

KLIOVANCE[®]
Oestradiol (as hemihydrate) 1 mg and Norethisterone Acetate 0.5 mg
CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Kliovance[®]. 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 Kliovance 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.

What Kliovance[®] is used for

A woman's last menstrual period is called the menopause and usually occurs between the ages of 45 and 55 years. Around the time of the menopause, the body slowly stops producing the two sex hormones called oestrogen and progesterone. Periods may become irregular until they finally stop. The falling hormone levels cause many women to experience uncomfortable symptoms such as hot flushes, night sweats, mood swings, sleeping difficulties, dry vagina, and urinary problems. Women lose a certain amount of their bone mass during the years after menopause, and this causes an increased risk of bone fractures. Oestrogens prevent bone loss in postmenopausal women and decrease the risk of fractures.

Kliovance is a hormone replacement therapy (HRT) for women who suffer menopausal symptoms and prefer not to have periods. Kliovance replaces the hormones called oestrogen and progesterone which your body stops making after the menopause. The oestrogen in Kliovance relieves the symptoms caused by a lack of oestrogen. The progestogen protects the lining of your womb from overstimulation by oestrogen.

Kliovance is used for the treatment of menopausal symptoms related to oestrogen deficiency and vaginal atrophy. Kliovance is also used for the prevention of osteoporosis (bone loss) in postmenopausal women. However, your doctor may have prescribed Kliovance for another reason. **Ask your doctor if you have any questions about why Kliovance has been prescribed for you.**

Before you take Kliovance[®]

- 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 oestrogen-only medicine, your doctor should examine you for a possible condition known as overstimulation of the lining of the womb.

Tell your doctor if:

- You have a history of blood clots or the presence of risk factors (see below)
- You have a history of oestrogen dependent tumours
- You have fibrocystic disease of the breast or any breast lumps
- You have migraine, diabetes, gall stones, severe kidney 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
- You are taking, or plan to take, other medicines. See section '*Taking other Medicines*' for further information
- You have, or ever had, fibroids of the womb, endometriosis or endometrial hyperplasia (abnormal growth in the lining of the womb). Fibroids may increase in size while taking oestrogen, as in Kliovance, and symptoms of endometriosis may worsen
- Any bleeding following menopause

Some studies have suggested that hormone replacement therapy is associated with a higher relative risk of developing venous thromboembolism (the formation of a blood clot in the vessels of your legs or in your lungs). **Tell your doctor before taking Kliovance if you have an increased risk for thrombosis (developing a blood clot) in your veins.** The risk may be increased if you or anyone in your immediate family has ever had a thrombosis in the blood vessels of the legs or the lungs, if you are overweight, and possibly also if you have varicose veins.

Use of hormone replacement therapy for more than five years has been associated with an increase in the risk of breast cancer. The risk increases with the time of the treatment and decreases after the treatment has been stopped. Breast cancers found in women on hormone replacement therapy tend to be more limited than those not associated with hormone replacement therapy. For this reason your doctor may perform regular breast examinations and, when appropriate, may request a breast x-ray.

If you have not told your doctor about any of the above, tell them before you take Kliovance. If you have further questions about your Kliovance treatment, or are unsure of any of the above information, please see your doctor or pharmacist who will be able to assist you.

When you must not take Kliovance®

Do not take Kliovance if:

- You are pregnant or suspect you may be
- You are breast-feeding
- You know or suspect you have a tumour which depends on hormones (eg cancer of the lining of the womb or breast) or have ever had breast cancer
- You have any unexplained vaginal bleeding
- You have or ever had blood clots in your legs or lungs
- You have acute or chronic liver disease or have previously had liver disease for which your liver tests have not yet returned to normal
- You are allergic to it or any of the ingredients listed at the end of this leaflet
- The packaging is torn or shows signs of tampering

- It is past the expiry date which is marked on the label on the calendar dial pack and on the carton. The medicine should not be used after the expiry date

Kliovance should not be taken by children or men.

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 shop.

How do I take Kliovance[®]?

Please follow the illustrations telling you how to correctly use the calendar pack which are included in this leaflet.

Take one tablet a day, preferably at the same time each day, until all 28 tablets have been taken. Swallow each tablet whole with a glass of water. When you have finished each pack, start the next pack immediately.

If you are not on any other hormone replacement therapy you can start taking Kliovance on any day that is convenient. If you are going to change from another type of hormone replacement therapy, you should start using Kliovance at the end of the period-like bleed.

