

NORETHINDRONE TABLETS, USP

Norethisterone 350 micrograms

What is in this leaflet

Please read this leaflet carefully before you start using NORETHINDRONE TABLETS, USP.

This leaflet answers some common questions about NORETHINDRONE TABLETS, USP. 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 NORETHINDRONE TABLETS, USP against the benefits they expect it will have for you.

Use NORETHINDRONE TABLETS, USP as directed by your doctor and follow advice given in this leaflet.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What NORETHINDRONE TABLETS, USP is used for

NORETHINDRONE TABLETS, USP is a birth control pill commonly known as a “progestogen-only” pill or “mini pill”. NORETHINDRONE TABLETS, USP is usually given to women who are unable to take other types of birth control pills (combined oral contraceptives) or use intrauterine devices (IUDs).

It is not known exactly how the “progestogen-only” pill works. However, NORETHINDRONE TABLETS, USP causes changes to the mucus of the cervix

and the lining of the womb and affects the hormonal control system of the body which may all contribute to its effectiveness.

The effectiveness of the “progestogen-only” pill is lower than that of other birth control pills.

If taken according to directions it is expected that if 100 women used the progestogen-only pill for 1 year approximately 4 pregnancies may occur compared to less than 1 pregnancy in women using an oral contraceptive containing an estrogen and progestogen.

NORETHINDRONE TABLETS, USP (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

NORETHINDRONE TABLETS, USP day is only available on a prescription from your doctor.

This medicine is prescribed for you and should not be given to others.

Before you use NORETHINDRONE TABLETS, USP

When you must not use it

NORETHINDRONE TABLETS, USP tablets are not suitable for some women.

If you have or have had any of these problems, do not take NORETHINDRONE TABLETS, USP until you have talked to your doctor:

Do not take if:

- you have had a stroke or a heart attack.
- you have clotting in any blood vessel(s) or in the lung.
- you have or have had liver disease (including tumours of any type), a history of jaundice or cholestatic jaundice of pregnancy, or severe generalised itch in the body during pregnancy; Dubin- Johnson Syndrome or Rotor Syndrome.
- you have abnormal vaginal bleeding, the cause of which is unknown.
- you are pregnant or suspect that you may be pregnant.
- you have cancer or suspected cancer of the breast or sex organs (e.g. cervix, ovaries, endometrium, womb).
- you have a lipid metabolism disorder or severe arterial disease.

- you have a history of ectopic pregnancy (a pregnancy in the fallopian tube rather than the womb).
- you have not had your first period.
- you have an allergy to norethisterone or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting.

Tell your doctor about any existing medical condition as this may be affected by taking the birth control pill.

Do not take NORETHINDRONE TABLETS, USP if the packaging is torn or shows signs of tampering.

Before you start to use it

You must have a thorough medical check up including personal and family history and a physical examination.

Tell your doctor if:

- you are a heavy smoker (15 or more cigarettes per day), especially if you are aged over 35 years.

Oral contraceptives increase your risk of having a stroke or heart attack. Smoking while taking oral contraceptives further increases this risk.

- you are over the age of 40
- you have ever had a blood clot
- you or anyone in your immediate family have had cancer or suspected cancer of the breast or sex organs (e.g. cervix, ovaries, endometrium, womb)

- you are overweight, have recently had or are planning to undergo major surgery, or are confined to bed for long periods of time
- you have uterine fibroids
- you have or have had ovarian cysts
- you have malabsorption syndrome
- you have gall bladder disease
- you have diabetes
- you have high blood pressure
- you have high cholesterol
- you suffer from epilepsy
- you have migraine
- you have asthma
- you have liver, heart or kidney disease
- you have or have had any form of depression
- any member of your family has suffered from blood clots, a stroke, or heart attack
- you are lactose intolerant.

This medicine contains lactose.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking NORETHINDRONE TABLETS, USP.

Some medicines may alter the effectiveness of NORETHINDRONE TABLETS, USP. These include medicines such as:

- Rifampicin for the treatment of tuberculosis
- Antibiotics such as ampicillin, oxacillin, tetracyclines, sulfamethoxazole and trimethoprim
- Anti-fungal agents such as griseofulvin
- Medicines for epilepsy or fits such as barbiturates, primidone, carbamazepine and phenytoin

- Medicines used to prevent or relieve the symptoms of allergy (such as hay fever)
- Medicines used to treat or prevent pain
- Anti-migraine preparations
- Phenylbutazone, a medicine used to relieve symptoms of inflammation, including arthritis.
- St John's Wort, an ingredient found in medicines you can purchase without a prescription from a pharmacy, supermarket or health food shop
- Some anti-viral medicines (including protease inhibitors) used in the treatment of HIV/AIDS and hepatitis C
- Antacids used for indigestion or heartburn.

