

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 or night sweats.

Trisequens[®] contains two hormones, an oestrogen (oestradiol) and a progestogen (norethisterone acetate). The oestradiol in Trisequens[®] is identical to the oestradiol produced in the ovaries of women, and is classified as a natural oestrogen. Norethisterone acetate is a synthetic progestogen which acts in a similar manner as progesterone, another important female sex hormone.

The oestrogen in Trisequens[®] relieves the symptoms caused by a lack of oestrogen. The progestogen 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, or you have had, a tumour which depends on hormones (e.g. cancer of the lining of the womb)
- you know or suspect you have, or you have had, breast cancer

- you have porphyria (a rare disease of blood pigments)
- you have recently developed liver disease; or you have a history of liver disease where your blood test results have not returned to normal
- you have any unexplained vaginal bleeding
- you have a condition known as endometrial hyperplasia (overgrowth of the lining of the womb), and it is not being treated by your doctor
- you know that you are allergic to any of the ingredients in Trisequens[®]
- you have or have ever had blood clots in a vein (venous thromboembolism), in the legs (e.g. deep vein thrombosis or 'DVT'), or the lungs (pulmonary embolism)
- you have a blood clotting disorder (thrombophilic disorder such as protein C, protein S or antithrombin deficiency)
- you have recently had angina, a heart attack, or a stroke
- 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

Medical check-ups

Before you start taking HRT, your doctor should ask about your own and your family's medical history.

Your doctor may decide to examine your breasts and/or your abdomen, and may do an internal examination — but only if these examinations are necessary for you, or if you have any special concerns.

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.

Be sure to:

- go for regular breast screening and pap smear tests
- regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple, or any lumps you can see or feel.

The experience of treating women older than 65 years' is limited.

Tell your doctor if:

- you have previously taken oestrogen by itself for menopausal symptoms. The long-term use of oestrogen without a progestogen can increase the risk of cancer of the lining of the womb.
- you have had a hysterectomy (surgical removal of the womb), because another medicine may be more suitable for you
- you have a family history of blood clots
- you need a blood test, as oestrogen can affect the results
- you 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 Trisequens[®] 4 to 6 weeks before your operation, to reduce the risk of a blood clot.
- you have an intolerance to some specific sugars e.g. lactose (found in milk and milk products). Trisequens[®] tablets contain lactose.

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

- fibroids of the womb or endometriosis. Fibroids may increase in size while taking Trisequens[®].
- a history of excessive growth of the cells which line the womb
- family history of hormone-dependent cancer e.g. cancer of the breast or of the lining of the womb
- risk factors for blood clots e.g. you are seriously overweight, you have previously experienced one or more miscarriages

- low levels of thyroid hormone requiring supplementation
- systemic lupus erythematosus (SLE)
- epilepsy
- migraine or severe headache,
- diabetes
- asthma
- gallstones
- a liver disorder (e.g. liver adenoma)
- kidney disease
- heart disease
- high blood pressure
- otosclerosis (hearing loss sometimes linked to pregnancy)
- you or your family have a history of swelling of the face, lips, mouth, tongue etc. (angioedema).

This is because you will need to be seen regularly by your doctor while you are taking Trisequens[®].

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

Tell your doctor immediately if any of the following conditions occur (because you may be told to stop taking Trisequens[®]):

- yellowing of your skin or eyes, or worsening of your liver function
- significant increase in your blood pressure
- migraine-like headache, and you have not previously had migraines
- sudden development of visual problems
- pregnancy
- or if you experience any of the conditions listed above under 'When you must not take it'.

Bleeding with Trisequens[®]

Trisequens[®] will cause a menstruation-like monthly bleeding, which usually occurs at the beginning of a new pack.

Tell your doctor as soon as possible if you have any breakthrough bleeding or spotting that continues on for more than the first few months, or starts after some time on HRT,

or continues even if you have stopped taking Trisequens[®].

Tell your doctor if your periods get heavier than normal.

Trisequens[®] will not prevent memory loss.

Review the risks and benefits of continued treatment with Trisequens[®] at least once a year with your doctor.

