

FEMOSTON® 1/10

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.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. When I must not use FEMOSTON?

Do not use FEMOSTON or other estrogens, with or without a progestogen to prevent heart attacks, stroke or dementia.

2. Why am I using FEMOSTON?

FEMOSTON contains the active ingredients estradiol and dydrogesterone. It is used to relieve the discomfort many women feel during and after the menopause. It also helps to prevent thinning of the bones, which can cause fractures. FEMOSTON is used by women who still have a uterus (womb). For more information, see Section [2. Why am I using FEMOSTON?](#) in the full CMI.

3. What should I know before I use FEMOSTON?

Do not use if you have ever had an allergic reaction to any medicine containing estradiol or dydrogesterone or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [3. What should I know before I use FEMOSTON?](#) in the full CMI.

4. What if I am taking other medicines?

Some medicines may interfere with FEMOSTON and affect how it works. A list of these medicines is in Section 4. What if I am taking other medicines? in the full CMI.

5. How do I use FEMOSTON?

- Follow all directions given to you by your doctor carefully. The usual dose is one tablet daily. More instructions can be found in Section [5. How do I use FEMOSTON?](#) in the full CMI.

6. What should I know while using FEMOSTON?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using FEMOSTON.If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.See your doctor at least once a year for a check-up.Check your breasts each month and report any changes promptly to your doctor.Include foods that are good sources of calcium and Vitamin D in your daily diet and exercise regularly.
Things you should not do	<ul style="list-style-type: none">Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.Do not give this medicine to anyone else, even if they have the same condition as you.Do not stop taking FEMOSTON, or change the dosage, without checking with your doctor.
Looking after your medicine	<ul style="list-style-type: none">Keep your tablets in the pack until it is time to take them.Keep the medicine in a cool, dry place where the temperature stays below 30°C.

For more information, see Section [6. What should I know while using FEMOSTON?](#) in the full CMI.

7. Are there any side effects?

Tell your doctor if you notice any irregular vaginal bleeding, painful or swollen breasts, period-like pain, vaginal itching or fluid discharge, swelling of the lower legs, ankles, fingers or abdomen, nausea, abdominal cramps, vomiting, heartburn, wind, diarrhoea, headache, migraine, rise in blood pressure, dizziness, depression, nervousness, changes in mood, difficulty sleeping, worsening of epilepsy, back pain, change in sex drive, weight change, acne, itchy or dry skin, skin discolouration.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you have signs of allergic reaction, sudden severe headache, sudden loss of coordination, blurred vision or sudden loss of vision, bulging of eyeball, slurred speech, numbness in an arm or leg, painful swelling in the calves or thighs, chest pain, difficulty breathing, coughing blood, pain or tenderness in the abdomen, a yellow colour to the skin or eyes, itching, dark coloured urine or light coloured bowel motions. For more information, including what to do if you have any side effects, see Section [7. Are there any side effects?](#) in the full CMI.

WARNING: Do not use FEMOSTON or other estrogens, with or without a progestogen to prevent heart attacks, stroke or dementia.

FEMOSTON® 1/10

Active ingredient(s): *estradiol and dydrogesterone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FEMOSTON. **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 FEMOSTON.**

Where to find information in this leaflet:

- [1. When I must not use FEMOSTON?](#)
- [2. Why am I using FEMOSTON?](#)
- [3. What should I know before I use FEMOSTON?](#)
- [4. What if I am taking other medicines?](#)
- [5. How do I use FEMOSTON?](#)
- [6. What should I know while using FEMOSTON?](#)
- [7. Are there any side effects?](#)
- [8. Product details](#)

1. When I must not use FEMOSTON?

Do not use FEMOSTON or other estrogens, with or without a progestogen to prevent heart attacks, stroke or dementia.

A study called the Women's Health Initiative indicated increased risk of stroke, breast cancer, and blood clots in the legs or lungs in women receiving treatment with a product containing conjugated estrogens 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.

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

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

2. Why am I using FEMOSTON?

FEMOSTON contains the hormones estradiol and dydrogesterone. FEMOSTON is a type of treatment called hormone replacement therapy (HRT).

FEMOSTON helps to relieve the discomfort many women feel during and after the menopause. It also helps to prevent thinning of the bones (osteoporosis), which can cause fractures. FEMOSTON is used by women who still have a uterus (womb).

Menopause may be natural or occur after surgery or medical treatment.

