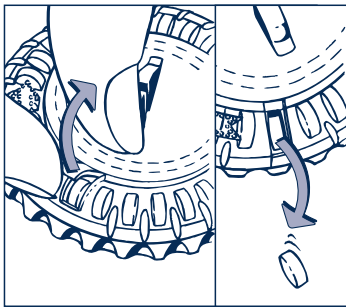
The first tablet to be taken is under the sealed opening in the see-through outer rim of the pack.



Each day turn the see-through dial clockwise one place to obtain the next tablet. Continue until all tablets have been taken.



Turn the inner white disc of the pack until the day of the week on which the first tablet is to be taken is next to the little plastic tab.



Break off the plastic tab using a finger nail and remove the first tablet from the pack. The see-through dial can only be turned after the tablet in the opening has been removed.