Antacids may decrease the absorption of NORETHINDRONE TABLETS, USP.

If you need to take an antacid while on NORETHINDRONE TABLETS, USP, you should take these medicines at least 2 hours apart.

While you are taking these medicines you should use a non- hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods).

This is particularly important if you need to take antibiotics or medicines for epilepsy.

NORETHINDRONE TABLETS, USP may alter the effectiveness of some medicines. These include:

- Medicines for high blood pressure such as guanethidine
- Medicines to prevent blood clots.

How to use NORETHINDRONE TABLETS, USP

How much to take

Swallow one NORETHINDRONE TABLETS, USP tablet with a glass of water at approximately the same time each day.

Follow the instructions below carefully to ensure birth control reliability.

- To begin NORETHINDRONE TABLETS, USP, take your first tablet on the first day of your next period, that is, the day your bleeding begins.
- Take your first tablet from the top row of the strip. Take the tablet which corresponds to the appropriate day of the week. For example, if your first day of bleeding is on TUESDAY, you should take the tablet marked "TUE" from the top row.
- Continue to take one tablet every day, following the arrows around the strip, until you finish all 28 tablets.
- When you have finished your first strip of tablets start the next strip the following day by taking a white tablet from the top row that matches the day of the week.
- Repeat this sequence of tablet taking for as long as birth control is required. Continue taking the tablets whether you have a period or not.

During the first two weeks of the course only, it is important to use an additional non-hormonal birth control method to provide added protection (such as condoms or a diaphragm with contraceptive gel, but not the rhythm or temperature methods).

Make sure you always have a new strip of tablets available so that you can continue to take the tablets without interruption.

If you are switching to NORETHINDRONE TABLETS, USP from another 21 or 28 Day oral contraceptive, please see your doctor or pharmacist for directions.

If you suffer from a stomach upset which results in vomiting or diarrhoea, the effectiveness of NORETHINDRONE TABLETS, USP will be reduced.

During any period of vomiting or diarrhoea, continue taking NORETHINDRONE TABLETS, USP tablets. Also use a non-hormonal method of contraception (such as condoms or a diaphragm with contraceptive gel, but not the rhythm or temperature methods) until your next period occurs.

When to take it

Take your tablet at approximately the same hour each day. Taking your tablet at the same time each day will also help you remember when to take the tablets.

If you forget to take it

If you forget to take NORETHINDRONE TABLETS, USP it may not work as well in protecting you from becoming pregnant.

Do not try to make up for missed doses by taking more than one tablet at a time.

If you miss a tablet:

If you are less than 3 hours late in taking your tablet, you should take that tablet at once and then take the next one at the usual time, even if it means taking two tablets in the same day.

If you are more than 3 hours late in taking your tablet, still take the tablet, but an additional, non-hormonal method of contraception must also be used for the next 48 hours, whether bleeding occurs or not (such as condoms or a diaphragm with contraceptive gel, but not the rhythm or temperature methods).

If you miss more than two tablets:

Stop taking NORETHINDRONE TABLETS, USP immediately and use a non-hormonal method of birth control (such as condoms or a diaphragm with contraceptive gel, but not the rhythm or temperature methods). Continue this until your period has occurred or until your doctor has confirmed that you are not pregnant.

When you begin taking NORETHINDRONE TABLETS, USP again, start the tablets from a new strip and follow the instructions as if starting NORETHINDRONE TABLETS, USP therapy for the first time. During the first 2 weeks of this first course only, it is important to use an additional, non-hormonal method of contraception (such as condoms or a diaphragm with contraceptive gel, but not the rhythm or temperature methods).

If your doctor has told you to take NORETHINDRONE TABLETS, USP differently, or you are unclear about the above directions, discuss this with him or her.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you miss a period

If you have taken all the tablets correctly, you should not be concerned if you have missed a period. Continue to take your tablets as usual.