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

FEMOSTON is not a contraceptive (birth control) and will not prevent pregnancy or restore fertility. 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.

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. Dydrogesterone is a hormone called a progestogen. It has effects like the female hormone, progesterone, which your ovaries also produced before the menopause.

Menopause generally occurs between the ages of 45 and 55, because your body's production of estrogen decreases. 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 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 if other treatments are not suitable.

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 your natural progestogen. After menopause, taking estrogen on its own as HRT may lead to irregular bleeding and to a disorder called endometrial hyperplasia. Progestogens such as dydrogesterone help to protect the lining of the uterus from developing this disorder.

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

Your doctor may have prescribed it for another purpose.

This medicine is not addictive.

3. What should I know before I use FEMOSTON?

Warnings

HRT should only be used if you have been fully informed of the risks.

The decision to use HRT should be based on your symptoms and health, and made after a careful medical evaluation.

Do not use FEMOSTON if:

- you have an allergy to any medicine containing estradiol or dydrogesterone, or any of the ingredients listed at the end of this leaflet

- Some symptoms of an allergic reaction include skin rash, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take FEMOSTON if you have/have experienced:

- A hysterectomy
- Cancer of the breast or uterus (endometrium) or any other estrogen or progestogen dependent cancer.
- Blood clots. Painful inflammation or blockages of a blood vessel in the legs, lungs, brain or heart.
- Any condition that increases the tendency for you to get blood clots
- Untreated endometrial hyperplasia (the lining of the uterus becomes too thick)
- 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 give FEMOSTON to a child under the age of 18 years.

Safety and effectiveness in children younger than 18 years have not been established.

You must stop taking FEMOSTON 4 weeks before certain types of surgery.

Tell your doctor or pharmacist if you have any allergies to any other medicines, foods, preservatives or dyes.

You must have a thorough medical check-up before starting HRT for the first time or recommencing HRT.

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

- 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)
- ovarian cancer
- unusual or irregular bleeding or spotting from the vagina
- endometriosis
- high blood pressure
- liver problems
- cholestatic jaundice (obstruction of bile)
- kidney problems
- heart problems
- diabetes
- migraine or severe headache
- asthma
- epilepsy
- systemic lupus erythematosus
- gall stones or gall bladder disease
- a high level of triglycerides (fats) in the blood
- high or low levels of calcium in the blood.
- Abnormal vision
- Hypothyroidism
- Otosclerosis - hearing loss due to a problem with the bones in the ear

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).

Your doctor will advise you whether or not to take FEMOSTON, or if you need to adjust the dose, or adapt your treatment.

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 [7. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant. Discuss with your doctor if you are planning on becoming pregnant.

Do not breastfeed if you are taking this medicine.

4. 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 and FEMOSTON may interfere with each other. These include:

- herbal medicines containing St John's wort
- some medicines for epilepsy such as phenytoin, phenobarbital, carbamazepine and lamotrigine
- some antibiotics and antivirals such as rifampicin and ritonavir
- some medicines with a narrow therapeutic index such as tacrolimus, ciclosporin, fentanyl and theophylline

These medicines may be affected by FEMOSTON, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking FEMOSTON.

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

5. How do I use FEMOSTON?

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

When to start taking it

If you are having regular periods, you may start taking FEMOSTON on the first day of your period. If you are having irregular periods, discuss the starting day with your doctor. If you have not had a period for 12 months or more, you can start FEMOSTON immediately.

How much to take

- The usual dose is one tablet daily.

How to take it

- **Swallow the tablets whole with a glass of water.**

When to take it

It does not matter if you take this medicine before or after food.

Take FEMOSTON at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

The tablets are labelled with the days of the week to help you make sure you are taking your tablets every day.

You must always start by taking the tablets in the half of the pack with an arrow marked "1". When you come to the end of these tablets, start taking the tablets in the other half of the pack marked "2".

You should start each new pack the day after you have finished the old pack. Do not leave a gap between packs.

How long to take it

Your doctor can advise you how long you may need to take FEMOSTON.

Your doctor can discuss the risks and benefits of long-term treatment with HRT. Some recent studies have shown that women using HRT have a small increase in breast cancer risk after several years of use. The risk increases with the length of HRT use.

Recent studies have also shown that HRT is associated with a small increase in the risk of strokes, blood clots, including clots in the lungs. The studies also showed that the risk of hip fractures and bowel cancer may be reduced.

