# Nordette* 21

(0.03 mg Ethinyloestradiol and 0.15 mg Levonorgestrel)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet?**


1. What Nordette is and what it is used for
2. What you need to know before you take Nordette
3. How to take Nordette
4. Possible side effects
5. How to store Nordette
6. Contents of the pack and other information


## 1. WHAT NORDETTE IS AND WHAT IT IS USED FOR

**Pharmacotherapeutic group**

Nordette is a monophasic combined oral hormonal contraceptive (pill).

Each tablet contains two female hormones: levonorgestrel (a progestin) and ethinyloestradiol (an oestrogen). Each blister contains 21 tablets, each containing the same amount of progestin and oestrogen. This pill should be taken for 21 days, followed by a break for 7 days. These hormones prevent the release of an ova so that pregnancy does not occur.

**Therapeutic indications**

Prevention of pregnancy, when the product is used in accordance with the instructions.

## 2. WHAT TO KNOW BEFORE YOU TAKE NORDETTE

**Do not take Nordette:**
- If you have or have had a venous thrombosis (a blood clot) in the blood vessels of the legs (deep vein thrombosis), lungs (pulmonary embolism) and eyes (see also the section entitled "*Blood clots*");
- If you have had a disease of the blood vessels (arteries), such as a heart attack or a stroke (see also the section entitled "*Blood clots*");
- If you have a hereditary predisposition to one of the diseases mentioned above;
- If you suffer from headaches or migraines accompanied by neurological symptoms such as aura (i.e., with an unusual sensation such as bursts of light);
- If you have damage to the heart valves or some heart rhythm disorders;
- If you have high blood pressure, which is not improved when you take blood

pressure medicines;
- If you have chest pain (angina pectoris);
- If you have diabetes with blood vessel damage;
- If you have, or have had, cancer of the breast, uterus or liver (see also the section entitled *"Cancer"*);
- If you have serious liver disease;
- If you have vaginal bleeding of unknown origin;
- If you are pregnant or think you may be;
- If you are allergic to levonorgestrel, ethinyloestradiol or any of the other ingredients of this medicine (listed in section 6);
- If you have or have had an inflammation of the pancreas, which was associated with severe increase of the lipids in your blood.

Do not use Nordette if you have hepatitis C and you are taking medicines that contain the combination of ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (also see section "Other medicines and Nordette").

If any of the situations listed above applies to you, you must stop Nordette and you should talk to your doctor BEFORE you start taking it.
If any of the situations appears for the first time while taking Nordette, you must contact your doctor immediately.

**Warnings and precautions**
Talk to your doctor before taking Nordette.
- If you smoke (especially if you are over 35 years old);
- If someone in your immediate family has had a disease caused by blood clots, such as deep vein thrombosis, pulmonary embolism, heart attack, or stroke;
- If your weight is excessive;
- If you are diabetic;
- If you have high blood pressure;
- If you suffer from headaches or migraines;
- If you have, or have had, one or more breast cysts and someone in your immediate family has had breast cancer;
- If you have a uterine fibroid;
- If you have liver disease or gallbladder disease (gallstones);
- If you have had a biliary problem when previously taking a contraceptive pill or during a pregnancy;
- If you suffer from a hypersensitivity reaction - called angioedema;
- If you have a high level of fats in the blood (cholesterol or triglyceride);
- If you are, or have been, severely depressed;
- If you have or have had a chloasma (brown spots on the skin, called "mask of pregnancy", particularly on the face). In this case, you must avoid excessive exposure to the sun or to ultraviolet radiation;
- If you suffer from haemolytic uraemic syndrome (a blood disease that causes renal insufficiency).

Also, careful consideration should be given to certain disorders, which can be exacerbated when taking the pill, such as systemic lupus erythematosus (skin damage extending to the whole body), varicose veins, asthma, epilepsy, pemphigoid

gestationis (herpes occurring during a pregnancy), hyperprolactinaemia, a disorder called "Saint Vitus Dance" or chorea and otosclerosis (disease of the inner ear).

