

Kliovance[®]

Estradiol/Norethisterone acetate

Consumer Medicine Information

What is in this leaflet

When you must not use Kliovance [®]	1
What Kliovance [®] is used for.....	1
Before you take Kliovance [®]	2
How to take Kliovance [®]	3
While you are taking Kliovance [®]	3
Side effects	3
Storage	4
Product Description	4
Directions for Use.....	5

This leaflet answers some common questions about Kliovance, the menopause (the 'change of life'), and hormone therapy. 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 Kliovance 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.

Kliovance is available only by prescription at pharmacies. It does not cause addiction.

When you must not use Kliovance[®]

Do not use Kliovance 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 other doses of conjugated estrogens and MPA or other 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 Kliovance.

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

What Kliovance[®] is used for

Kliovance is a type of treatment called hormone therapy (HT). Each tablet contains the hormones, estradiol and norethisterone acetate (NETA).

Kliovance is used to relieve symptoms associated with the menopause. It is a short-term symptomatic treatment for women who have passed their menopause (at least a year after they have seen their last period) and prefer not to have periods.

Kliovance can also be used to prevent thinning of the bones in women with a high risk of fractures due to osteoporosis who cannot use other treatments.

Kliovance is intended for use in women who still have a uterus (womb).

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

The menopause occurs naturally in the course of a woman's life, usually between the ages of 45 and 55. After menopause, your body produces much less estrogen than it did before. 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 dryness of the vagina causing discomfort during or after sex. Estrogens can be given to

reduce or eliminate 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. Exercise, calcium and Vitamin D can help reduce the risk of osteoporosis. 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 should take both estrogen and progestogen as part of HT. 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 a natural progestogen. After menopause, taking estrogen on its own as HT may lead to irregular bleeding and to a disorder called endometrial hyperplasia (overgrowth or thickening of the endometrium). Progestogens such as NETA help to protect the lining of the uterus from developing this disorder.

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

Your doctor may have prescribed it for another purpose.

HT should not be used to prevent heart disease or dementia.

Before you take Kliovance®

When you must not take it

Do not take Kliovance if:

- you are pregnant or suspect you may be pregnant
- you know or suspect you have a tumour which depends on hormones (e.g. cancer of the lining of the womb or breast) or have ever had breast cancer

- you have porphyria (a rare disease of blood pigments)
- you have severe liver or kidney disease
- you have any unexplained vaginal bleeding
- you know that you are allergic to estradiol or NETA, the active ingredients, or to any of the other ingredients listed at the end of this leaflet
- you are allergic to any other medicine containing estrogen or progestogen, including the birth control pill
- you have or ever had blood clots in the blood vessels of your legs or lungs
- 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 Kliovance. The check-up should include a gynaecological examination, blood pressure test and examination of the breasts and abdomen.

If you have previously taken an estrogen-only medicine, your doctor should examine you for a possible condition known as endometriosis (where material similar to the lining of the uterus (womb) grows outside the uterus, causing pain or bleeding).

Tell your doctor if:

- you have previously taken estrogen by itself for menopausal symptoms. The long-term use of estrogen without a progesterone can increase the risk of endometrial cancer (cancer of the inner lining of the uterus or womb).
- you have had a hysterectomy (surgical removal of the womb), because another medicine may be more suitable for you
- it is less than one year since your last natural menstrual

period, because another medicine may be more suitable for you

- you have a family history of thrombosis (blood clots inside the blood vessels)
- you are to be hospitalised or undergoing surgery

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

- thrombosis related to the use of estrogen (e.g. while using an oral contraceptive pill)
- varicose veins
- a high level of triglycerides in the blood
- unusually high or low calcium levels in the blood
- low levels of thyroid hormone requiring supplementation
- breast lumps, systemic lupus erythematosus (SLE or lupus), epilepsy, migraine, diabetes, asthma, gallbladder or liver disease, heart disease or high blood pressure (because you will need to be seen regularly by your doctor while you are taking Kliovance)
- fibroids of the womb or endometriosis. Fibroids may increase in size while taking Kliovance and symptoms of endometriosis may worsen.

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

Taking other medicines

Tell your doctor if you are taking birth control pills.

Kliovance is not a contraceptive. 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.

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.

Some medicines and Kliovance may interfere with each other. These include:

- some medicines to help you sleep, including barbiturates
- some medicines for epilepsy, i.e. phenytoin and carbamazepine
- some antibiotics and other anti-infective medicines, i.e. rifampicin and ketoconazole
- other oestrogen medicines
- medicines for depression

You may need to take different amounts of your medicines or to take different medicines while you are using Kliovance. Your doctor and pharmacist have more information.

How to take Kliovance®

When to start it

Kliovance treatment should usually start a year after your periods stop.

If you are not already using HT, you can start Kliovance at a convenient time for you. If you are already using a different type of HT, your doctor can advise you when to switch to Kliovance.