Taking other medicines

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

- other oestrogen medicines
- 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, penicillin, cyclosporin
- St. John's Wort – used to treat depression
- antihistamines – used to treat allergies
- anticoagulants and antifibrinolytics – used to manage blood clotting processes
- antidiabetic drugs – used to treat diabetes
- medicines which decrease serum folate
- thyroid hormones – used to treat malfunction of the thyroid gland
- corticosteroids – used to treat inflammatory conditions

Or other specific medicines including:

- imipramine
- 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, and may affect your vaginal bleeding pattern.

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.

How long to take it

HRT should be prescribed at the lowest effective dose and for the shortest duration necessary (see 'Before you start to take it'). 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 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.

Do not take a double dose to make up for a forgotten tablet.

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. You may experience the following side effects:

- breast tenderness, pain or enlargement
- irregular periods or excessive bleeding during your periods
- period pain
- abdominal (stomach) pain, indigestion, feeling sick (nausea), vomiting, diarrhoea, bloating, flatulence
- skin rash or itching, skin reactions, acne, changes in hair growth, hair loss
- headache, migraine, dizziness
- changes in sexual appetite, problems getting to sleep, nervousness
- gall bladder problems, gallstones
- leg cramps
- back pain
- weight change
- swelling due to fluid retention (oedema)
- visual disturbances
- increase in size of uterine fibroids
- fungal infection of the vagina (thrush), vaginal inflammation or itching
- Trisequens® does not treat your symptoms effectively

These side effects are usually temporary and disappear.

Tell your doctor if:

- you think you may be suffering from depression
- 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, and you have not previously had migraines
- problems with your eyesight which develop suddenly
- marked rise in blood pressure
- you can see or feel a lump in your breast, or you notice dimpling of the skin or changes in the nipple
- you know or suspect you are pregnant

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- skin rashes over a large part of the body
- shortness of breath, wheezing
- swelling of the face, lips or tongue
- fast pulse
- sweating

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Effects on your heart or circulation

Heart disease

Talk to your doctor to see if you should be taking HRT if you have ever had heart disease.

HRT is not recommended for women who have heart disease, or have had heart disease recently. If you have ever had heart disease,

HRT will not help to prevent heart disease.

Studies with one type of HRT (containing conjugated oestrogen plus the progestogen MPA) have shown that women may be slightly more likely to get heart disease during the first year of taking the medication. For other types of HRT, the risk is likely to be similar, although this is not yet certain.

See a doctor as soon as possible and do not take any more HRT until your doctor says you can if you get:

- a pain in your chest that spreads to your arm or neck.

This pain could be a sign of heart disease.

Stroke

Recent research suggests that HRT slightly increases the risk of having a stroke. Other things that can increase the risk of stroke include:

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

Talk to your doctor to see if you should take HRT if you are worried about any of these things, or if you have had a stroke in the past.

See a doctor as soon as possible and do not take any more HRT until your doctor says you can if you get:

- unexplained migraine-type headaches, with or without disturbed vision. These headaches may be an early warning sign of a stroke.

Blood clots

HRT may increase the risk of blood clots in the veins (also called deep vein thrombosis, or DVT), especially during the first year of taking it.

These blood clots are not always serious, but if one travels to the lungs, it can cause chest pain, breathlessness, collapse or even death. This condition is called pulmonary embolism, or PE.

DVT and PE are examples of a condition called venous thromboembolism, or VTE.

You are more likely to get a blood clot if:

- you are seriously overweight
- you have had a blood clot before
- any of your close family have had blood clots
- you have had one or more miscarriages
- you have any blood clotting problem that needs treatment with a medicine such as warfarin

- you're off your feet for a long time because of major surgery, injury or illness
- you have a rare condition called systemic lupus erythematosus (SLE – an autoimmune disease).

If any of these things apply to you, talk to your doctor to see if you should take HRT.

See a doctor as soon as possible and do not take any more HRT until your doctor says you can if you get:

- painful swelling in your leg
- sudden chest pain
- difficulty breathing.

These may be signs of a blood clot.

Effects on your risk of developing cancer

Breast cancer

Women who have breast cancer, or have had breast cancer in the past, should not take HRT.

Taking HRT slightly increases the risk of breast cancer; so does having a later menopause. The risk for a post-menopausal woman taking oestrogen-only HRT for 5 years is about the same as for a woman of the same age who's still having periods over that time and not taking HRT. The risk for a woman who is taking oestrogen plus progestogen HRT is higher than for oestrogen-only HRT (but oestrogen plus progestogen HRT is beneficial for the endometrium, see 'Endometrial cancer' below).

