

Norinyl-1[®] 28 Day

Mestranol and Norethisterone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Norinyl-1 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 Norinyl-1 against the benefits it is expected to have for you.

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 Norinyl-1 is used for

Norinyl-1 is a combined oral contraceptive, commonly known as a "birth control pill" or "the Pill". It contains both an

oestrogen (mestranol) 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.

Ask your doctor if you have any questions about why Norinyl-1 has been prescribed for you.

Your doctor may have prescribed Norinyl-1 28 for another reason.

Norinyl-1 28 Day is only available on a prescription from your doctor.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you start to take Norinyl-1

When you must not take it

Do not take Norinyl-1 if you have an allergy to:

- any medicine containing mestranol or norethisterone
- any of the ingredients listed at the end of this leaflet

- any other similar medicines (such as other oral contraceptives).

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.

Do not take Norinyl-1 if you have or have had any of the following medical conditions:

- venous thromboembolism (VTE) and are on medicines called anticoagulants which are used to "thin the blood"
- blood clots or a history of blood clots in the:
 - legs (thrombophlebitis or deep vein thrombosis (DVT))
 - lungs (pulmonary embolism)
 - eyes.
- hereditary or an acquired disposition for venous thromboembolism
- multiple risk factors VTE including obesity, age above 35 years, smoking, high cholesterol

- major surgery and have been confined to bed for long periods of time
- arterial thromboembolism (ATE) or a past history of these that include:
 - stroke
 - angina
 - transient ischaemic attack or "mini stroke".
- hereditary or an acquired disposition for ATE
- history of migraine, accompanied by blurred vision, difficulty in speaking, muscle weakness, or increased sensitivity to light, sound, or noise
- multiple risk factors for ATE or a serious risk factor for ATE that include:
 - uncontrolled high blood pressure
 - diabetes with blood vessel damage
 - severe lipid disease
 - sickle cell anaemia.
- disease in any blood vessel(s)
- inflammation of the pancreas which is associated with very high blood levels of triglycerides (fatty substances)
- 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

- vaginal bleeding, the cause of which is unknown
- pregnant or suspect that you may be pregnant
- cancer or suspected cancer of the breast or sex organs (e.g. cervix, vagina, ovaries, endometrium, womb) and known or suspected oestrogen-dependent tumours
- a family history of breast nodules, fibrocystic disease or have had an abnormal mammograph
- a history of herpes of pregnancy
- otosclerosis (an ear disorder) which worsened in past pregnancies.

If you are not certain whether these may apply to you, or you are worried by anything in this list, tell your doctor.

Do not take this medicine if you are taking anti-viral hepatitis C virus (HCV) medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin.

If you are not sure about your anti-HCV medication, tell your doctor.

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

Do not take Norinyl-1 if the packaging is torn or shows signs of tampering.

If it is expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

You must have a thorough medical check-up, including a Pap smear, breast check, blood pressure check and urine test.

You must tell your doctor if you or anyone in your immediate family has, or has had blood clots in the legs or lungs.

Blood clots are a rare occurrence when taking an oral contraceptive.

The risk of a blood clot is highest during the first year of taking an oral contraceptive for the first time or if you are re-starting the "pill" after a break of 4 weeks or more.

The risk of having a blood clot is higher in oral contraceptive users than in non-users, but is not as high as during pregnancy.

Tell your doctor about any of the following conditions as these are risk factors for developing blood clots:

- cancer
- systemic lupus erythematosus (SLE)
- haemolytic uraemic syndrome (HUS) - a disorder of blood coagulation causing failure of the kidneys)

- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- sickle cell disease
- smoking particularly if you are heavy smoker (15 or more cigarettes per day) and are aged over 35 years
- have had any recent surgery or trauma
- are pregnant
- had major surgery and have been confined to bed for long periods of time
- also tell your doctor if you are planning a long haul plane flight (greater than 4 hours).

You must tell your doctor if you or anyone in your immediate family has, or has had a stroke or heart attack.

Taking oral contraceptives is linked with an increased risk of having a heart attack, angina, stroke or a "mini stroke".

Tell your doctor if you have any of the following conditions:

- heart disease including heart valve disorders or certain heart rhythm disorders
- high blood pressure
- high cholesterol

- hepatitis C
- diabetes
- migraine or other headaches
- hyperhomocysteinemia.

Tell your doctor if over 35 years of age or are overweight.