What if I forget to take a dose of Kliovance[®]?

You can always see if you have taken your tablet by looking at the day on the calendar dial pack.

If it is almost time for your next tablet, skip the tablet you missed and take your next tablet when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally. You may have vaginal bleeding or spotting if you forget to take your tablets.

What if I take too much Kliovance[®] (overdose)?

If you take more tablets than you have been prescribed, contact your doctor or the national poisons centre (0800 POISON or 0800 764766) for advice. Overdose may cause nausea and vomiting.

While you are using Kliovance[®]

- You can expect your symptoms to improve within a few weeks of starting Kliovance
- Kliovance can be stopped at any time. You should discuss this with your doctor
- Kliovance is not a contraceptive and will not prevent pregnancy. Kliovance is recommended for women who have menopausal symptoms
- **Tell your doctor if you will be hospitalised or undergoing surgery**
- **If you have further questions on your Kliovance treatment, or are unsure of any of**

the above information, please see your doctor or pharmacist who will be able to assist you

Things you must not do

- **Do not give Kliovance to anyone else, even if they have the same condition or symptoms as you**
- **Do not use 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 unwanted effects. Most side effects associated with Kliovance are mild.

If while taking Kliovance, you feel unwell or experience any unwanted effects or symptoms which may be due to Kliovance (whether or not it is mentioned below) tell your doctor or pharmacist as soon as possible. You may need medical treatment if you experience some of the unwanted effects.

When you start taking Kliovance your body has to adjust to new hormone levels. Irregular vaginal bleeding or spotting is a common unwanted effect. It may take some months before you become period-free. A few women will continue to have some vaginal bleeding or spotting. The most frequently reported unwanted effect during treatment is breast tenderness. Others include headache, abdominal pain, nausea, flatulence, breast enlargement, skin rash and itching, insomnia, depression, increase in size of uterine fibroids, venous thromboembolism and oedema. These unwanted effects are usually temporary and disappear.

Tell your doctor if:

- You are not feeling well or find any unwanted effect too uncomfortable or unacceptable
- Any unwanted effect becomes worse
- Vaginal bleeding or spotting suddenly becomes heavier

Tell your doctor immediately if any of the following things happen.

- Severe pain or swelling in your legs
- Yellow colouring of the skin and eyes (jaundice)
- Sudden severe headache or migraine
- Problems with your eyesight
- Marked rise in blood pressure
- You know or suspect you are pregnant

Cancer of the breast, blood clots and changes in liver function have been reported with hormone replacement therapy.

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**

Disposal

- **If your doctor tells you to stop taking Kliovance, return any unused medicine to your pharmacist**

Product Description

Each tablet contains 1 mg oestradiol (as hemihydrate) and 0.5 mg norethisterone acetate as the active ingredients. Oestradiol is identical to natural human oestrogen. Norethisterone acetate is a hormone similar to progesterone. Both of these hormones are derived from plants.

Kliovance tablets also contain lactose, maize starch, copovidone, talc, magnesium stearate, hypromellose and glycerol triacetate. Kliovance is gluten-free. Kliovance is available only by prescription at pharmacies.

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 and the Novo Nordisk logo (Apis bull) is on the other side.

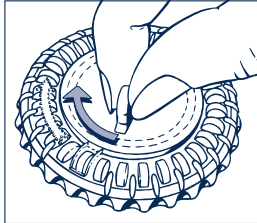
Marketed by:
Novo Nordisk Pharmaceuticals Ltd
Auckland

Manufactured in Denmark by:
Novo Nordisk A/S
2880 Bagsvaerd, Denmark

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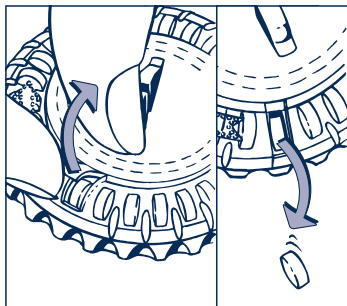
HOW TO USE KLIOVANCE®

Follow these steps to use the calendar dial pack

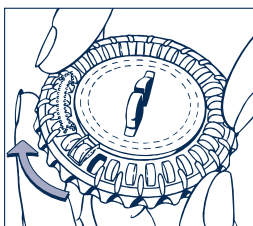


The first tablet to be taken is under the sealed opening in the see-through outer rim of the pack.

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.