However, if you have missed two periods, you should stop taking NORETHINDRONE TABLETS, USP immediately and use a non-hormonal

method of birth control (such as condoms or a diaphragm with contraceptive gel, but not the rhythm or temperature methods). Continue this until your doctor has confirmed that you are not pregnant.

If you have missed taking one or more tablets or have not taken them correctly, and you miss a period, you should stop taking the tablets immediately and use another non-hormonal method of birth control (such as condoms or a diaphragm with contraceptive gel, but not the rhythm or temperature methods). Continue this until your doctor has confirmed that you are not pregnant.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much NORETHINDRONE TABLETS, USP.

Do this even if there are no signs of discomfort or poisoning.

Serious ill effects have not been reported in young children who have taken large doses of birth control pills.

Overdosage may cause nausea or vomiting, breast tenderness, dizziness and/or fatigue. This may be followed by vaginal bleeding and breast enlargement in some women.

While you are using NORETHINDRONE TABLETS, USP

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking NORETHINDRONE TABLETS, USP.

Tell the hospital doctor that you are taking NORETHINDRONE TABLETS, USP birth control pills if you need to have an operation, or go to hospital in an emergency.

If you are about to be started on any new medicine, tell your doctor or dentist and your pharmacist that you are taking NORETHINDRONE TABLETS, USP.

If you become pregnant while taking NORETHINDRONE TABLETS, USP, see your doctor immediately.

If you are planning to become pregnant, speak to your doctor about discontinuing NORETHINDRONE TABLETS, USP.

Visit your doctor regularly for medical check-ups, which may include blood tests, breast, abdomen and pelvic organs checks including a Pap smear and urine tests.

A Pap smear can detect any abnormal cells from the cervix, which may develop into cancer. Cervical cancer has been reported to occur more frequently in women who use oral contraceptives.

Your doctor will advise you of the type and frequency of any tests required.

Perform regular, breast self- examination.

Examining your breasts for lumps or any changes in size or shape can help you find a breast cancer early. Breast cancer has been found more frequently in women who use oral contraceptives. It is not known whether this increase is caused by the use of oral contraceptives, or if it is due to the fact that users were examined more often, and therefore the breast cancer was detected earlier.

If you are unsure, ask your doctor about breast self-examination.

If you are worried about contracting a sexually transmitted disease (STD) use a barrier contraceptive method.

NORETHINDRONE TABLETS, USP does not protect against the transmission of STDs such as HIV-AIDS, chlamydia, genital herpes and warts, gonorrhoea, hepatitis B or human papilloma virus. To protect against STDs ask your partner to wear a condom when having sexual intercourse with you.

Tell your doctor if you feel depressed, think you are retaining water, experience headaches or experience persistent or recurrent irregular bleeding. Your doctor will make an assessment of your condition and advise whether or not you should continue to take NORETHINDRONE TABLETS, USP.

Tell your doctor if you are breastfeeding, or are planning to breastfeed. Small amounts of the drug are found to be excreted into breast milk and there are rare reports of adverse effects on the nursing child, including jaundice.

Your doctor can discuss the risks and benefits involved with you.

Things you must not do

Do not smoke while you are taking oral contraceptives.

Cigarette smoking increases the risk of blood clotting and damage to the heart and blood vessels from birth control pills. The risk increases with age and with heavy

smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age.

Do not stop taking your tablets if a full monthly period or slight spotting starts before all tablets have been taken. Slight spotting during tablet taking is normally of no significance.

See your doctor if bleeding persists, or if heavier bleeding occurs.

Do not take NORETHINDRONE TABLETS, USP past the expiry date shown on the label.

If you take the tablets after the expiry date has passed, they may not work as well.

Things to be careful of

Slight breast tenderness or a feeling of sickness may occur in the first few months of use. This usually improves or stops with continued use.

If vaginal irritation or discharge occurs, it may be an indication of yeast infection for which treatment is available from your doctor.

Women who take **NORETHINDRONE TABLETS, USP** may find a change in the pattern of their period. Changes may occur to the amount of flow as well as the duration of the period. A change in length of your menstrual cycle may also occur.

