

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

FEMIGEL transdermal gel

Oestradiol hemihydrate equivalent to 1,5 mg oestradiol per 2,5 g gel

Read all of this leaflet carefully before you start applying FEMIGEL.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.
- FEMIGEL has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FEMIGEL is and what it is used for
2. What you need to know before you use FEMIGEL
3. How to use FEMIGEL
4. Possible side effects
5. How to store FEMIGEL
6. Contents of the pack and other information

1. What FEMIGEL is and what it is used for

FEMIGEL is a hormone replacement therapy (HRT) which contains the female hormone, oestrogen.

FEMIGEL is used in postmenopausal women for:

- The relief of symptoms occurring after menopause.

During menopause, the amount of oestrogen produced by a woman's body lowers. This can cause hot flushes in your neck and chest. FEMIGEL alleviates these symptoms after menopause. Your doctor will only prescribe FEMIGEL if your symptoms seriously hinder your daily life.

- Prevention of osteoporosis.

After the menopause some women may develop fragile bones (osteoporosis). You should discuss all available options with your doctor. If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use FEMIGEL to prevent osteoporosis after menopause.

FEMIGEL works by replacing the oestrogen in your body, so that you have a similar amount of oestrogen as before your menopause.

2. What you need to know before you use FEMIGEL

Do not use FEMIGEL:

- if you are hypersensitive (allergic) to oestradiol or any of the other ingredients of FEMIGEL (listed in section 6),
- if you are pregnant (see **Pregnancy and breastfeeding**),
- if you have a personal or family history of breast cancer,
- if you have cancer which is sensitive to oestrogens, such as cancer of the womb lining (endometrium), or if you are suspected of having it,
- if you have any unexplained vaginal bleeding,
- if you have excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated,
- if you have a blood clot in a vein (thrombosis), such as in the legs (deep venous thrombosis),
- if you have previously been diagnosed with a blood clot in a vein (thrombosis), such as in the legs (deep venous thrombosis),

- if you have previously been diagnosed with a blood clot in your lungs (pulmonary embolism),
- if you have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency),
- if you have a blood clotting disorder called “thrombophilia” which is been passed down in families (inherited),
- if you have or recently have had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina,
- if you have or have ever had a liver disease and your liver function tests have not returned to normal,
- if you have a rare blood condition called “porphyria” which is passed down in families (inherited),
- if you have genetic mutations passed down in families (inherited), called BRCA1 and BRCA2 genes,
- if your menstrual periods started early (before the age of 12 years),
- if you have ever had any non-cancerous breast diseases,
- if you have ever had treatment using radiation therapy to your chest or breast(s),
- if you have ever been exposed to a hormonal medicine called diethylstilbestrol (DES).

If any of the above conditions appear for the first time while applying FEMIGEL, stop using it immediately and contact your doctor.

Warnings and precautions

Tell your doctor or health care provider if you had any of the following before applying FEMIGEL:

- fibrosis (noncancerous growths) inside your womb,
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia),
- increased risk of developing blood clots (see ***Blood clots in a vein (thrombosis)***),

- increased risk of getting an oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer),
- high blood pressure,
- a liver disorder, such as a benign liver tumour,
- diabetes (high blood sugar),
- gallstones,
- migraine or severe headaches,
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus [SLE]),
- epilepsy (fits/seizures),
- asthma,
- a disease affecting the eardrum and hearing (otosclerosis),
- a very high level of fat in your blood (triglycerides),
- fluid retention due to heart or kidney problems,
- hereditary or acquired angioedema (swelling under the skin).

Stop using FEMIGEL and see a doctor immediately

If you notice any of the following when using FEMIGEL:

- any of the conditions mentioned in section 2 – **Do not use FEMIGEL**,
- yellowing of your skin or the whites of your eyes (jaundice), which may be signs of a liver disease,
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness),
- migraine-like headaches which happen for the first time,
- if you become pregnant,
- if you notice signs of a blood clot, such as:
 - painful swelling and redness of the legs,
 - sudden chest pain,

- difficulty in breathing.
- swollen face, tongue, and/or throat and/or difficulty swallowing or hives, together with difficulty breathing which are suggestive of angioedema.

Note: FEMIGEL 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. Speak to your doctor for advice.

HRT and cancer

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer)

Using oestrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the womb lining (endometrial cancer).

Using a progestogen in addition to the oestrogen for at least 12 days of each 28 day cycle protects you from this extra risk. Your doctor will prescribe a progestogen separately if you still have your womb. If you have had your womb removed (a hysterectomy), discuss with your doctor whether you can safely use FEMIGEL without a progestogen.

Unexpected bleeding

You will have a bleed once a month (so-called withdrawal bleed) while using FEMIGEL. **Consult your doctor as soon as possible**, if you have unexpected bleeding or drops of blood (spotting) besides your monthly bleeding, which carries on after you have stopped using FEMIGEL.