If you are not certain whether any of the above may apply to you, check with your doctor. Tell your doctor if you have the following conditions:

- uterine fibroids
- gallbladder disease
- liver, kidney or heart disease
- epilepsy
- asthma
- experience a change in vision or intolerance to your contact lenses. Your doctor may refer you to an eye specialist
- depression
- hereditary angioedema (swelling of the face, lips, mouth, tongue or throat).

If you have any of these conditions you should have regular check-ups with your doctor to make sure that taking Norinyl-1 is not making the conditions worse.

Tell your doctor if you plan to become pregnant or are breastfeeding.

Your doctor can discuss the risks and benefits with you.

If you have not told your doctor about any of the above, tell him/her before you start taking Norinyl-1.

Norinyl-1 contains lactose. If you know that you are intolerant to some sugars, or your doctor has told you so, speak to your doctor before taking it.

Tell your doctor if you are allergic to any foods, dyes, preservatives or any other medicines.

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 Norinyl-1. These include medicines such as:

- anti-viral hepatitis C virus (HCV) medicines such as ombitasvir, paritaprevir, ritonavir and dasabuvir
- rifampicin and rifabutin for the treatment of tuberculosis

- antibiotics such as ampicillin, oxacillin, tetracyclines, sulfamethoxazole and trimethoprim
- anti-fungal agents such as griseofulvin
- barbiturates (medicines prescribed for epilepsy, such as phenobarbitone)
- medicines for epilepsy such as carbamazepine, primidone, topiramate and phenytoin
- ritonavir for the treatment of HIV infection
- modafinil used to treat excessive daytime sleepiness
- corticosteroids such as dexamethasone.
- 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 must 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 white active tablet from the current pack. Skip the 7 orange tablets.

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

Ask your doctor or pharmacist about how long you need to use additional non-hormonal contraception.

Tell your doctor or pharmacist if you are taking any of the following:

- Atorvastatin used to treat high cholesterol
- Indinavir for the treatment of HIV infection
- Anti-fungal medicines such as itraconazole and fluconazole
- Paracetamol and ascorbic acid (Vitamin C).
- Cyclosporin used to prevent organ rejection
- Theophyllines used for asthma and other breathing difficulties
- Corticosteroids
- Lamotrigine for seizures

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Norinyl-1.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are taking this medicine.

How to take Norinyl-1

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Swallow one Norinyl-1 tablet with a glass of water.

When to take it

You must take Norinyl-1 every day, regardless of how often you have sex.

Norinyl-1 will work best if you do not miss any tablets and take it at the same time each day. Taking Norinyl-1 at the same time each day will also help you remember when to take your tablets.

If you are concerned about this, please speak to your doctor or pharmacist.

Starting a hormonal contraceptive for the first time

- To begin Norinyl-1 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 green section of the strip (i.e. the section which contains all the white 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 white tablet marked "TUE" from the top row of the green section of the strip.
- Continue to take one tablet every day, following the arrows around the strip, until you finish all 21 white tablets in the green 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 white tablet from the top row of the green 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 Norinyl-1 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 Norinyl-1 28 Day pack on the eighth day by taking a white active tablet from the top row of the green 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 white tablets in the green 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 white 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 Norinyl-1 28 Day pack on the next day by taking a white 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 white tablets in the green 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 white tablet has been taken daily for 7 days without a break.

If you vomit or have diarrhoea after taking Norinyl-1

If you suffer from a stomach upset which results in vomiting or diarrhoea, the effectiveness of Norinyl-1 may be reduced.

During any period of vomiting or diarrhoea, continue taking Norinyl-1 tablets. Also use a non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature method), 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 white tablet from the green section of the current pack (i.e. skip the orange inactive tablets).

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

If you have vomiting or diarrhoea after taking an orange tablet, do not worry.

If you forget to take a tablet

If you forget to take Norinyl-1 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 white 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, then start a new pack on the day after taking the last white active tablet from the current pack. Take your first tablet from the top row of the new 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 more than one white tablet, contact your doctor for advice on what to do.

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 Norinyl-1 differently, or you are unclear about the above directions, discuss this with him or her.

If you have trouble remembering to take Norinyl-1, 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 Norinyl-1. 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 Norinyl-1

Things you must do

Tell all doctors, dentists, and pharmacists who are treating you that you are taking Norinyl-1.