If you develop symptoms of angioedema, such as swelling of the face, tongue and/or throat and/or difficulties swallowing or hives with potential difficulties breathing, talk to your doctor immediately. Products containing oestrogens can trigger or worsen symptoms of hereditary or acquired angioedema.

Consult your doctor if any of the warnings mentioned above apply to you, or applied in the past. If any of these situations appear for the first time while taking Nordette or worsens while taking Nordette, you must contact your doctor.

**Psychiatric disorders**
Some women who take hormonal contraceptives including Nordette have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for medical advice as soon as possible.

As all contraceptive pills, Nordette does not protect against HIV infections (AIDS), or against the other sexually transmitted diseases.

**Potentially serious situations**
**Blood clots**
Thrombosis is the formation of a blood clot that can block a blood vessel (vein or artery). If a blood clot forms in the deep veins of the leg (deep vein thrombosis), it could detach and block arteries in the lungs (pulmonary embolism). Deep vein thrombosis is a rare phenomenon, which may occur whether the woman takes the pill or not. The risk is a little higher for women who take the pill than for those who do not take it, but remains lower than the risk of thrombosis during pregnancy.

The risk of deep vein thrombosis increases temporarily after surgery, childbirth, second trimester termination of pregnancy and in case of prolonged immobilization (for example if you have a leg in plaster), and all the more if you take simultaneously the pill. Your doctor may advise you to stop the pill several weeks before any surgery or for the time of immobilization. He/she will also tell you when you can start taking the pill again after return to full mobility and after childbirth or second trimester termination of pregnancy.

In rare cases, a blood clot may also form in the arteries, such as those of the heart (heart attack) or brain (stroke), as well as the liver, gut, kidneys or eyes.

**The risk of heart attack or stroke increases with age and smoking. You must stop smoking if you take the pill, especially if you are 35 years and older and smoke more than 15 cigarettes per day.**

Thrombosis does not always heal completely. It can sometimes cause a permanent disability or even be fatal. **If you notice signs of a potential thrombosis, you should contact your doctor immediately** (see also the section entitled "*When should you contact your doctor*").

**Cancer**
Established risk factors for development of breast cancer include older age, family history, obesity, not having had children and having had a first pregnancy and childbirth at an older age.

Breast cancer has been diagnosed slightly more often in women taking the pill than in women of the same age who do not take it. This slight increase in the number of breast cancer diagnoses gradually disappears 10 years after stopping the pill. It is not known whether this difference is caused by the pill. It also may be that the women have been examined more carefully and more often, so that breast cancer had been detected earlier. The pill could also increase the risk of cervical cancer, but this has not been scientifically proven.

In rare cases, non-cancerous liver tumours, and even more rarely, malignant liver tumours have been reported in users of the pill. The risk of developing such tumours increases with the duration of taking the pill, but remains low overall.

## When should you contact your doctor?

**Regular check-ups**
Your doctor will ask you to return for periodic regular medical examinations. In general, the frequency and nature of these examinations will depend on various personal medical factors. Your doctor will need to assess the different aspects and will provide you with the necessary explanations.

**Contact your doctor as soon as possible in the following cases:**
- If you feel possible signs of thrombosis, as for example:
  - Pain or tightness in the chest, possibly irradiating in the left arm
  - Severe pain or abnormal swelling of a leg
  - Severe and sudden headache
  - Sudden vision or speech alteration (partial or total loss of sight or difficulty talking)
  - Vomiting, dizziness or fainting
  - Sudden weakness or numbness of one side or half of the body
  - Severe and intolerable abdominal pain
  - Sudden cough
- If you feel a lump in your chest;
- At least four weeks in advance, if you must undergo surgery or remain bed-ridden for some time (see also the section entitled "*Blood clots"*);
- After childbirth or second trimester termination of pregnancy (see also the section entitled "*Blood clots"*);
- If you notice abundant unusual vaginal bleeding;
- If you think you may be pregnant;
- If your period does not appear during the week not taking the pill.

