

Trisequens[®] tablets

Oestradiol/Norethisterone acetate

Consumer Medicine Information

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

Trisequens is available only by prescription at pharmacies.

What Trisequens[®] is used for

Trisequens is a type of hormone replacement therapy (HRT) that relieves the symptoms of oestrogen deficiency associated with the menopause. It is a short term symptomatic treatment, also used where these symptoms arise from medical or surgical procedures affecting the ovaries.

The menopause, a woman's last menstrual period, usually occurs between the ages of 45 and 55 years. During this natural life transition, a woman slowly stops producing two female hormones called oestrogen and progesterone. Menstrual periods become less frequent until they finally stop.

The falling hormone levels may cause you to experience uncomfortable symptoms such as hot flushes, night sweats, sleeplessness, dry vagina, urinary problems, headaches, mood swings, lack of concentration or loss of energy.

The oestrogen in Trisequens relieves the symptoms caused by a lack of oestrogen. The progesterone protects the lining of your womb from overstimulation by oestrogen.

Your doctor may have prescribed Trisequens for another reason. Ask your doctor if you have any questions about why Trisequens has been prescribed for you.

Before you take Trisequens[®]

When you must not take it

Do not take Trisequens if:

- you are pregnant or suspect you may be pregnant
- you know or suspect you have a tumour which depends on hormones (eg cancer of the breast or the lining of the womb) or have ever had breast cancer
- you have porphyria (a rare disease of blood pigments)
- you have severe liver disease or abnormal liver function tests
- you have any unexplained vaginal bleeding

- you know that you are allergic to any of the ingredients in Trisequens
- you have or ever had blood clots, especially if they occurred while you were taking oestrogens (e.g. an oral contraceptive pill)
- 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 Trisequens. 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 endometriosis (overstimulation of the lining of the womb).

Tell your doctor if:

- you have previously taken oestrogen by itself for menopausal symptoms. The long-term use of oestrogen without a progesterone can increase the risk of cancer of the lining of the womb
- you have had a hysterectomy, because another medicine may be more suitable for you
- you have a family history of blood clots
- you are to be hospitalised or undergoing surgery

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

- venous blood clots related to the use of oestrogen (e.g. while using an oral contraceptive pill)
- varicose veins

- breast lumps, 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 Trisequens)
- fibroids of the womb or endometriosis. Fibroids may increase in size while taking Trisequens.

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

Taking other medicines

Tell your doctor if you are taking or plan to take other medicines, including:

- other oestrogen medicines
- medicines for epilepsy, tuberculosis, blood disorders, sleeping problems, diabetes, thyroid problems or depression.

Or other specific medicines including:

- corticosteroids
- antihistamines
- pethidine

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.

The effect of Trisequens can be reduced by other medicines.

How to take Trisequens[®]

How to take it

Read carefully the instructions included in this leaflet, in order to correctly use the calendar pack.

Your doctor will tell you when to start taking the tablets. If you are still having periods, you would usually take the first tablet on the fifth day after the start of your period. If your periods have stopped or have become infrequent, the first tablet can be taken as soon as you get the product.

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, unless your doctor tells you to do otherwise.

Trisequens should not be taken by children, men, during pregnancy or while breast-feeding.

Duration of therapy: HRT should be prescribed at the lowest effective dose and for the shortest duration necessary. The continuation of the treatment should be re-evaluated annually. Women who have undergone a premature menopause (e.g. hysterectomy) may require longer term treatment.

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 more than 1 tablet. **Ask your doctor for advice.**

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, headache, dizziness, swelling due to fluid retention (oedema), breast enlargement and build up of the lining of the womb.

While you are taking Trisequens[®]

You can expect your symptoms to improve within a few months of starting Trisequens. You will normally have a period while taking the red tablets or the last few white tablets. This is because Trisequens mimics the natural menstrual cycle.

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

At your routine check-up, your doctor may reassess your continued need for Trisequens.

Trisequens is not a contraceptive and will not prevent pregnancy.

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

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

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

When you start taking Trisequens your body has to adjust to new hormone levels. Breast tenderness and irregular vaginal bleeding or spotting are common side effects. You may experience the following side effects:

stomach or bowel problems such as:

- nausea

skin or hair problems such as:

- skin rash or itching
- changes in hair growth

other changes or problems such as:

- headache
- swelling due to fluid retention (oedema)
- visual disturbances
- 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 Trisequens):

- severe pain or swelling in your legs
- any type of blood clots
- yellow colouring of the skin and eyes (jaundice)
- migraine or sudden severe headache
- problems with your eyesight
- rise in blood pressure
- you know or suspect you are pregnant

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Storage

Keep all medicines out of reach of children.

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

Product Description

What Trisequens® looks like

Trisequens comes in a calendar dial pack. Each pack holds 28 round tablets.

Trisequens contains:

12 blue tablets marked 'NOVO 280' on one side.

10 white tablets marked 'NOVO 281' on one side

6 red tablets marked 'NOVO 282' on one side

Ingredients

Oestradiol is identical to natural human oestrogen. Norethisterone acetate is a hormone similar to progesterone.

Each blue tablet contains 2mg oestradiol (as hemihydrate) as the active ingredient and indigo carmine CI73015 as a colouring agent.

Each white tablet contains 2mg oestradiol (as hemihydrate) and 1mg norethisterone acetate as the active ingredients.

Each red tablet contains 1mg oestradiol (as hemihydrate) as the active ingredient and iron oxide red CI77491 as a colouring agent.

The tablets also contain lactose, maize starch, gelatin, talc, magnesium stearate, hypromellose, titanium dioxide, glycerol triacetate, macrogol 400 and propylene glycol.

Trisequens is gluten-free.

Manufacturer

Trisequens is made in Denmark and supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

ABN 40 002 879 996

Level 3

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

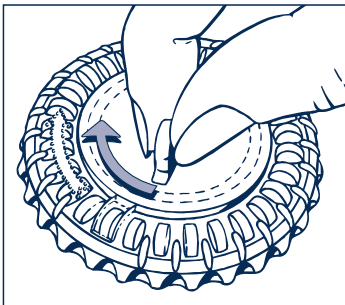
Trisequens[®]

Oestradiol/Norethisterone acetate

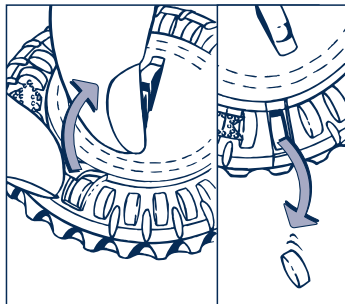
Directions for Use

Follow these steps to use the calendar dial pack.

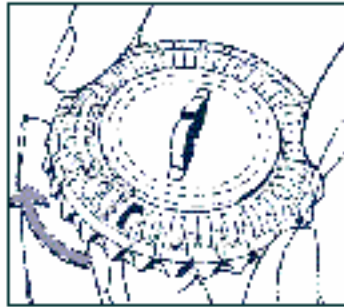
The first tablet to be taken is under the sealed opening in the see-through outer rim of the pack. This is a blue tablet.



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. Do not turn the dial until you have lifted off the plastic tab. Continue until all tablets have been taken.

Begin by taking the blue tablets for 12 days, followed by the white tablets for 10 days and finally the red tablets for 6 days.