Tell the hospital doctor that you are taking Norinyl-1 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 Norinyl-1.

If you become pregnant while taking Norinyl-1, see your doctor immediately.

If you are about to have any blood tests, tell your doctor you are taking Norinyl-1.

It may interfere with the results of some tests.

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 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.

Tell your doctor you are taking Norinyl-1 at least 4 weeks before any planned hospitalisation or surgery.

Your doctor may tell you to stop taking Norinyl-1 several weeks before surgery or at the time of immobilisation. Your doctor will tell you when you can start taking Norinyl-1 after you are back on your feet.

To avoid pregnancy during this time you must use a non-hormonal method of contraception such as condoms or a diaphragm.

If you are worried about contracting a sexually transmitted disease (STD) use a condom during sexual intercourse.

Norinyl-1 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 Norinyl-1.

Things you must not do

Do not take Norinyl-1 to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else even if they have the same condition as you.

Do not stop taking Norinyl-1, or change the dosage, without checking with your doctor.

If you stop taking Norinyl-1 or do not take a tablet every day, without using another form of contraception, you may become pregnant.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Norinyl-1.

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.

It can be difficult to tell whether side effects are the result of taking Norinyl-1 or are side effects of another medicine you are taking.

Do not be alarmed by the list of side effects.

You may not experience any of them.

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

Tell your doctor if...

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

- changes in bleeding patterns, including break-through bleeding
- spotting
- painful periods

- absence of periods, but if you have not taken Norinyl-1 as directed you should check whether you are pregnant
- gastric or stomach discomforts including abdominal pain, cramps, bloating, nausea, vomiting and diarrhoea
- change in appetite
- change in menstrual flow
- change in cervical secretions
- change in weight
- swelling of the hands, ankles or feet
- 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 including migraines
- nervousness, dizziness
- mood change including depression
- fatigue or tiredness
- hair growth or loss of scalp hair
- increase in body hair

- acne, rashes, itching
- leg cramps
- back ache
- change in sexual drive
- vaginal thrush (candida), vaginal irritation, change in mucus from the vagina
- pre-menstrual-like symptoms
- suppression of milk production
- contact lenses becoming difficult to wear.

The above list contains the more common side effects of your medicine.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any worsening of conditions that you may already have such as:

- chorea (involuntary muscle spasm)
- porphyria
- Systemic lupus erythematosus (Lupus)
- varicose veins

- gallbladder disease
- kidney disease
- hereditary angioedema (swelling of the face, lips, mouth, tongue or throat).

Go to hospital if...

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, arm or below the breastbone
- severe pain, swelling or discolouration in either of your legs
- shortness of breath
- rapid or irregular heartbeat
- blurred or double vision
- partial or complete loss of sight
- eye protrusion, swelling of the eye or eye lesions
- dizziness or fainting, sometimes with loss of balance
- sweating, nausea or vomiting
- an unusual cough

- weakness or numbness in any part of your body
- discomfort radiating to the back, jaw, throat or stomach
- confusion, trouble speaking or understanding
- bloody diarrhoea
- abdominal pain
- fever
- feeling of indigestion or choking
- rectal bleeding
- feeling tired
- lose your appetite or lose weight
- 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

You may experience headache, blurred vision or palpitations. Sometimes your blood pressure may rise without you experiencing any of these symptoms. It is important to keep your routine doctor's appointments so that your blood pressure can be checked.

- swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.

Whilst these side effects are rare, they are serious. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

After stopping Norinyl-1

Delays in becoming pregnant may occur after Norinyl-1 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 Norinyl-1

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 Norinyl-1 tablets in a dry place, at a temperature below 25°C.

Do not keep your tablets in the refrigerator.

Do not store Norinyl-1 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 Norinyl-1 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

Norinyl-1 28 Day is available in calendar packs consisting of four strips of tablets (4 months' supply) each with 21 white active tablets marked "SEARLE" on one side and "1" on the other, and 7 orange inactive tablets.

Ingredients

Each white tablet contains:

- norethisterone 1 milligram (mg)
- mestranol 50 micrograms (mcg)
- magnesium stearate
- povidone
- maize starch
- lactose monohydrate.

The orange inactive tablets contain:

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

Norinyl-1 contains lactose.

Norinyl-1 does not contain sucrose, gluten or tartrazine.

Supplier

Norinyl-1 is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia

Toll Free number: 1800 675 229

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