

# Norimin-1<sup>®</sup> 28 Day

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## 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.

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### 1. Why am I using Norimin-1 28 Day?

Norimin-1 28 Day contains the active ingredients ethinylestradiol and norethisterone. Norimin-1 28 Day is used to prevent pregnancy. For more information, see Section [1. Why am I using Norimin-1 28 Day?](#) in the full CMI.

### 2. What should I know before I use Norimin-1 28 Day?

Do not use if you have ever had an allergic reaction to ethinylestradiol or norethisterone, or any other similar oral contraceptives, or any of the ingredients listed in Section 7. Product Details in the full 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 Norimin-1 28 Day?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interact with Norimin-1 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 Norimin-1 28 Day?

- Take one tablet at the same time every day, regardless of how often you have sex.
- See the full CMI for instructions on how to start taking Norimin-1 28 Day for the first time or how to change to Norimin-1 28 Day from a different contraceptive.

More instructions can be found in Section [4. How do I use Norimin-1 28 Day?](#) in the full CMI.

### 5. What should I know while using Norimin-1 28 Day?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are using Norimin-1 28 Day.</li><li>• Tell your doctor immediately if you become pregnant while taking Norimin-1 28 Day.</li><li>• See your doctor if you have not taken your</li></ul>
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	<p>tablets correctly and have missed a period.</p> <ul style="list-style-type: none"> <li>• Have regular check ups from your doctor, including a Pap smear.</li> <li>• Perform regular breast self-examination</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine or change the dosage, without checking with your doctor.</li> </ul> <p>If you stop taking Norimin-1 28 Day or do not take a tablet every day without using another form of contraception, you may become pregnant.</p>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Make sure you know how Norimin-1 28 Day affects you before you drive or use machines. Norimin-1 28 Day may cause dizziness in some people.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep Norimin-1 28 Day in a cool, dry place where the temperature stays below 25°C.</li> </ul>

- 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 Norimin-1 28 Day?](#) in the full CMI.

## **6. Are there any side effects?**

Common side effects include changes to your bleeding patterns, painful periods, 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, e.g. epileptic seizures, asthma attack.

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

# Norimin-1<sup>®</sup> 28 Day

**Active ingredient(s):** *ethinylestradiol and norethisterone*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Norimin-1 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 Norimin-1 28 Day.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Norimin-1 28 Day?

Norimin-1 28 Day contains the active ingredients **ethinylestradiol (an oestrogen hormone) and norethisterone (a progestogen hormone)**. Norimin-1 28 Day is a combined oral contraceptive, commonly known as a "birth control pill" or "the Pill".

Norimin-1 28 Day is used to prevent you from becoming pregnant in several ways, if taken correctly:

- By preventing ovulation (the release of an egg from the ovary) during each menstrual cycle.
- It changes the cervical mucus consistency making it difficult for the sperm to reach the egg.
- It changes the lining of the uterus making it less suitable for implantation.

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

Ask your doctor if you have any questions about why Norimin-1 28 Day has been prescribed for you.

## **2. What should I know before I use Norimin-1 28 Day?**

### **Warnings**

#### **Do not use Norimin-1 28 Day if:**

1. You are allergic to ethinylestradiol or norethisterone, or any other similar medicines (such as other oral contraceptives) 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.
2. You have, or have had a blood clot in the:
- legs (deep vein thrombosis (DVT)), or lungs (pulmonary embolism (PE)) and you are currently taking an anticoagulant medicine
  - heart (heart attack)
  - brain (stroke)
  - other parts of the body
3. You are at increased risk of a blood clot in the legs (DVT) or lungs (PE) due to any of the following:
- A family history of blood clots (DVT or PE) or you have been advised that you have an increased risk of blood clots.
  - Prolonged immobilisation, major surgery, any surgery to the legs or pelvis, neurosurgery, or major trauma.
  - Biochemical factors, such as Activated Protein C resistance (including Factor V Leiden), antithrombin-III deficiency, protein C deficiency, protein S deficiency.
  - Cancer, systemic lupus erythematosus (SLE), haemolytic uraemic syndrome (HUS) (a disorder of blood coagulation causing failure of the kidneys), chronic inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis).
  - Sickle cell disease
  - Obesity, age above 35 years, high cholesterol

