

NORIDAY[®] 28 DAY

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NORIDAY 28 DAY?

NORIDAY 28 DAY contains the active ingredient norethisterone. NORIDAY 28 DAY is used to prevent pregnancy.

For more information, see Section [1. Why am I using NORIDAY 28 DAY?](#) in the full CMI.

2. What should I know before I use NORIDAY 28 DAY?

Do not use if you have ever had an allergic reaction to norethisterone, or any other similar oral contraceptives, or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use NORIDAY 28 DAY?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NORIDAY 28 DAY and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use NORIDAY 28 DAY?

- Take one tablet at the same time every day, regardless of whether you have sex.
- See the full CMI for instructions on how to start taking NORIDAY 28 DAY for the first time.

More instructions can be found in Section [4. How do I use NORIDAY 28 DAY?](#) in the full CMI.

5. What should I know while using NORIDAY 28 DAY?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, or pharmacist you visit that you are using NORIDAY 28 DAY.• Tell your doctor immediately if you become pregnant while taking NORIDAY 28 DAY.• See your doctor if you have not taken your tablets correctly and have missed a period.• Have regular check-ups from your doctor, including a Pap smear.• Perform regular breast self-examination.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine or change the dosage, without checking with your doctor. If you stop taking NORIDAY 28 DAY or do not take a tablet every day without using another form of contraception, you may become pregnant.
Driving or using machines	<ul style="list-style-type: none">• Make sure you know how NORIDAY 28 DAY affects you before you drive or use machines. NORIDAY 28 DAY may cause dizziness in some people.
Looking after your medicine	<ul style="list-style-type: none">• Keep NORIDAY 28 DAY in a cool, dry place where the temperature stays below 25°C.• Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack, they may not keep well.

For more information, see Section [5. What should I know while using NORIDAY 28 DAY?](#) in the full CMI.

6. Are there any side effects?

Common side effects include changes to your bleeding patterns, breast tenderness, changes in sex drive, abdominal pain, cramps or bloating, changes to your mood, headaches, weight changes, swelling of the hands, ankles or feet, acne, loss of scalp hair, increase in body hair. More serious side effects include blood clots, worsening or new onset of migraines/headaches, jaundice (yellowing of skin or eyes), significant rise in blood pressure, worsening of existing conditions such as porphyria.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

NORIDAY[®] 28 DAY

Active ingredient(s): *norethisterone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NORIDAY 28 DAY. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NORIDAY 28 DAY.**

Where to find information in this leaflet:

- [1. Why am I using NORIDAY 28 DAY?](#)
- [2. What should I know before I use NORIDAY 28 DAY?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use NORIDAY 28 DAY?](#)
- [5. What should I know while using NORIDAY 28 DAY?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using NORIDAY 28 DAY?

NORIDAY 28 DAY contains the active ingredient norethisterone. NORIDAY 28 DAY is a birth control pill commonly known as a "progestogen-only" pill or "mini pill". **NORIDAY 28 DAY is used to prevent you from becoming pregnant.**

NORIDAY 28 DAY is usually given to women who are unable to take other types of birth control pills (oral contraceptives) or use intrauterine devices (IUDs).

NORIDAY 28 DAY 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 the birth control (contraceptive) action.

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.

Your doctor may have prescribed NORIDAY 28 DAY for another reason.

Ask your doctor if you have any questions about why NORIDAY 28 DAY has been prescribed for you.

2. What should I know before I use NORIDAY 28 DAY?

Warnings

Do not use NORIDAY 28 DAY if:

- You are allergic to norethisterone, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - Shortness of breath
 - Wheezing or difficulty breathing
 - Swelling of the face, lips, tongue or other parts of the body

- Rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

- You have, or have had, any of the following conditions:
 - a stroke or heart attack
 - inflammation, infection or clotting in any blood vessel(s), including a clot in the lung
 - 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
 - sickle cell anaemia
 - lipid metabolism disorders
 - a history of herpes of pregnancy
 - otosclerosis (an ear disorder) which worsened in past pregnancies
 - a family history of breast nodules, fibrocystic disease or have had an abnormal mammograph.
 - cancer or suspected cancer of the breast or sex organs (e.g. cervix, vagina, ovaries, womb) or known or suspected estrogen-dependent tumours
 - abnormal vaginal bleeding, the cause of which is unknown
- You are pregnant or suspect that you may be pregnant
- You have not had your first period

Check with your doctor if you:

- Take any medicines for any other condition
- 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 or anyone in your immediate family has, or has had blood clots in the legs or lungs
- Are overweight, has recently had or are planning to undergo major surgery, or are confined to bed for long periods of time
- Have, or have had, any other medical conditions, such as:
 - liver, kidney or heart disease
 - high blood pressure
 - high cholesterol
 - diabetes
 - epilepsy
 - asthma
 - migraine
 - depression
- Are lactose intolerant. This medicine contains lactose.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend 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.

