

# KLIOGEST®

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## 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.

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

## 1. Why am I using Kliogest®?

Kliogest® contains the active ingredients estradiol (as hemihydrate) and norethisterone acetate.

Kliogest® is a hormone replacement therapy (HRT). It is used to help relieve symptoms of menopause and to help prevent the loss of bone density (fragile bones) following menopause.

For more information, see Section [1. Why am I using Kliogest®?](#) in the full CMI.

## **2. What should I know before I use Kliogest®?**

Do not use Kliogest® if you have ever had an allergic reaction to Kliogest® or any of the ingredients listed at the end of the CMI.

**Talk to your doctor about your medical history and your family's medical history, and if you take any other medicines, before starting Kliogest®. Do not use if pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Kliogest®?](#) in the full CMI.

## **3. What if I am taking other medicines?**

Some medicines may interfere with Kliogest® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

## **4. How do I use Kliogest®?**

- Kliogest® must be taken once a day, at about the same time each day.
- It is supplied in a 28-day calendar dial pack.

More instructions can be found in Section [4. How do I use Kliogest?](#) in the full CMI.

## 5. What should I know while using Kliogest®?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>• Remind any doctor, dentist or pharmacist you visit that you are using Kliogest®.</li> <li>• Keep all of your doctor's appointments so that you can be carefully monitored.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly.</li> <li>• Do not change the way you take Kliogest®.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• There are is no specific information on driving or using machines while you are taking Kliogest®.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• There is no specific information of the effect of drinking alcohol while you are taking Kliogest®.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep Kliogest® in a cool, dark place where</li> </ul>

	the temperature stays below 25°C.
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For more information, see Section [5. What should I know while using Kliogest®?](#) in the full CMI.

## **6. Are there any side effects?**

Serious side effects may include the potential for blood clots (in veins, lungs or brain), severe allergic reaction (anaphylaxis), sudden onset headache or migraine, changes to breasts suggestive of breast cancer, unexpected vaginal bleeding.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

**WARNING:**

**Estrogens and progestogens should not be used for the prevention of heart attacks, stroke or dementia.**

**A large study called the Women's Health Initiative reported that women who took these hormones in combination or alone after menopause, compared to a placebo (a medicine with no active ingredient), had an increased risk of heart attacks and strokes, breast cancer, blood clots in the lungs or legs, and a higher risk of developing dementia (memory loss) in older women.**

**Any estrogen with or without progestogen should be prescribed at the lowest effective dose and for the shortest duration determined by considering the risk and benefits for you as an individual. Speak to your doctor if you have any questions.**

## **KLIOGEST®**

**Active ingredients:** *estradiol (as hemihydrate) and norethisterone acetate*

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### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Kliogest®. **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 Kliogest®.

**Where to find information in this leaflet:**

- [1. Why am I using Kliogest®?](#)
- [2. What should I know before I use Kliogest®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Kliogest®?](#)
- [5. What should I know while using Kliogest®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using Kliogest®?**

**Kliogest® contains the active ingredients estradiol (as hemihydrate) (an estrogen) and norethisterone acetate (a progestogen).**

Kliogest® is a hormone replacement therapy (HRT). It is used to help relieve symptoms of menopause and to help prevent the loss of bone density (fragile bones) following menopause.

## **2. What should I know before I use Kliogest®?**

### **Medical history and regular check-ups**

The use of HRT carries risks which need to be considered when deciding whether to start taking it, or whether to carry on taking it.

Before you start (or restart) HRT, your doctor must ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and/or an internal examination, if necessary.

Note: Kliogest® 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 before starting Kliogest® if you have any questions or concerns.**

## **Warnings**

### **Do not use Kliogest® if:**

- you have, have had or suspect having breast cancer
- you have, have had or suspect having cancer of the uterus lining (endometrial cancer), or any other estrogen dependent cancer
- you have any unexplained vaginal bleeding
- you have excessive thickening of the uterus lining (endometrial hyperplasia) that is not being treated
- you have or have ever had a blood clot in a vein (venous thromboembolism), such as in the legs (e.g. deep vein thrombosis), or the lungs (pulmonary embolism)
- you have a blood clotting disorder (such as protein C, protein S or antithrombin deficiency)

- you have or previously have had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina
- you have or have ever had a liver disease and your blood test results have not returned to normal
- you have a rare blood problem called 'porphyria' which is passed down in families (inherited)
- you are pregnant or suspect you may be pregnant, or you are breastfeeding
- you are allergic to estradiol or norethisterone, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