- Smoking, particularly if you are a heavy smoker (15 or more cigarettes per day).
  - Pregnancy
  - Planned long-haul travel (greater than 4 hours).
4. You have, or have had, blood clots in the arteries (known as arterial thromboembolism (ATE)).  
Examples of these include:
- Stroke
  - Angina (chest pain)
  - Transient ischaemic attack or "mini stroke"
5. You are at increased risk of ATE, including:
- A family history of ATE or you have been advised that you have an increased risk of ATE
  - 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 (high levels of fatty substances in the blood)
    - Sickle cell anaemia
    - History of migraine, accompanied by blurred vision, difficulty in speaking, muscle weakness, or increased sensitivity to light, sound, or noise
6. You have any of the following conditions:
- 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.
  - Cancer or suspected cancer of the breast or sex organs (e.g. cervix, vagina, ovaries, endometrium, womb) and known or suspected oestrogen-dependent tumours.
  - Vaginal bleeding, the cause of which is unknown
  - 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.
7. You are pregnant or you think you are pregnant.  
Pregnancy must be excluded before you start taking Norimin-1 28 Day.
8. 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.

### **Check with your doctor if you:**

- Take any medicines for any other condition

- Have any other medical conditions or health problems, such as:
  - Heart disease including heart valve disorders or certain heart rhythm disorders
  - High blood pressure
  - High cholesterol
  - Hepatitis C
  - Diabetes
  - Migraine or other headaches
  - Hyperhomocysteinemia
  - Breast lumps, abnormal breast X-ray or mammogram
  - 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 Norimin-1 28 Day is not making the conditions worse.

- Are 35 years of age or are overweight.
- Are intolerant to some sugars, or your doctor has told you so. Norimin-1 28 Day contains lactose.

- Are allergic to any foods, dyes, preservatives or any other medicines.

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.

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

## **Blood clots**

- 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.

## Stroke

- 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".

## Medical Check-ups

- Before you start to take Norimin-1 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 interact with Norimin-1 28 Day and affect how well it or the other medicine works. This may lead to unwanted side effects, reduce the effect of Norimin-1 28 Day and/or the other medicine.**

**These medicines include:**

- Atorvastatin used to treat high cholesterol
- Indinavir for the treatment of HIV infection

- Anti-fungal medicines such as itraconazole and fluconazole
- Paracetamol
- Ascorbic acid (Vitamin C)
- Cyclosporin used to prevent organ rejection
- Theophyllines used for asthma and other breathing difficulties
- Corticosteroids
- Lamotrigine for seizures.

**Medicines that may reduce the effect of Norimin-1 28 Day include:**

- Anti-viral hepatitis C virus (HCV) medicines such as ombitasvir, paritaprevir, ritonavir and dasabuvir
- Rifampicin and rifabutin for the treatment of infections such as 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 phenytoin, primidone, carbamazepine and topiramate
- 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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Norimin-1 28 Day.**

## **4. How do I use Norimin-1 28 Day?**

### **How much to take**

- Take one tablet every day.
- Follow the instructions provided and use Norimin-1 28 Day until your doctor tells you to stop.

### **When to take Norimin-1 28 Day**

- Norimin-1 28 Day should be taken at the same time every day regardless of how often you have sex.

- Norimin-1 28 Day will work best if you do not miss any tablets and take it at the same time each day. Taking Norimin-1 28 Day 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.

## **How to take Norimin-1 28 Day**

- Swallow the tablet whole with a full glass of water.

## **How to start taking Norimin-1 28 Day for the first time**

- To begin Norimin-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 silver 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 silver 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 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 white 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.

## **Going on to further blister packs**

### **How to switch to Norimin-1 28 Day from a different oral contraceptive**

If you are switching to Norimin-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 Norimin-1 28 Day pack on the eighth day by taking a white 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 white 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 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 Norimin-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 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 white tablet has been taken daily for 7 days without a break.**

## **If you forget to use Norimin-1 28 Day**

Norimin-1 28 Day should be used 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 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, 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 Norimin-1 28 Day differently, or you are unclear about the above directions, discuss this with them.

If you have trouble remembering to take Norimin-1 28 Day, ask your pharmacist for some hints.

### **If you vomit or have diarrhoea after taking Norimin-1 28 Day**

If you suffer from a stomach upset which results in vomiting or diarrhoea, the effectiveness of Norimin-1 28 Day may be reduced.

During any period of vomiting or diarrhoea, continue taking Norimin-1 28 Day 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 white 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.

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

## **If you take too much Norimin-1 28 Day**

If you think that you have taken too much Norimin-1 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.**

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.

