

NORIMIN(R) 28 Day Tablets

Ethinylloestradiol and Norethisterone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NORIMIN 28 Day tablets.

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 NORIMIN against the benefits it is expected to have for you.

Use NORIMIN as directed by your doctor and follow advice given in this leaflet.

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 NORIMIN is used for

NORIMIN is a birth control pill commonly known as a "Combined Oral Contraceptive" that contains both an oestrogen (ethinylloestradiol) and progestogen (norethisterone) hormone.

Oral contraceptives belonging to this group produce their birth control (or contraceptive) effect by preventing ovulation (the release of an egg from the ovary) during each menstrual

cycle. Combined Oral Contraceptives also cause changes to the mucus of the cervix and the lining of the womb, which contribute to the contraceptive action.

If taken according to directions the combined oral contraceptives are very effective in preventing pregnancy. The failure rate of this type of contraceptive is such that for every 1,000 women using the pill for one year, two will become pregnant.

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

NORIMIN 28 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 start to take NORIMIN

When you must not take it

NORIMIN 28 Day tablets are not suitable for some women.

If you have or have had any of these problems, do not take NORIMIN until you have talked to your doctor.

Do not take it if:

- * you have had a stroke or heart attack.

- * you have or have had inflammation, infection or clotting in any blood vessel(s), including a clot 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, vagina, ovaries, endometrium, womb) and known or suspected oestrogen-dependent tumours.
- * you have a family history of breast nodules, fibrocystic disease or have had an abnormal mammograph.
- * you have sickle cell anaemia.
- * you have lipid metabolism disorders such as congenital hyperlipidaemia.
- * you have diabetes with blood vessel damage.
- * you have a history of herpes of pregnancy.
- * you have otosclerosis (an ear disorder) which worsened in past pregnancies.
- * you have an allergy to ethinylloestradiol, 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 NORIMIN if the packaging is torn or shows signs of tampering.

Before you start to take it

You must 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 have gallbladder disease.
- * you have kidney or heart disease.
- * you have high blood pressure.
- * you have high cholesterol.
- * you have diabetes.
- * you have epilepsy.
- * you have asthma.
- * you have migraine
- * you have or have had depression.
- * you are breastfeeding.

Small amounts of oral contraceptives have been found in breast milk.

- * you wear contact lenses.
- * you are lactose intolerant. This medicine contains lactose.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from

your pharmacy, supermarket or health food shop.

Some medicines may interfere with the effectiveness of NORIMIN.

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.
- * Barbiturates.
- * Medicines for epilepsy such as carbamazepine and phenytoin.
- * 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.

While you are taking these medicines, and for seven days after stopping them, you should use a non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods). If the seven days extend into the inactive orange tablet section, then you should start a new pack on the next day after having taken the last blue active tablet from the current pack.

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

How to take NORIMIN

How to take it

Swallow one NORIMIN tablet with a glass of water at the same time each day, preferably at bedtime.

Starting a hormonal contraceptive for the first time

- * To begin NORIMIN 28 Day, take your first tablet on the first day of your next period, that is, the day your bleeding starts.
- * Take your first tablet from the top row of the silver section of the strip (ie the section which contains all the blue tablets). Take the tablet which corresponds to the appropriate day of the week. For example, if your first day of bleeding is on TUESDAY, take the blue tablet marked "TUE" from the top row of the silver section of the strip.
- * Continue to take one tablet every day, following the arrows around the strip, until you finish all 21 blue tablets in the silver section of the strip.
- * Then take one orange tablet daily for the next 7 days, following the arrows so that you are taking the correct tablet for the day of the week. Taking these orange tablets helps you to remember to take a tablet every day.

You can expect your period during the week that you are taking these orange inactive tablets. Your protection continues during this week.

- * On the day after your last orange tablet, begin the next strip with a blue tablet from the top row of the silver section that matches the day of the week. Do this even if you are still bleeding.
- * You should start your tablets the same day of the week every 4 weeks.
- * Repeat this sequence of tablet taking for as long as birth control is required.

This product is effective from the first day if taken as directed above.

Although spotting and break-through bleeding may occur in some women, these tend to disappear in the majority of patients after the first three to four cycles.

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

Changing from a different oral contraceptive

If you are switching to NORIMIN 28 Day from another 21 or 28 Day oral contraceptive, follow the instructions below carefully.

If switching from a 21 day oral contraceptive:

- * Stop taking your current oral contraceptive after you have taken the last active tablet.
- * Leave 7 tablet-free days.
- * Start the new NORIMIN 28 Day pack on the eighth day by taking a blue active tablet from the top row of the silver section which corresponds to the day of the week.
- * Continue to take one tablet every day, following the arrows around the strip until you finish all 21 blue tablets in the silver section of the strip.
- * Then take one orange tablet daily for the next 7 days, before starting your new strip.

You must use an additional, non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a blue tablet has been taken daily for 7 days without a break.