Long-term use

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

The most serious known side effect with Combined Oral Contraceptive use is abnormal blood clotting and the increased risk of a woman having a heart attack.

See further information under Section [6. Are there any side effects?](#)

Medical check ups

Before you start to take NORIDAY 28 DAY you must have a thorough medical check-up, including a Pap smear, breast check, blood pressure check and urine test.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NORIDAY 28 DAY and affect how well it or the other medicine works. This may lead to unwanted side effects, reduce the effect of NORIDAY 28 DAY and/or the other medicine.

These medicines include:

- Rifampicin for the treatment of tuberculosis.
- Medicines used to treat epilepsy or fits such as barbiturates, primidone, phenytoin and carbamazepine.
- Antibiotics such as ampicillin
- Anti-fungal agents such as griseofulvin.
- St John's Wort, an ingredient found in medicines you can purchase without a prescription from a pharmacy, supermarket or health food shop.
- Some antiviral 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 NORIDAY 28 DAY. If you need to take an antacid while on NORIDAY 28 DAY, you should take these medicines at least 2 hours apart.

Your doctor will advise you if you need to take extra contraceptive precautions for the time that you are taking these medicines or if you have recently stopped taking these medicines.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NORIDAY 28 DAY.

4. How do I use NORIDAY 28 DAY?

How much to take

- Take one tablet every day.
- Follow the instructions provided and use NORIDAY 28 DAY until your doctor tells you to stop.

When to take NORIDAY 28 DAY

- NORIDAY 28 DAY should be taken at the same time every day regardless of whether you have sex.

How to take NORIDAY 28 DAY

- Swallow one NORIDAY 28 DAY tablet with a glass of water.

How to start taking NORIDAY 28 DAY for the first time:

- To begin NORIDAY 28 DAY, 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.

Switching to NORIDAY 28 DAY from another 21 or 28 Day oral contraceptive:

See your doctor or pharmacist for directions.

If you vomit or have diarrhoea after taking NORIDAY 28 DAY

If you suffer from a stomach upset which results in vomiting or diarrhoea, the effectiveness of NORIDAY 28 DAY will be reduced.

During any period of vomiting or diarrhoea, continue taking NORIDAY 28 DAY 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.

If you forget to take NORIDAY 28 DAY

NORIDAY 28 DAY should be taken regularly at the same time each day. If you miss your dose at the usual time, it may not work as well in protecting you from becoming pregnant.

Do not take a double dose to make up for the dose you missed.

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.
- 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 until your next period occurs (such as condoms or a diaphragm with contraceptive gel, but not the rhythm or temperature methods).

If you miss two or more tablets:

- Stop taking NORIDAY 28 DAY 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 NORIDAY 28 DAY again, start the tablets from a new strip and follow the instructions as if starting NORIDAY 28 DAY 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 NORIDAY 28 DAY differently, or you are unclear about the above directions, discuss this with them.

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

If you take too much NORIDAY 28 DAY

If you think that you have taken too much NORIDAY 28 DAY, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while using NORIDAY 28 DAY?

Things you should do

- Tell all doctors, dentists and pharmacists who are treating you that you are taking NORIDAY 28 DAY.

- Tell the hospital doctor that you are taking NORIDAY 28 DAY 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 NORIDAY 28 DAY.
- Tell your doctor if you feel depressed, think you are retaining water, experience headaches or experience persistent or recurrent irregular bleeding.

Your doctor will assess your condition and advise whether or not you should continue to take NORIDAY 28 DAY.

- If you are about to have any blood tests, tell your doctor you are taking NORIDAY 28 DAY. It may interfere with the results of some tests.

Missed periods

- 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 NORIDAY 28 DAY 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 have not had a period within 6 weeks of your last 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.