### **Check with your doctor if you:**

- have premature menopause
- have fibroids or a growth of the uterus lining outside your uterus (endometriosis)
- have a history of excessive growth of the uterine lining (endometrial hyperplasia)
- have an increased risk of developing blood clots (see *Blood clots in a vein (venous thromboembolism)*)
- are to be hospitalised or undergoing surgery, particularly where you are or will be off your feet for a long time. You may need to stop taking Kliogest® for several weeks before your operation, to reduce the risk of a blood clot
- have an increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)



- have high blood pressure
- have a liver disorder, such as a benign liver tumour
- have diabetes
- have or have had gallstones
- have migraine or severe headaches
- have systemic lupus erythematosus (SLE)
- have epilepsy
- have asthma
- have or have had otosclerosis (hearing loss caused by changes to the bones in your ear)
- have very high levels of fat in your blood (triglycerides)
- have fluid retention due to heart or kidney problems
- have a condition where your thyroid gland fails to produce enough thyroid hormone (hypothyroidism) and you are treated with thyroid hormone replacement therapy
- have a hereditary condition causing recurrent episodes of severe swelling (hereditary angioedema) or if you have had episodes of rapid swelling of the hands, face, feet, lips, eyes, tongue, throat (airway blockage) or digestive tract
- have a lactose intolerance
- have any other medical conditions
- take any medicines for any other condition.

## **Cancer risk**

### **Endometrial hyperplasia and cancer**

Taking estrogen-only HRT will increase the risk of excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the uterus lining (endometrial cancer).

The progestogen in Kliogest® reduces this extra risk.

In women who still have a uterus and who are not taking HRT, on average, 5 in 1,000 will be diagnosed with endometrial cancer between the ages of 50 and 65.

For women aged 50 to 65 who still have a uterus and who take estrogen-only HRT, between 10 and 60 women in 1,000 will be diagnosed with endometrial cancer, depending on the dose and for how long it is taken.

### **Irregular bleeding**

You may have irregular bleeding or drops of blood (spotting) during the first 3-6 months of taking Kliogest®. However, see your doctor as soon as possible if the irregular bleeding:

- carries on for more than the first 6 months, or
- starts after you have been taking Kliogest® more than 6 months, or
- carries on after you have stopped taking Kliogest®.

## **Breast cancer**

Evidence shows that taking combined estrogen-progestogen or estrogen-only (HRT) increases the risk of breast cancer. The extra risk depends on how long you use HRT. The additional risk becomes clear within 3 years of use. After stopping HRT, the extra risk will decrease with time, but the risk may persist for 10 years or more if you have used HRT for more than 5 years.

### *Risk with 5 years of use*

For women aged 50 who start taking estrogen-progestogen HRT for 5 years, it is estimated that 21 cases of breast cancer in 1,000 users are diagnosed, compared with 13-17 cases per 1000 in those who do not take HRT.

### *Risk with 10 years of use*

For women aged 50 who start taking estrogen-progestogen HRT for 10 years, it is estimated at 48 cases of breast cancer in 1,000 users are diagnosed, compared with 27 cases per 1,000 in those who did not take HRT.

## **Ovarian cancer**

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

## **Blood clots in a vein (venous thromboembolism)**

The risk of blood clots in the veins is about 1.3 to 3 times higher in HRT users than in non-users, especially during the first year of taking it.

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

Inform your doctor if any of these risks apply to you:

- you are unable to walk for a long time because of major surgery, injury or illness
- you have had one or more miscarriages
- you are overweight or obese (BMI >30 kg/m<sup>2</sup>)
- 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 HRT will prevent a heart attack.

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

## Stroke

The risk of experiencing 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 increases with age.

Other things that can increase the risk of stroke include:

- high blood pressure
- smoking
- drinking too much alcohol
- an irregular heartbeat.

## Other conditions

HRT will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65.

Tell your doctor or the laboratory staff that you are taking Kliogest® if you need a blood test. Kliogest® can affect the results of some tests.

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

## Pregnancy and breastfeeding

Do not take Kliogest® if you are pregnant or suspect you are pregnant.

Do not take Kliogest® if you are breastfeeding.