## Other medicines and Nordette

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

When your doctor or your dentist wants to prescribe you a new medicine, you must always tell them that you take Nordette. Your doctor will tell you if you need to

temporarily use another form of contraception while taking this medicine.

**Several medicines may interfere with the way the pill works. Medicines that increase the activity of your liver enzymes may prevent your pill from working, and may cause breakthrough bleeding and irregular periods. These may be:**
- Some medicines used to treat epilepsy (primidone, phenytoin, barbiturates, topiramate, phenylbutazone, carbamazepine, felbamate)
- Griseofulvin (a product used to treat fungal infections)
- Some treatments against HIV (AIDS) and other viral infections (ritonavir)
- Rifampicin (to treat tuberculosis)
- Products containing St. John's Wort (*Hypericum perforatum*)
- Modafinil (mood-brightening substance)
- Dexamethasone (substance used to treat various inflammatory and autoimmune diseases)
- Such drugs include drugs that increase the activity of your liver enzymes.

Other medicines that do not affect your liver enzymes may also have this effect.
These include drugs that speed up the passage of food through your body and certain antibiotics.

Women on short term treatment with any of these medicines should temporarily use a barrier method, such as the condom, in addition to the pill or choose another non-hormonal method of contraception. The barrier method should be used during time of concomitant drug administration and for 28 days after their discontinuation.

If you are receiving long-term therapy with drugs that make the Pill less effective, another method of contraception should be used.

Oral contraceptives may influence the outcome of certain laboratory tests. Tell your doctor that you take Nordette if you must undergo a blood test.

Do not use Nordette if you have hepatitis C and you are taking medicines that contain the combination of ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir as these products can result in elevations in liver function blood tests (elevated ALT liver enzyme).

Your doctor will prescribe a different type of contraceptive before starting treatment with these medicines.

Nordette may be resumed approximately two weeks after the end of this treatment. See section “Do not take Nordette”.

**Nordette with food and drink**
Nordette can be taken with food and drink.

**Pregnancy, breast-feeding and fertility**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Nordette cannot be used if you are pregnant or if you think you might be.

Nordette cannot be used if you are breast-feeding.

**Driving and using machines**
The effect on driving or using machines has not been studied for Nordette.

**Nordette contains lactose and sucrose**
If your doctor has informed you of intolerance to some sugars, contact them before taking this medicine.

## 3. HOW TO TAKE NORDETTE

**Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.**

**When and how to take the tablets?**
The Nordette blister contains 21 tablets. The day of the week when it must be taken is shown on the blister for each tablet. Take one tablet each day, in the order shown on the blister, preferably at the same time for 21 consecutive days. During the 7 days following the 21 days do not take any tablets. Your period should start during these 7 days without tablets (usually on the 3rd day). After this 7 days period without tablets, start a new blister on the 8th day, even if your period is not finished.

**Accordingly, you will always start a new blister on the same day of the week, and you will have your period on about the same days every 4 weeks.**

Taking the pill is not indicated before the appearance of the first period and in post-menopausal women.

**When to start the first blister?**
**If you have not used contraceptive pills the previous month**
Take the first tablet (marking the corresponding day of the week) on the first day of your period. For example, if your period starts on a Friday, take a tablet marked "Fri".

**If you take another combined pill**
Take the first tablet the day that follows taking the last active tablet of the previous contraceptive.

**If you take an only progestin pill ("mini pill")**
Take the first tablet at any time of your cycle, the day that follows stopping the mini pill. You must use an additional non-hormonal mechanical contraceptive method (such as a condom or spermicide) during the first 7 days of treatment.

**If you are using an injectable contraceptive or an implant or an IUD**
Take the first tablet the day the implant or the IUD is removed or the day planned for your next injection. You must use an additional non-hormonal mechanical contraceptive method (such as a condom or spermicide) during the first 7 days of treatment.