How to take it

Read carefully the instructions printed at the end of 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.

Kliovance should not be taken by children, men, if you know or suspect you are pregnant, or while breast-feeding.

How long to use it

HT should be prescribed at the lowest effective dose and for the shortest duration necessary. Your

doctor can advise you how long you may need to take Kliovance.

The continuation of the treatment should be re-evaluated regularly. Women who have undergone a premature menopause (e.g. hysterectomy) may require longer term treatment.

If you need to continue using HT, discuss the possible risks and benefits with your doctor.

You may have an increased risk of developing breast cancer, heart disease, stroke, blood clots on the lungs and dementia. On the other hand, the risk of hip fractures and bowel cancer may be reduced. Your doctor should discuss these risks and benefits with you, taking into account your particular circumstances.

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.

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

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 Kliovance®

You can expect your symptoms to improve within a few weeks of starting Kliovance. However, you will not be aware of the effect of Kliovance on your bones.

Kliovance can be stopped at any time. You should discuss this with your doctor.

You should 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. Your doctor can advise you on which foods and type of exercise are best for you.

Kliovance is not a contraceptive and will not prevent pregnancy. Kliovance is only recommended for women who have passed their menopause.

At your routine check-up, your doctor may reassess your continued need for Kliovance. Your doctor may consider alternative HT treatments if troublesome symptoms remain.

If you have any concerns about taking Kliovance, ask your doctor or pharmacist. If your doctor tells you to stop taking Kliovance, 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 Kliovance to treat any other complaints unless your doctor tells you to.

Do not change the way you take Kliovance, 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 Kliovance (whether or not they are mentioned below).

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

When you start taking Kliovance your body has to adjust to new hormone levels. Irregular vaginal bleeding or spotting is a common side effect. It may take some months before you become period-free. The most frequently reported side effect during treatment is mild breast pain. You may also experience the following side effects:

stomach or bowel problems such as:

- nausea or vomiting
- bloating, flatulence or indigestion
- abdominal pain

skin or hair problems such as:

- skin rash or itching
- changes in hair growth

mood or behaviour changes such as:

- depression
- insomnia
- changes in libido

other changes or problems such as:

- headache
- breast enlargement
- thrush
- gallbladder problems
- increase in blood pressure
- increase or decrease in weight
- leg cramps
- increase in size of uterine fibroids

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
- 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 Kliovance):

- severe pain or swelling in your legs

- yellow colouring of the skin and eyes (jaundice)
- migraine or sudden severe headache
- problems with your eyesight
- rise in blood pressure
- 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 therapy.

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.

Storage

Keep all medicines out of reach of children.

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

Product Description

What Kliovance[®] looks like

Kliovance comes in a calendar dial pack. Each pack holds 28 tablets. Each Kliovance tablet is white and round and marked 'NOVO 288' on one side. The Novo Nordisk logo (Apis bull) is on the other side.

Ingredients

Each tablet contains 1mg estradiol (as hemihydrate) and 0.5mg norethisterone acetate as the active ingredients. Estradiol is identical to natural human estrogen. Norethisterone acetate is a hormone similar to progesterone.

The tablets also contain lactose, maize starch, copovidone, talc,

magnesium stearate, hypromellose and glycerol triacetate. Kliovance is gluten-free.

Manufacturer

Kliovance is made in Denmark and supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

ABN 40 002 879 996

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21 Solent Circuit

Baulkham Hills NSW 2153

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

www.novonordisk.com.au

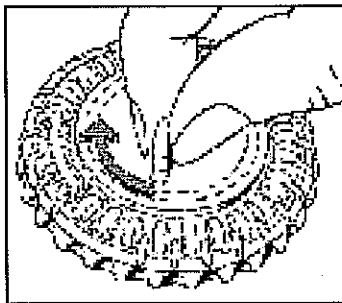
Kliovance®

Estradiol/Norethisterone acetate

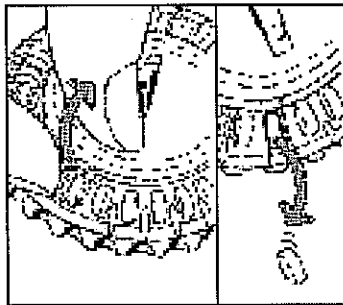
Directions for Use

Follow these steps to use the calendar dial pack

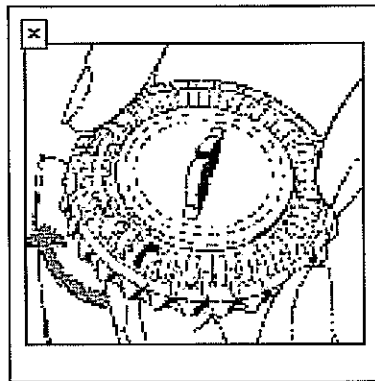
The first tablet to be taken is under the sealed opening in the see-through outer rim of the pack.



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.



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