Breast cancer

Evidence shows that using combined oestrogen-progestogen or oestrogen-only HRT increases the risk of breast cancer. The extra risk depends on how long you use HRT. After stopping HRT

the extra risk will decrease with time, but the risk may persist for 10 years or more.

Regularly check your breasts. See your doctor if you notice any changes such as:

- dimpling of the skin,
- changes in the nipple,
- any lumps you can see or feel.

For mammogram screening, it is important that you inform the nurse/health care provider who is taking the X-ray that you use HRT, as this medicine may increase the density of your breasts which may affect the outcome of the mammogram. Where the density of the breast is increased, mammography may not detect all lumps.

Ovarian cancer

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

Effect of FEMIGEL on heart and circulation

Blood clots in a vein (thrombosis)

The risk of blood clots in the veins is higher in patients using FEMIGEL, especially during the first year of using it.

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

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations applies to you:

- you are unable to walk for a long time because of major surgery, injury or illness (see section 3 – **If you need to have surgery**),

- you are overweight (body mass index [BMI] > 30 kg/m²),
- 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 FEMIGEL will prevent a heart attack.

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

For women who have had their womb removed and are using oestrogen-only therapy there is no increased risk of developing a heart disease.

Stroke

The risk of getting a 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 will increase with age.

Other conditions

FEMIGEL will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using FEMIGEL after the age of 65 years. Consult your doctor for advice.

Children

FEMIGEL can be accidentally transferred from the skin to other people. Do not allow others, especially children, to come into contact with the exposed area of your skin and cover the area, if needed, after the gel has dried. If a child comes in contact with the area of the skin where FEMIGEL was applied on, wash the child's skin with soap and water as soon as possible.

Other medicines and FEMIGEL

Always tell your health care provider if you are taking any other medicine (this includes all complementary or traditional medicines).

The following medicine may cause an interaction with FEMIGEL:

- Phenobarbital, phenytoin and carbamazepine (used for epilepsy).
- Rifampicin, rifabutin (used for tuberculosis [TB]).
- Nevirapine, efavirenz, ritonavir and nelfinavir (used for human immunodeficiency virus [HIV] infection).
- St John's wort (herbal product containing *Hypericum perforatum*).
- Skin cleansers and detergents containing benzalkonium chloride or sodium laurilsulfate.
- Skin products containing alcohol (e.g. astringents or sunscreens).
- Products to treat skin and scalp disorders (e.g. products to cure warts, acne or dandruff).
- Skin medicine which changes how skin is made (e.g. anticancer products).

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are using FEMIGEL, because this medicine can affect the result of some tests.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using FEMIGEL.

FEMIGEL is for use in postmenopausal women only.

If you become pregnant, stop using FEMIGEL and contact your doctor.

Driving and using machines

None known.

It is not always possible to predict to what extent FEMIGEL may interfere with the daily activities of a patient. Do not engage in the above activities until you are aware of the measure to which FEMIGEL affects you.

FEMIGEL contains alcohol (ethanol)

FEMIGEL contains 0,5 g alcohol (ethanol) in each dose of 1,25 g gel. It may cause burning sensation on damaged skin. FEMIGEL is flammable until dry.

3. How to use FEMIGEL

Do not share medicines prescribed for you with any other person.

Always use FEMIGEL exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- If you have never used any other HRT medicines or you are switching to FEMIGEL from a period-free HRT product, you can start using FEMIGEL on any convenient day.
- If you are currently using another type of HRT where you have a period, finish your current medicine pack before you start using FEMIGEL.
- Do not ask anyone else to apply FEMIGEL. Only you should apply your medicine.
- Do not use strong skin cleaners or detergents when washing the area where you will apply FEMIGEL.
- Avoid close skin contact with your partner for one hour after application.
- Do not wash the skin or apply other skin care products until at least one hour after application.
- If the prescribed dose does not provide relief, consult your doctor. Do not use more than the prescribed dose.

Your doctor will aim to prescribe the lowest dose to treat your symptoms for as short as necessary.

Your doctor will tell you how long your treatment with FEMIGEL will last. If you have the impression that the effect of FEMIGEL is too strong or too weak, tell your doctor or pharmacist.

Preparing your new FEMIGEL pump pack

Before using your new FEMIGEL pump pack for the first time, you need to prepare it for use as follows:

- Remove the cap from the canister.
- Press the plunger down a few times until the gel comes out.
- Do not use this first dose of gel from your pump pack. This dose should be discarded.
- Your pump pack is now ready to use.