If switching from a 28 day oral contraceptive:

- * Stop taking your current oral contraceptive after you have taken the last inactive tablet in the strip.
- * Start the new NORIMIN 28 Day pack on the next day by taking a blue active tablet from the top row which corresponds to the day of the week.
- * Continue to take one tablet every day, following the arrows around the strip until you finish all 21 blue tablets in the silver section of the strip.

- * Then take one orange tablet daily for the next 7 days, before starting your new strip.

You must use an additional, non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a blue tablet has been taken daily for 7 days without a break.

If you suffer from a stomach upset which results in vomiting or diarrhoea, the effectiveness of NORIMIN may be reduced.

During any period of vomiting or diarrhoea, continue taking NORIMIN tablets. Also use a non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods), and continue for seven days following the episode of vomiting or diarrhoea. If these seven days extend into the inactive orange tablet section you should start a new pack on the next day after having taken the last active blue tablet from the silver section of the current pack (i.e. skip the orange inactive tablets).

You may not have a period until you finish the second pack.

When to take it

Take your tablet at approximately the same time each day, preferably at bedtime.

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

If you forget to take a tablet

If you forget to take NORIMIN 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 blue active tablet:

If you are less than 12 hours late in taking your tablet, you should take that tablet at once and then take the next one at your usual time.

If you are more than 12 hours late in taking your tablet, do not take it.

Take the next day's tablet at the usual time and use an additional, non-hormonal method of contraception for the next seven days (such as condoms or a diaphragm, but not the rhythm or temperature methods).

If the seven days extend into the inactive orange tablet section, do not take the orange tablets. Start a new pack on the day after taking the last active tablet from the silver section of the current pack. Take your first tablet from the top row of the silver section of the strip, then repeat the sequence of tablet taking for as long as birth control is required. This will mean that you will not have a period until you finish the second pack.

If you miss an orange (inactive) tablet, take it as soon as you remember and continue on as before.

Additional birth control method is not necessary in this case.

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

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

If you miss a period

If you have missed a period you may be pregnant.

Contact your doctor to check if you are pregnant.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much NORIMIN. 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. This may be followed by vaginal bleeding in some women.

While you are taking NORIMIN

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking NORIMIN.

Tell the hospital doctor that you are taking NORIMIN 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 NORIMIN.

If you become pregnant while taking NORIMIN, see your doctor immediately.

Visit your doctor regularly for check-ups, including a Pap smear.

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 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.

NORIMIN 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, experience persistent or recurrent irregular bleeding, or your eyes are uncomfortable whilst wearing contact lenses.

Your doctor will make an assessment of your condition and advise whether or not you should continue to take NORIMIN.

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 such bleeding persists, or if heavier bleeding occurs.

Do not take NORIMIN 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.

Talk to your doctor if you are breast feeding.

NORIMIN may affect the amount and quality of breast milk as the components of NORIMIN are found in breast milk.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NORIMIN.

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 side 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:

- * break-through bleeding
- * spotting
- * gastric or stomach discomforts including nausea, vomiting and diarrhoea
- * change in appetite
- * change in menstrual flow
- * absence of periods
- * change in weight
- * retention of fluids
- * dark discolouration of the skin
- * blotchy discolouration on the face or arms or legs (which may persist after the tablets have been stopped)

- * breast changes (tenderness, enlargement and secretion)
- * headache, dizziness
- * mental depression
- * fatigue or tiredness
- * hair growth or loss of scalp hair
- * acne, rashes, itching
- * leg cramps
- * back ache
- * change in sexual drive
- * vaginal thrush, vaginal irritation, bladder irritation or urinary tract infection
- * pre-menstrual-like symptoms
- * change in cervical secretions
- * suppression of milk production

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 toxæmia 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:

- * unexplained or persistent pains in the head, chest, stomach or legs
- * 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 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 NORIMIN may also occur.

If you notice anything unusual while you are taking NORIMIN, see your doctor.

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

You may not experience any of them.

After stopping NORIMIN

Delays in becoming pregnant may occur after NORIMIN 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 taking NORIMIN

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 NORIMIN tablets in a dry place, at a temperature below 25 degrees C.

Do not keep your tablets in the refrigerator.

Do not store NORIMIN 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 NORIMIN 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

NORIMIN 28 Day is available in calendar packs consisting of four strips of tablets (4 months' supply) each with 21 blue active tablets marked "SEARLE" on one side and "BX" on the other, and 7 orange inactive tablets.

Ingredients

Each blue tablet contains

- * norethisterone 500 micrograms (mcg)
- * ethinylloestradiol 35 micrograms (mcg)
- * magnesium stearate

- * povidone
- * maize starch
- * lactose
- * indigo carmine CI 73015.

The orange inactive tablets contain

- * magnesium stearate
- * cellulose microcrystalline
- * lactose
- * sunset yellow FCF (CI No. 15985).

NORIMIN does not contain sucrose, gluten or tartrazine.

Identification

NORIMIN can be identified by the Australian Register Number on the carton labels.

NORIMIN 28 Day Tablets -

AUST R 62133

Supplier

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia

Toll Free number: 1800 675 229

This leaflet was prepared in December 1997, revised in September 2005.

(C) Pfizer Australia Pty Ltd (2005)

(R) Registered trademark