### **3. 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 may interfere with Kliogest® and affect how it works. Kliogest® may interfere with some medicines and affect how they work.**

**Medicines that may increase the effect of Kliogest® include:**

- other medicines containing estrogens
- some anti-infectives, e.g. ketoconazole

**Medicines that may reduce the effect of Kliogest® include:**

- medicines to help you sleep, including barbiturates
- medicines for epilepsy e.g. phenytoin, carbamazepine, lamotrigine
- some antibiotics and other anti-infective medicines, e.g. - rifampicin, rifabutin, nevirapine, efavirenz, ritonavir, telaprevir and nelfinavir
- medicines for hepatitis C infections, e.g. telaprevir
- St John's Wort - used to treat depression, low mood
- antihistamines - used to treat allergies

**Kliogest® may increase the effectiveness of some medicines. These include:**

- corticosteroids - used to treat inflammatory conditions
- Imipramine

- pethidine
- cyclosporin

**Kliogest® may reduce the effectiveness of some medicines. These include:**

- lamotrigine - a medicine to treat epilepsy
- some medicines used to treat depression
- blood thinners used to prevent clots
- medicines used to treat diabetes
- thyroid hormones - used to treat poorly functioning thyroid gland

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

## **4. How do I use Kliogest®?**

### **How much to take**

- Carefully follow all instructions provided.  
Take one tablet once a day, at about the same time each day.
- Once you have finished all 28 tablets in a pack, start the new pack continuing the treatment without interruption.
- Use Kliogest® until your doctor tells you to stop.

## When to take Kliogest®

- Your doctor will tell you when to start taking the tablets. Kliogest® treatment should usually start a year after your periods stop.
- If you are not already using HRT, you can start Kliogest® at a convenient time for you.
- If you are already using a different type of HRT, your doctor can advise you when to switch to Kliogest®.

## How to use the calendar dial pack:

### 1. Set the day reminder

Turn the inner disc to set the day of the week opposite the little plastic tab.



### 2. Take the first day's tablet.

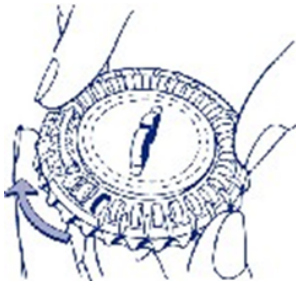
Break the plastic tab and tip out the first tablet.





### **3. Move the dial every day.**

On the next day, simply move the transparent dial clockwise 1 space as indicated by the arrow. Tip out the next tablet. Remember to take only one tablet once a day.



**You can only turn the transparent dial after the tablet in the opening has been removed.**

### **If you forget to take Kliogest®**

Kliogest® should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

**If it is longer than 12 hours, skip the dose you missed and take your next dose when you are meant to.**

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

You may have vaginal bleeding or spotting if you forget to take your tablets.

## **If you take too much Kliogest®**

If you think that you or anyone else have taken too many Kliogest® tablets, you may need medical attention.

### **You should:**

- phone the Poisons Information Centre (**by calling 13 11 26**), 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.**

## **5. What should I know while using Kliogest®**

### **Things you should do**

- **Regularly check your breasts.**

See your doctor if you notice changes such as:

- dimpling of the skin
- changes to the nipple
- any lumps you can feel.

Go for regular breast screening and pap smear tests.

- Once you've started on HRT, you should see your doctor for regular check-ups (at least once a year). At these check-ups, your doctor may discuss with you the benefits and risks of continuing to take HRT.

- Include foods that are good sources of calcium and Vitamin D in your daily diet, and exercise regularly. Calcium, Vitamin D and exercise help prevent thinning of the bones.
- If you need to have surgery, tell your surgeon you are taking HRT, and specifically Kliogest®. You may need to stop taking your tablets a few weeks prior to your surgery.

If you have stopped therapy, ask your doctor when you can start taking Kliogest® again.

### **Call your doctor straight away if you:**

- Become pregnant while taking Kliogest®. Kliogest is for use in postmenopausal women, only.

Remind any doctor, dentist or pharmacist you visit that you are using Kliogest®.

### **Things you should not do**

- Do not stop using this medicine suddenly.
- Do not change the way you are taking Kliogest®.
- Do not give Kliogest® to anyone else, even if you think they may have the same condition as you.
- Do not take Kliogest® if you are breastfeeding.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Kliogest® affects you.**

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

## **Looking after your medicine**

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight, where the temperature stays below 25°C; for example, do not store it:

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

Keep the calendar pack in the outer carton in order to protect from light.

