

Femoston[®] 2/10

estradiol and dydrogesterone

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Femoston.

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 this medicine 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.

When you 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 heart attack, 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.

The Women's Health Initiative Memory Study indicated increased risk of dementia in women aged

65-79 years taking conjugated estrogens and MPA. There are no comparable data currently available for others doses of conjugated estrogens and MPA or others combinations of estrogens and progestogens. Therefore, you should assume the risks will be similar for other medicines containing estrogen and progestogen combinations.

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.

What Femoston is used for

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

This medicine 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 progesterone. 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.

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

Before you take Femoston

When you must not take it

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 take Femoston if you have an allergy to:

- any medicine containing estradiol or dydrogesterone
- 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 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.

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.

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.

Before you start to take it

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.

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 store.

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 (phenobarbitone) and carbamazepine
- some antibiotics and anti-infectives 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.

How to take 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 heart attacks, strokes, blood clots, including clots in the lungs. The studies also showed that the risk of hip fractures and bowel cancer may be reduced.

Another study has shown that in women older than 65 years, HRT is

associated with a small increase in the risk of dementia, including Alzheimer's disease. It is not known if this finding applies to younger women.

Continue taking Femoston for as long as your doctor recommends.

If you forget to take it

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 take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre 13 11 26, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Femoston. Do this even if there are no signs of discomfort or poisoning.

While you are taking Femoston

Things you must 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 must 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.

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.

Tell your doctor if you notice any of the following:

- 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
- worsening of a condition called epilepsy

- back pain
- change in sex drive
- weight gain or weight loss
- acne, itchy or dry skin, skin discolouration.

The above list includes common and uncommon side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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.

The above list includes very serious side effects. You may need urgent medical attention. These side effects are rare.

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

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

After using Femoston

Storage

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.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and dampness can destroy some medicines.

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.

Disposal

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.

Product description

What it looks like

Femoston 2/10 contains two types of tablets:

- 14 round, brick-red, estradiol 2 mg tablets bearing the inscription "379" on one side.
- 14 round, yellow, 2 mg estradiol combined with 10 mg dydrogesterone tablets bearing the inscription "379" on one side.

Femoston 2/10 is available in packs of 28 tablets.

Ingredients

The brick-red tablets each contain 2 mg of estradiol (as hemihydrate).

The yellow tablets each contain 2mg of estradiol (as hemihydrate) and 10 mg of dydrogesterone.

Femoston 2/10 tablets also contain:

- lactose monohydrate
- hypromellose
- maize starch
- colloidal anhydrous silica
- magnesium stearate

The colour ingredients used in Femoston 2/10 is Opadry OY-6957 pink (for 2 mg estradiol tablet only) and Opadry OY-02B22764 yellow (for combination tablet with 2 mg estradiol and 10 mg dydrogesterone). The tablets contain sugars (as lactose).

Supplier

Femoston is made in the Netherlands.

Femoston is supplied in Australia by:

Mylan Health Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

Phone: 1800 314 527

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This leaflet was prepared in August 2020.

Australian Registration Number(s)

AUST R 75889

Femoston 2-10_cmi\Aug20/00