**If you have had a first trimester termination of pregnancy**

You can start Nordette immediately.

**If you have just given birth or if you had a second trimester termination of pregnancy**
Your doctor may advise you to start taking Nordette from the 28th day after childbirth or after a second trimester termination of pregnancy. You must use an additional non-hormonal mechanical contraceptive method (such as a condom or spermicide) during the first 7 days of treatment. If you have already had sexual intercourse, you must exclude pregnancy before starting to take the pill or wait until the next period.

**What to do if you have an unexpected bleeding?**
Unexpected vaginal bleeding may appear between the periods (spotting), especially during the first months of use. In general, the irregular bleeding ceases once your body has become accustomed to the pill (after about three blisters). However, if the bleeding persists or appears for the first time after prolonged use of Nordette, see your doctor immediately.

**What to do if your period does not appear?**
If you do not have your period after 7 days without the pill and if you have scrupulously respected the instructions, pregnancy is unlikely. Start the new blister on the 8th day. However, if you still do not have a period after two complete 21 days cycles of treatment, see your doctor immediately and do not start the next blister before having his/her agreement.

**If you take more Nordette than you should**
We do not know of cases where there have been serious adverse effects after taking a significant quantity of Nordette pills.

***Symptoms:***
If you have taken several Nordette tablets at once, you can have nausea, vomiting, stomach pain, dizziness, somnolence, fatigue, tense breasts or light vaginal bleeding.

***Treatment:***
Specific treatment is probably not necessary.

If you discover that a child has taken Nordette, you must immediately inform your doctor.

If you used or taken too much Nordette, contact immediately your doctor or pharmacist.

**If you forget to take Nordette**
- If you missed taking one tablet for **less than 12 hours**, the contraceptive reliability of the pill is maintained. Take the missed dose as soon as you remember and take the next tablet at the usual time.
- If you missed taking one tablet for **more than 12 hours** or if you have forgotten more than one tablet, the contraceptive reliability of the pill may be compromised. In this case:
    - Take the last forgotten tablet immediately, even if 2 tablets must be taken on the same day and continue the contraceptive treatment until the end of the

blister;

- At the same time use an additional non-hormonal mechanical contraceptive method (such as a condom or spermicide) during the next 7 days; if this safety period of 7 days with condom extends beyond the last tablet of the blister, do not take a break between the two blisters and start the next blister immediately after taking the last tablet.

However, it is recommended to ask the advice of your doctor.

**What to do if you vomit or have significant diarrhoea?**
If you vomit or if you have significant diarrhoea in the 4 hours after taking a tablet, it is possible that the active components of Nordette had not been sufficiently absorbed by your body. You must then follow the instructions in the section entitled "*If you forget to take Nordette"* by taking a tablet from the backup blister. If diarrhoea or vomiting persists, see your doctor.

**If you stop taking Nordette**
When you stop taking Nordette it may be that your period does not return spontaneously (post-therapeutic amenorrhoea). In this case, you should contact your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Serious side effects**
The serious side effects associated with the use of the contraceptive pill are described in the sections entitled "*Blood clots"* and *"Cancer"*. Please read these sections for more information in section 2 "*Potentially serious situations*".

Angioedema
Talk to your doctor immediately if you develop any symptoms of angioedema, such as swelling of the face, tongue and/or throat and/or difficulties swallowing or hives with potential difficulties breathing (also see "*Warnings and precautions*").