## 5. What should I know while using Norimin-1 28 Day?

### Things you should do

- Tell all doctors, dentists and pharmacists who are treating you that you are taking Norimin-1 28 Day.
- Tell the hospital doctor that you are taking Norimin-1 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 Norimin-1 28 Day.
- If you become pregnant while taking Norimin-1 28 Day, see your doctor immediately.
- If you are about to have any blood tests, tell your doctor you are taking Norimin-1 28 Day.

It may interfere with the results of some tests.

- Tell your doctor you are taking Norimin-1 28 Day at least 4 weeks before any planned hospitalisation or surgery.

Your doctor may tell you to stop taking Norimin-1 28 Day several weeks before surgery or at the time of immobilisation. Your doctor will tell you when you can start taking Norimin-1 28 Day 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.

- 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 assess your condition and advise whether or not you should continue to take Norimin-1 28 Day.
- Tell your doctor if you experience feelings of sickness or breast tenderness that do not improve or stop after the first few months of continued use.
- Tell your doctor if you experience vaginal irritation or discharge. It may be an indication of yeast infection for which treatment is available from your doctor.

## **Missed periods**

- If you miss a period and you have taken your tablets correctly, continue taking your tablets as you would normally.
- Sometimes you might not have a menstrual period while taking Norimin-1 28 Day.
- If you miss a period and you have not taken your tablets correctly, keep taking your tablets and see your doctor immediately.

Not taking your tablets correctly includes missing one or more tablets or starting a new pack later than you should have.

- If you miss two menstrual periods, stop taking your tablets and see your doctor, even if you have taken the tablets correctly. You must use a non-hormonal

method of contraception, (such as condoms or a diaphragm) during this time.

- Your doctor should make sure you are not pregnant before you start taking Norimin-1 28 Day again.

## **Medical Check Up**

- Visit your doctor regularly for check-ups and physical examinations, including Pap smears, blood pressure checks and breast, abdomen and pelvic organ examinations.
- 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.
- Norimin-1 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 Norimin-1 28 Day if the packaging is torn or shows signs of tampering.
- If it is expired or is damaged, return it to your pharmacist for disposal.

Norimin-1 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 take Norimin-1 28 Day 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 Norimin-1 28 Day, or change the dosage, without checking with your doctor.
- If you stop taking Norimin-1 28 Day or do not take a tablet every day, without using another form of contraception, you may become pregnant.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Norimin-1 28 Day affects you.**

Norimin-1 28 Day may cause dizziness in some people

## **Drinking alcohol**

No information available.

## **Looking after your medicine**

- Keep your Norimin-1 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.

Do not use this medicine after the expiry date.

## **Keep it where young children cannot reach it.**

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

## **After stopping Norimin-1 28 Day**

Delays in becoming pregnant may occur after Norimin-1 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 Norimin-1 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.

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 data-bbox="204 432 735 533"><b>Reproductive or breast problems:</b></p> <ul data-bbox="204 568 754 2022" style="list-style-type: none"><li data-bbox="204 568 754 734">● changes in bleeding patterns, including break-through bleeding</li><li data-bbox="204 757 416 801">● spotting</li><li data-bbox="204 824 564 869">● painful periods</li><li data-bbox="204 891 754 1227">● absence of periods, but if you have not taken Norimin-1 28 Day as directed you should check whether you are pregnant</li><li data-bbox="204 1249 687 1350">● change in menstrual flow</li><li data-bbox="204 1373 635 1473">● change in cervical secretions</li><li data-bbox="204 1496 612 1720">● breast changes (tenderness, enlargement and secretion)</li><li data-bbox="204 1742 730 1787">● change in sexual drive</li><li data-bbox="204 1809 740 2022">● vaginal thrush (Candida), vaginal irritation, change in mucus from the vagina</li></ul>	<p data-bbox="810 432 1337 656"><b>Speak to your doctor if you have any of these side effects and they worry you.</b></p>

<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● pre-menstrual-like symptoms</li> <li>● suppression of milk production</li> </ul> <p><b>Stomach problems such as:</b></p> <ul style="list-style-type: none"> <li>● gastric or stomach discomforts including abdominal pain, cramps, bloating, nausea, vomiting and diarrhoea</li> <li>● change in appetite.</li> </ul> <p><b>Difficulties thinking or working because:</b></p> <ul style="list-style-type: none"> <li>● headache, including migraines</li> <li>● nervousness, dizziness</li> <li>● mood change, including depression</li> <li>● fatigue or tiredness</li> <li>● contact lenses becoming uncomfortable to wear</li> </ul> <p><b>Changes to your appearance such as:</b></p> <ul style="list-style-type: none"> <li>● change in weight</li> <li>● swelling of the hands, ankles or feet</li> </ul>	