See your doctor if such bleeding persists, or if heavier bleeding occurs.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NORETHINDRONE TABLETS, USP.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- dizziness, tiredness, nervousness
- changes in appetite
- reduced sex drive

- gastric or stomach discomforts including abdominal pain, cramps, nausea and vomiting
- pain or bleeding after intercourse
- break-through bleeding
- spotting
- change in menstrual flow
- absence of periods
- changes in cervical secretions and erosions
- discharge, itching or pain in the vaginal area
- breast changes (pain, tenderness, enlargement or secretions)
- change in weight
- feeling very thirsty, dry mouth, frequently needing to urinate
- swelling, retention of fluids
- acne
- dark discolouration of the skin
- blotchy discolouration on the face or arms or legs (which may persist after the tablets have been stopped)
- rash (with or without itching)
- changes in mood, including depression
- excessive hair growth or hair loss
- may affect the development of your fetus
- changes to the results of your cholesterol and liver function tests
- exacerbation of porphyria.

Since the effects of long term use of “progestogen-only” pills are not known, women should be aware of the serious side effects which have occurred with other oral contraceptives known as “Combined Oral Contraceptives”. The “Combined Oral Contraceptives” contain estrogen and progestogen hormones.

The most serious known side effect with Combined Oral Contraceptive use is abnormal blood clotting which may have serious consequences. Deaths have occurred in some women as a result of blood clots carried by the blood stream causing obstruction of blood vessels in the lungs or in the brain. The risk of developing blood clotting disorders and other blood vessel diseases in oral contraceptive users increases with age from 30 years onwards. Cigarette smoking also increases the risk. These problems may persist after a woman has stopped taking the birth control pill.

The use of a Combined Oral Contraceptive can increase the risk of a woman having a heart attack. Other risk factors for a heart attack include cigarette smoking; high blood pressure; high cholesterol; obesity; diabetes; a history of pre- eclamptic toxemia in pregnancy and age over 40 years.

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

- sharp, one-sided abdominal pain
- weakness or paralysis of the face, arm or leg on either or both sides of the body
- difficulty speaking, understanding or swallowing
- unexplained or persistent pains in the head, chest, stomach or legs
- swelling, warmth and tenderness in the leg
- shortness of breath
- gradual or sudden, partial or complete loss of vision
- double vision, or symptoms of severe vision impairment
- eye protrusion, swelling of the eye or eye lesions
- migraine headaches for the first time
- more frequent or severe migraines if you already suffer from them
- breast lumps
- jaundice or a yellowing of the skin or eyes, often with fever, fatigue, loss of appetite, dark coloured urine, nausea and vomiting. Taking oral contraceptives may be associated with liver disease, including liver cancer
- rise in blood pressure
- swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Rarer side effects associated with the use of NORETHINDRONE TABLETS, USP and combined oral contraceptives are not listed here. You may wish to discuss these, or any of the side effects listed above, with your doctor if you are concerned.

Side effects not previously reported with NORETHINDRONE TABLETS, USP may also occur. **If you notice anything unusual while you are taking NORETHINDRONE TABLETS, USP, see your doctor.**

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

You may not experience any of them.

After stopping NORETHINDRONE TABLETS, USP

Delays in becoming pregnant may occur after NORETHINDRONE TABLETS, USP therapy is stopped. This is more likely to occur in women whose periods were irregular before using birth control pills.

See your doctor if you continue to experience difficulties in falling pregnant.

After using NORETHINDRONE TABLETS, USP

Storage

Keep your tablets in a safe place away from the sight and reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your NORETHINDRONE TABLETS, USP tablets in a dry place, at 20°C to 25°C.

Do not keep your tablets in the refrigerator.

Do not store NORETHINDRONE TABLETS, USP or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking NORETHINDRONE TABLETS, USP or if the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

NORETHINDRONE TABLETS, USP is available in carton packs consisting of three dispensers of tablets (3 months' supply) each with 28 light yellow to yellow round, flat faced beveled edged, uncoated tablets with '305' debossed on one side and a 'G' on the other side

Ingredients

Active ingredient:

- norethisterone 350 micrograms (µg).

Inactive ingredients:

- silicon dioxide
- corn starch
- D&C Yellow No. 10
- ethylcellulose, unspecified
- anhydrous lactose
- magnesium stearate
- microcrystalline cellulose
- povidone, unspecified
- talc

Sponsor Details

NORETHINDRONE TABLETS, USP is supplied in New Zealand by:

ORSPEC Pharma Management Limited
PO BOX 59013
Mangere Bridge
Auckland 2151
NEW ZEALAND

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