Call your doctor straight away if you:

- Become pregnant, or think you are pregnant, while taking NORIDAY 28 DAY.

Things to be aware 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 NORIDAY 28 DAY 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.

Medical check up

- Visit your doctor regularly for check-ups, including blood pressure, 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.

Breast cancer risk

- 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.

Sexually transmitted disease (STD)

- If you are worried about contracting a sexually transmitted disease (STD) use a barrier contraceptive method.
- NORIDAY 28 DAY 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.

Things you should not do

- Do not take NORIDAY 28 DAY if the packaging is torn or shows signs of tampering.
- Do not use this medicine after the expiry date. If it is expired or is damaged, return it to your pharmacist for disposal. NORIDAY 28 DAY may have no effect at all, or worse, have an entirely unexpected effect, if you take it after the expiry date.
- Do not stop taking NORIDAY 28 DAY, or change the dosage, without checking with your doctor.

If you stop taking NORIDAY 28 DAY or do not take a tablet every day, without using another form of contraception, you may become pregnant.

- 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), especially 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 NORIDAY 28 DAY 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NORIDAY 28 DAY affects you.

NORIDAY 28 DAY may cause dizziness in some people.

Drinking alcohol

No information available.

Looking after your medicine

- Keep your NORIDAY 28 DAY tablets in a dry place, at a temperature below 25°C.
- Do not keep your tablets in the refrigerator.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

After stopping NORIDAY 28 DAY

Delays in becoming pregnant may occur after NORIDAY 28 DAY 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.

When to discard your medicine

If your doctor tells you to stop taking NORIDAY 28 DAY or if the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
<p>Reproductive or breast problems:</p> <ul style="list-style-type: none"> • pain or bleeding after intercourse • break-through bleeding • spotting • change in menstrual flow • absence of periods • changes in cervical secretions • discharge, itching, pain in the vaginal area, or changes in vaginal secretions • breast changes (pain, tenderness, enlargement or secretion) • reduced sex drive <p>Stomach problems, such as:</p> <ul style="list-style-type: none"> • changes in appetite • gastric or stomach discomforts including abdominal pain, cramps, nausea and vomiting <p>Difficulties thinking or working because of:</p> <ul style="list-style-type: none"> • Dizziness, tiredness, nervousness • changes in mood, including depression • feeling very thirsty, dry mouth, frequently needing to urinate <p>Changes to your appearance such as:</p> <ul style="list-style-type: none"> • change in weight • 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) • excessive hair growth or hair loss <p>NORIDAY 28 DAY may also impact the results of your cholesterol and liver function tests.</p>	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Reproductive problems:</p> <ul style="list-style-type: none"> • effects on the development of your foetus <p>Worsening of your existing conditions such as:</p> <ul style="list-style-type: none"> • porphyria (a group of disorders that can cause skin or nerve problems) <p>Pain or discomfort:</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • sharp, one-sided abdominal pain • unexplained or persistent pains in the head, chest, stomach or legs • severe pain, swelling or discolouration in either of your legs <p>Problems with your eyes or eyesight:</p> <ul style="list-style-type: none"> • 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 <p>Migraines:</p> <ul style="list-style-type: none"> • migraine headaches for the first time • more frequent or severe migraines if you already suffer from them <p>Changes to your body:</p> <ul style="list-style-type: none"> • 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. • swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing. • rise in blood pressure <p>You may experience headache, blurred vision or palpitations. Sometimes your blood pressure may rise without you experiencing any symptoms. It is important to keep your routine doctor's appointments so that your blood pressure can be checked.</p>	<p>these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

You may wish to discuss these, or any of the side effects listed above, with your doctor if you are concerned.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NORIDAY 28 DAY contains

Active ingredient (main ingredient)	norethisterone 350 micrograms (mcg)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• magnesium stearate• povidone• maize starch• lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

NORIDAY 28 DAY does not contain sucrose, gluten or tartrazine.

What NORIDAY 28 DAY looks like

NORIDAY 28 DAY is available in calendar packs consisting of four strips of tablets (4 months' supply) each with 28 white tablets marked "SEARLE" on one side and "NY" on the other. (AUST R 10052).

Who distributes NORIDAY 28 DAY

Pfizer Australia Pty Ltd

Sydney NSW

Toll free number: 1800 675 229

www.pfizermedicalinformation.com.au

This leaflet was prepared in November 2023.