The other side effects are listed by category of frequency as follows:
Very common: more than one in 10 users
Common: between one in 10 users and one in 100 users
Uncommon: between one in 100 users and one in 1,000 users
Rare: between one in 1,000 users and one in 10,000 users
Very rare: fewer than one in 10,000 people
Frequency not known (cannot be estimated from the available data)

| System/organ class | Side effect |
|---|---|
| **Infections and infestations** | |

| System/organ class | Side effect |
|---|---|
| Common | Vaginal infection, including vaginal candidiasis (yeast infection) |
| **Neoplasms benign, malignant and unspecified (incl. cysts and polyps)** | |
| Very rare | An increased risk of benign liver tumours, malignant liver tumours |
| **Immune system disorders** | |
| Rare | Hypersensitivity reactions, including very rare cases of urticaria, allergic oedema affecting the face (angio-oedema), severe breathing and circulation disorders |
| Very rare | Aggravation of disseminated lupus erythematosus |
| **Metabolism and nutrition disorders** | |
| Uncommon | Increased or decreased appetite |
| Rare | Glucose intolerance |
| Very rare | Worsening of porphyria (accumulation of porphyrin in the tissues) |
| **Psychiatric disorders** | |
| Common | Changes in mood and libido (sexual desire), depression. |
| **Nervous system disorders** | |
| Very common | Headache, migraine |
| Common | Nervousness, dizziness |
| Very rare | Worsening of the Saint Vitus Dance (chorea) |
| **Eye disorders** | |
| Rare | Contact lens intolerance |
| Very rare | Inflammation of the optic nerve*, thrombosis (blood clot) of vessels of the retina |
| **Cardiac and vascular disorders** | |
| Very rare | Worsening of varicose veins |
| **Gastrointestinal disorders** | |
| Common | Nausea, vomiting, stomach pain |
| Uncommon | Cramps in the stomach, bloating |
| Very rare | Inflammation of the pancreas, inflammation of the colon due to a lack of oxygen |
| Frequency not known | Inflammatory bowel disease (Crohn's disease, ulcerative colitis) |
| **Hepatobiliary disorders** | |
| Rare | Jaundice by obstruction of the bile ducts |
| Very rare | Gallstones, decrease of biliary secretion** |
| Frequency not known | Hepatic injury (e.g., inflammation of the liver, abnormal liver function) |
| **Skin and subcutaneous tissue disorders** | |
| Common | Acne |
| Uncommon | Rash, appearance of persistent brown spots on the face, abnormal development of hairiness, hair loss |

| System/organ class | Side effect |
|---|---|
| Rare<br>Very rare | Rash with nodules (nodular erythema)<br>Vesiculobullous rashes (erythema multiforme) |
| **Renal and urinary disorders**<br>Very rare | <br>Haemolytic uraemic syndrome (specific tendency to bleeding) |
| **Reproductive system and breast disorders**<br>Very common<br>Common | <br>Bleeding between periods (spotting)<br>Pain and tension in the breasts, increase in the volume of the breasts and secretions, painful periods, change in the volume of the periods, absence of periods, changes in cervical secretions |
| **General disorders and administration site conditions**<br>Common | <br>Water retention, oedema |
| **Investigations**<br>Common<br>Uncommon<br><br>Rare | <br>Change in body weight (increase or decrease)<br>Increase in blood pressure, change in the level of fats in the blood<br>Decrease in the level of folates*** in the blood |

* Inflammation of the optic nerve can cause partial or total loss of sight.

** The pill can aggravate an existing gallbladder disease or may enable the development of such a disease.

*** The level of folates in the blood can decrease if you take the pill. This can be important if you fall pregnant quickly after stopping the pill.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE NORDETTE

Please refer to the outer package for storage condition.

**Keep this medicine out of the sight and reach of children.**

**Do not use this medicine after the expiry date which is stated on the outer package.**

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

Each pack of Nordette contains one blister foil of 21 sugar coated tablets, each containing 150 micrograms of levonorgestrel and 30 micrograms of ethinyloestradiol.

Nordette tablets also contain lactose monohydrate, maize starch, povidone K-25, magnesium stearate, talc, sucrose, macrogol 6000, calcium carbonate, povidone K-90,

white wax, carnauba wax.

Pfizer Corporation Hong Kong Limited
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