How much to use and when to use

- Apply FEMIGEL once a day, either in the morning or evening.
- Try to use FEMIGEL at about the same time each day.
- Your doctor will prescribe the lowest dose for the shortest time to treat your symptoms.
- The usual daily dose is 2 measures (2 pumps) of gel (one pump is equal to one measure).
- Spread the gel on a large area of skin on each shoulder, arm or thigh.

How to apply FEMIGEL

1. Make sure that your hands and the skin where you are going to apply the gel are clean, dry and unbroken.
2. Remove the canister cap to reveal the plunger.
3. Hold the FEMIGEL pump pack in one hand and place your other hand under the spout, ready collect the gel.
4. Push the plunger down firmly. This will dispense one measure of the gel.
5. **Do not apply on or near the breasts, or near the genital area.**
6. Spread the gel over a large area of skin on each shoulder, outer arm or mid-inner thigh.

7. If your doctor has prescribed 2 measures of gel, spread 1 measure over each outer arm and shoulder, or each mid-inner thigh. If 4 measures of gel have been prescribed, spread 2 measures over each outer arm and shoulder or each mid-inner thigh (see steps 4 – 8).
8. Replace the cap.
9. Allow to dry for 5 minutes before covering the skin with clothes.
10. Wash hands with soap and water after applying the gel.
11. Do not allow other people to touch the area of skin where the gel was applied until the gel has dried and cover with clothing if needed.

If FEMIGEL has been transferred to another person (man or child)

Wash the skin area which may have been affected immediately with soap and water.

If you need to have surgery

If you are going to have surgery, tell the doctor that you are using FEMIGEL. You may need to stop using FEMIGEL about 4 to 6 weeks before the operation to reduce the risk of a blood clot (see section 2 – ***Blood clots in a vein (thrombosis)***). Ask your doctor when you can start using FEMIGEL again.

If you use more FEMIGEL than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Always take the labelled medicine package with you, whether there are any FEMIGEL left or not.

Overdose symptoms may include breast tenderness, nausea and vaginal bleeding. These symptoms disappear when treatment with FEMIGEL is stopped or the dose is reduced.

If you forget to apply FEMIGEL

- If it is more than 12 hours until your next dose, apply FEMIGEL as soon as you remember and

apply the next dose at the normal time.

- If it is less than 12 hours until your next dose, skip the missed dose and apply the next dose at the normal time.
- Do not use a double dose (two doses at the same time) to make up for forgotten individual doses.
- If you forget a dose, you may have breakthrough bleeding or spotting.

4. Possible side effects

FEMIGEL can have side effects.

Not all side effects reported for FEMIGEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using FEMIGEL, please consult your health care provider for advice.

If any of the following happens, stop applying FEMIGEL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to FEMIGEL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- abdominal pain,
- breast swelling or breast enlargement,
- painful periods,

- menstrual periods which are heavier or last longer than usual,
- abnormal or irregular bleeding,
- white or yellow vaginal discharge,
- fluid retention (oedema),
- weight changes,
- abnormal growth of the lining of the womb (endometrial hyperplasia).

Less frequent side effects:

- mood swings or feeling depressed,
- migraine,
- vertigo (sensation of spinning or swaying),
- wind (flatulence),
- vomiting (being sick),
- increase in the volume of the uterus,
- vaginal yeast infection (candidiasis),
- feeling of weakness,
- intolerance to glucose, which may affect your blood sugar,
- if you have epilepsy (fits/seizures), your symptoms may get worse,
- high blood pressure,
- a blood test may show changes in the way the liver is working,
- acne or skin discolouration,
- unusual production of breast milk,
- blood clots in the veins of the legs or lungs (venous thromboembolism),
- change in libido (sex drive).

Frequency unknown:

- nausea (feeling sick),

- dizziness,
- headache,
- hair loss (alopecia),
- intense itching (pruritus),
- breast pain,
- infection,
- pain,
- inflamed vagina causing discharge, itching and pain (vaginitis).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA's website. By reporting side effects, you can help provide more information on the safety of FEMIGEL.

5. How to store FEMIGEL

Store at or below 25 °C and protect from light.

Keep in the original container until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the carton or container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What FEMIGEL contains

The active ingredient is oestradiol. This is a synthetic form of the female hormone oestrogen.

Each metered dose of 1,25 g of gel (1 pump) of FEMIGEL contains 0,75 mg of oestradiol (as hemihydrate) (0,06 % *m/m*).

The other ingredients are: carbomer, trolamine, absolute ethanol (40 % *m/m*) and purified water.

What FEMIGEL looks like and contents of the pack

Translucent, slightly opalescent gel with an alcoholic odour.

FEMIGEL is packed into a metering canister composed of a polypropylene (PP) bottle, a low-density polyethylene (LDPE) pouch, a polypropylene (PP) metering pump and closed with a polypropylene (PP) cap in a pack size of 80 g.

Holder of certificate of registration

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Access to corresponding Professional Information

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