<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dark discolouration of the skin</li> <li>● blotchy discolouration on the face or limbs (which may persist after the tablets have been stopped)</li> <li>● hair growth or loss of scalp hair</li> <li>● increase in body hair</li> <li>● acne, rashes, itching</li> </ul> <p><b>Aches and pains:</b></p> <ul style="list-style-type: none"> <li>● leg cramps</li> <li>● back ache</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Worsening of your existing conditions such as:</b></p> <ul style="list-style-type: none"> <li>● chorea (involuntary muscle spasm)</li> <li>● porphyria (a group of disorders than can cause skin or nerve problems)</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● systemic lupus erythematosus (Lupus)</li> <li>● varicose veins</li> <li>● gallbladder disease</li> <li>● kidney disease</li> <li>● hereditary angioedema (swelling of the face lips, mouth tongue or throat)</li> <li>● epileptic seizures</li> <li>● asthma attack</li> </ul> <p><b>Pain or discomfort:</b></p> <ul style="list-style-type: none"> <li>● fever</li> <li>● unexplained or persistent pains in the head, chest, arm or below the breastbone</li> <li>● severe pain, swelling or discolouration in either of your legs</li> <li>● discomfort radiating to the back, jaw, throat or stomach</li> <li>● abdominal pain</li> <li>● weakness or numbness in any part of your body</li> </ul> <p><b>Digestive system problems:</b></p>	<p>You may need urgent medical attention or hospitalisation.</p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● bloody diarrhoea</li> <li>● feeling of indigestion or choking</li> <li>● rectal bleeding</li> <li>● loss of appetite or weight loss</li> </ul> <p><b>Problems with your eyes or eyesight:</b></p> <ul style="list-style-type: none"> <li>● blurred or double vision</li> <li>● partial or complete loss of sight</li> <li>● eye protrusion, swelling of the eye or eye lesions</li> </ul> <p><b>Migraines:</b></p> <ul style="list-style-type: none"> <li>● migraine headaches for the first time</li> <li>● more frequent or severe migraines if you already suffer from them</li> </ul> <p><b>General feelings of unwellness, including:</b></p> <ul style="list-style-type: none"> <li>● feeling tired</li> <li>● shortness of breath</li> <li>● rapid or irregular heartbeat</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dizziness or fainting, sometimes with loss of balance</li> <li>● sweating, nausea or vomiting</li> <li>● an unusual cough</li> </ul> <p><b>Changes to your body:</b></p> <ul style="list-style-type: none"> <li>● confusion, trouble speaking or understanding</li> <li>● breast lumps</li> <li>● 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</li> <li>● 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.</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p>It is important to keep your routine doctor's appointments so that your blood pressure can be checked.</p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing.</li> </ul>	

**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.

## **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](http://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 Norimin-1 28 Day contains

<b>Active ingredient (main ingredient)</b>	Each white active tablet contains: <ul style="list-style-type: none"><li>• norethisterone 1 milligram (mg)</li><li>• ethinylestradiol 35 micrograms (mcg)</li></ul> The orange tablets do not contain active ingredients.
<b>Other ingredients (inactive ingredients)</b>	The white active tablets also contain: <ul style="list-style-type: none"><li>• magnesium stearate</li><li>• povidone</li><li>• maize starch</li><li>• lactose monohydrate</li></ul> The orange inactive tablets contain: <ul style="list-style-type: none"><li>• magnesium stearate</li><li>• microcrystalline cellulose</li><li>• lactose</li></ul>

- |  |  |
|--|--|
|  | <ul style="list-style-type: none"><li>• lactose monohydrate</li><li>• sunset yellow FCF (CI No. 15985)</li></ul> |
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**Do not take this medicine if you are allergic to any of these ingredients.**

**Norimin-1 28 Day contains lactose.**

**Norimin-1 28 Day does not contain sucrose, gluten or tartrazine.**

## **What Norimin-1 28 Day looks like**

Norimin-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 "BX" on the other, and 7 orange inactive tablets.

(AUST R 62136)

## **Who distributes Norimin-1 28 Day**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

This leaflet was prepared in June 2022.