For all kinds of HRT, the extra risk of breast cancer goes up the longer you take it, but seems to return to normal after stopping HRT.

Your risk of breast cancer is also higher if:

- you have a close relative (mother, sister or grandmother) who has had breast cancer
- you are seriously overweight.

Make an appointment to see your doctor as soon as possible if you notice any changes in your breast, such as:

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

Endometrial cancer (cancer of the lining of the womb)

Taking oestrogen-only HRT for a long time can increase the risk of cancer of the lining of the womb (the endometrium). Taking a progestogen as well as the oestrogen helps to lower the extra risk.

If you still have your womb, your doctor may prescribe a progestogen as well as oestrogen. If so, these may be prescribed separately, or as a combined HRT product.

If you have had your womb removed (a hysterectomy), your doctor will discuss with you whether you can safely take oestrogen without a progestogen.

If you have had your womb removed because of endometriosis, any endometrium left in your body may be at risk. So your doctor may prescribe HRT that includes a progestogen as well as an oestrogen.

Your product, Trisequens[®], contains a progestogen.

If you get breakthrough bleeding or spotting, it's usually nothing to worry about, especially during the first few months of taking HRT.

Make an appointment to see your doctor if the bleeding or spotting:

- carries on for more than the first few months
- starts after you've been on HRT for a while
- carries on even after you've stopped taking HRT.

It could be a sign that your endometrium has become thicker.

Ovarian cancer

Long-term (at least 5 or 10 years') use of oestrogen-only HRTs and oestrogen plus progestogen HRTs has been associated with an increased risk of ovarian cancer in some epidemiological studies.

In addition to the possible side effects listed above, dementia has been reported with HRT.

Do not be alarmed by these lists of possible side effects.

You may not experience any of them.

Storage

Keep all medicines out of reach of children.

Do not use Trisequens[®] after the expiry date stated on the carton and label.

The expiry date refers to the last day of that month.

Keep Trisequens[®] in a cool dry place where the temperature stays below 25°C. Do not put Trisequens[®] in the refrigerator.

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

Do not dispose of medicines down the sink or in your household rubbish. Ask your pharmacist how to dispose of medicines you no longer require.

These measures will help to preserve the environment.

Product Description

What Trisequens[®] looks like

Trisequens[®] comes in a calendar 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

Each blue tablet contains 2mg oestradiol (as hemihydrate) as the active ingredient and indigo carmine CI73015 (E132) 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 (E172) as a colouring agent.

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

stearate, hydroxypropylcellulose, hypromellose, titanium dioxide (E171) (red and blue tablets only), glycerol triacetate (white tablets only), macrogol 400 (blue tablets only) and propylene glycol (red tablets only).

Trisequens[®] is gluten-free.

Manufacturer

Trisequens[®] is made in Denmark and supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 3

21 Solent Circuit

Baulkham Hills NSW 2153

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Trisequens[®] is a registered trademark of Novo Nordisk FemCare AG.

NovoCare[®] is a registered trademark of Novo Nordisk A/S.

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Further information

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

www.novonordisk.com.au

Trisequens[®]

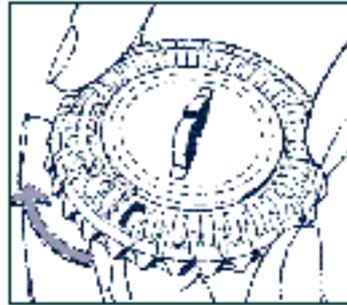
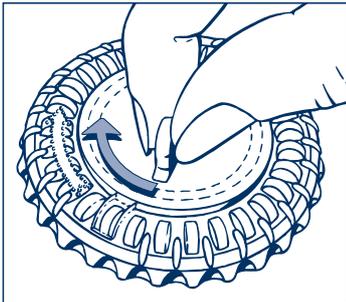
Oestradiol/Norethisterone acetate

Directions for Use

How to use the calendar pack.

1. Set the day reminder

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

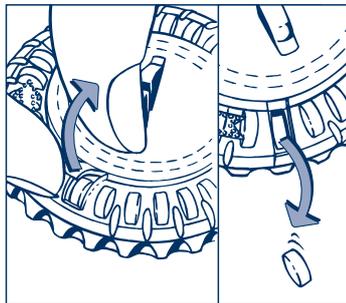


Continue until all tablets have been taken.

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.

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 one 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.