Do not put Kliogest® in the refrigerator.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

**Discard all medicine if it is after the expiry date printed on the pack. The expiry date refers to the last day of that month.**

**Do not use your medicine if the packaging is torn or shows signs of tampering.**

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When you start taking Kliogest® your body has to adjust to new hormone levels.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Breast and gynaecological:</b> <ul style="list-style-type: none"><li>• breast tenderness, pain or enlargement</li><li>• irregular periods or excessive bleeding during your periods</li><li>• period pain</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• fungal infection of the vagina (thrush), vaginal inflammation or itching</li> <li>• aggravation, occurrence or recurrence of uterine fibroids (benign tumours)</li> <li>• vaginal bleeding or spotting suddenly becoming heavier.</li> </ul> <p><b>Blood vessel-related:</b></p> <ul style="list-style-type: none"> <li>• inflammation of a vein.</li> </ul> <p><b>Gut-related:</b></p> <ul style="list-style-type: none"> <li>• abdominal (stomach) pain</li> <li>• indigestion</li> <li>• feeling sick (nausea), vomiting</li> <li>• diarrhoea, bloating, flatulence</li> <li>• gallbladder problems, gallstones.</li> </ul> <p><b>Head and brain:</b></p> <ul style="list-style-type: none"> <li>• you think you may be suffering from depression</li> <li>• changes in libido</li> </ul>	

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• problems getting to sleep</li> <li>• nervousness</li> <li>• anxiety</li> <li>• headache, migraine</li> <li>• dizziness.</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• any side effect becomes worse</li> <li>• Kliogest® does not treat your symptoms effectively</li> <li>• you are not feeling well or find any side effect too uncomfortable or unacceptable</li> <li>• skin rash or itching</li> <li>• skin reactions, acne</li> <li>• changes in hair growth, hair loss</li> <li>• leg cramps</li> <li>• back pain</li> <li>• weight change</li> <li>• swelling due to fluid retention (oedema)</li> <li>• visual disturbances.</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Breast and gynaecological:</b></p> <ul style="list-style-type: none"> <li>• you can see or feel a lump in your breast, or you notice dimpling of the skin or changes in the nipple</li> <li>• you know or suspect you are pregnant.</li> </ul> <p><b>Blood vessel-related:</b></p> <ul style="list-style-type: none"> <li>• a pain in your chest that spreads to your arm or neck</li> <li>• unexplained migraine-type headaches, with or without disturbed vision</li> <li>• difficulty breathing</li> <li>• severe pain or swelling in your legs.</li> </ul> <p><b>Head and brain:</b></p> <ul style="list-style-type: none"> <li>• migraine or sudden severe headache, and you have not previously had migraines</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>



Serious side effects	What to do
<ul style="list-style-type: none"> <li>• problems with your eyesight which develop suddenly.</li> </ul> <p><b>Severe allergic reaction (anaphylaxis):</b></p> <ul style="list-style-type: none"> <li>• skin rashes over a large part of the body</li> <li>• shortness of breath, wheezing</li> <li>• swelling of the face, lips or tongue</li> <li>• fast pulse</li> <li>• sweating</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• yellow colouring of the skin and eyes (jaundice)</li> <li>• large rise in blood pressure (you may have a headache, feel tired or dizzy).</li> </ul>	

**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](http://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.**

## 7. Product details

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

### What Kliogest® contains

<b>Active ingredient (main ingredient)</b>	estradiol (as hemihydrate) 2 mg norethisterone acetate 1 mg
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• maize starch</li><li>• hypromellose</li><li>• purified talc</li><li>• magnesium stearate</li><li>• hypromellose</li><li>• triacetin</li></ul>

<b>Potential allergens</b>	lactose monohydrate
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**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Kliogest® looks like**

Kliogest® tablets are white, round (biconvex), film-coated tablets 6mm in diameter. The tablets are marked with 'NOVO 281' on one side and blank on the other side.

They are supplied in a calendar dial pack. Each pack holds 28 tablets.

AUST R 183856

## **Who distributes Kliogest®**

Novo Nordisk Pharmaceuticals Pty Ltd

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North Sydney NSW 2060

Australia

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## **Further information**

For further information call Novo Nordisk Medical Information on 1800 668 626.

Always check the following websites to ensure you are reading the most recent version of the Consumer Medicine Information:

- [www.novonordisk.com.au](http://www.novonordisk.com.au)
- [www.ebs.tga.gov.au](http://www.ebs.tga.gov.au)

This leaflet was prepared in December 2025.