Continue taking FEMOSTON for as long as your doctor recommends.

If you forget to use FEMOSTON

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

A slight vaginal bleeding, like an irregular period, may occur.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you have forgotten to take more than one tablet, discuss this with your doctor.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

If you use too much FEMOSTON

If you think that you or anyone else may have used too much FEMOSTON, you may need urgent medical attention. Symptoms such as nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness/fatigue, and withdrawal bleeding could occur in cases of overdosing.

You should immediately:

- phone the Poisons Information Centre

(Australia telephone 13 11 26 for advice, 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.

6. What should I know while using FEMOSTON?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking FEMOSTON.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

Tell your doctor that you are using FEMOSTON 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 after surgery, serious injury or having to stay in bed for a long period of time. If possible, FEMOSTON should be stopped at least 4 weeks before surgery and it should not be restarted until you are fully mobile.

If you become pregnant while you are taking this medicine, tell your doctor or pharmacist immediately.

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**
- **your uterus and cervix and do a pap smear at regular intervals**
- **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.

If you notice any changes to your breasts, see your doctor.

Include foods that are good sources of calcium and Vitamin D in your daily diet and exercise regularly. Calcium, Vitamin D and exercise may help prevent thinning of the bones. Your doctor can advise you on which foods and types of exercise are best for you.

Things you should not do

- **Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.**
- **Do not give this medicine to anyone else, even if they have the same condition as you.**
- **Do not stop taking FEMOSTON, or change the dosage, without checking with your doctor.**

Looking after your medicine

- **Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the box or the blister pack they may not keep well.

- **Keep the medicine in a cool, dry place where the temperature stays below 30°C.**
- **Keep it where children cannot reach it.**

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

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

When to discard your medicine

If your doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry date, ask your pharmacist what to do with any that are left over.

Getting rid of any unwanted medicine

Do not take it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

If it has expired or is damaged return it to your pharmacist for disposal.

7. Are there any side effects?

Tell your doctor as soon as possible if you do not feel well while you are taking FEMOSTON.

It helps most people, but it may have unwanted side effects in a few people. All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side-effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • 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 • vaginal itching, inflammation or fluid discharge • swelling of the lower legs, ankles, fingers or abdomen due to fluid retention • nausea (feeling sick), abdominal cramps, vomiting, heartburn, wind, diarrhoea • headache, migraine • rise in blood pressure • weakness or dizziness • depression, nervousness, rapid changes in mood, difficulty sleeping 	<p>Tell your doctor if you notice any of these common and uncommon side effects of your medicine. They are usually mild and short-lived.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> • worsening of a condition called epilepsy • back pain • change in sex drive • weight gain or weight loss • acne, itchy or dry skin, skin discolouration. 	

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • signs of allergic reaction such as a rash or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath or troubled breathing • sudden severe headache • sudden loss of coordination • blurred vision or sudden loss of vision, bulging of eyeball • 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. 	<p>Tell your doctor immediately or go to the Emergency Department at your nearest hospital if you notice any of these very serious side effects. These side effects are rare.</p>

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.

8. Product details

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

What FEMOSTON contains

<p>Active ingredient (main ingredient)</p>	<p>The white tablets each contain 1 mg of estradiol (as hemihydrate). The grey tablets each contain 1mg of estradiol (as hemihydrate) and 10 mg of dydrogesterone.</p>
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactose monohydrate • hypromellose • maize starch • colloidal anhydrous silica • magnesium stearate • The colour ingredients used in FEMOSTON 1/10 is Opadry White Y-1-7000 E171 (ARTG PI No. 2731) (for 1 mg estradiol tablet only) and Opadry II complete film coating system 85F27664 Grey (ARTG PI No. 109308) (for combination tablet with 1 mg estradiol and 10 mg dydrogesterone).
Potential allergens	The tablets contain sugars as lactose.

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

What FEMOSTON looks like

FEMOSTON 1/10 contains two types of tablets:

14 round, white, estradiol 1 mg tablets bearing the inscriptions "379" on one side.

14 round, grey, 1 mg estradiol combined with 10 mg dydrogesterone tablets bearing the inscriptions "379" on one side.

(AUST R 219882)

FEMOSTON 1/10 is available in packs of 28 tablets.

Who distributes FEMOSTON

Viatrix Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatrix.com.au

Phone: 1800 274 276

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