

NORDETTE 21 TABLET

Levonorgestrel/Ethinylestradiol (150 micrograms/30 micrograms)

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What Nordette21 is used for

Nordette 21 is used for prevention of pregnancy.

How Nordette 21 works

Nordette 21 acts by suppressing hormones called gonadotropins. These hormones prevent an egg being released from your ovaries.

Before you use Nordette21

- When you must not use it

Do not take Nordette 21 if any of the following apply to you as it would put your health at risk.

- If you are pregnant, think you might be pregnant or breast-feeding
- If you have cancer affected by sex hormones, such as cancers of the breast
- If you have vaginal bleeding that has not been explained by your doctor
- If you or anyone in your close family has ever had a problem with their blood circulation. This includes a blood clot (thrombosis) in the legs (deep vein thrombosis), lungs (pulmonary embolism), heart (heart attack), brain (stroke), hypertension (high blood pressure) or any other parts of the body

- If you have an irregular heartbeat (atrial fibrillation) or a heart valve disorder
- If you have inflammation of the pancreas, which is associated with very high blood levels of triglycerides (body fats)
- If you have ever had liver tumors or severe liver disease and been told by your doctor that your liver function tests are not yet back to normal
- If you are allergic to levonorgestrel or ethinylestradiol or any of the other ingredients of this medicine (see section, Product description, Ingredients)
- If you have migraine with visual disturbances
- If you have diabetes which has affected your circulation
- If you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir

Pregnancy and lactation

Do not use Nordette 21 if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm before you stop or start taking Nordette 21.

If you are breast-feeding, your doctor or pharmacist may advise you not to take Nordette 21. Talk to them about alternative contraception.

- Before you start to use it

Your doctor will ask about you and your family's medical problems and check your blood pressure. You may also need other checks, such as a physical examination.

Do not use this medication if you smoke cigarettes and are over 35 years old. Smoking raises your risk

of heart problems. The risk of these serious problems increases with age and with the number of cigarettes you smoke.

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

- if you are seriously overweight
- surgery or serious injury with increased risk of clotting
- if you recently delivered a baby or had a second trimester abortion
- if you are off your feet for a long time because of any major surgery, injury or illness
- as you get older
- if you or any of your close family have had blood clots or any blood clotting problem

Very rarely, blood clots can also form in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

You are more at risk of having a heart attack or stroke:

- if you smoke
- if you have high blood pressure
- if you have high cholesterol
- if you are overweight
- as you get older
- if you have migraines
- if you have an irregular heartbeat (atrial fibrillation)
- if you or someone in your close family has had a heart attack or stroke at a young age

Tell your doctor about any of the following conditions as your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight.
- if you have never given birth or have the first full term pregnancy at late age

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Tell your doctor if you have any other health problems, especially if you have

- liver problems or previously had a condition called cholestasis (collection of bile) associated with usage of oral contraceptives or during pregnancy
- hereditary angioedema. (swelling of the face, lips, mouth, tongue or throat)
- impaired glucose tolerance or diabetes
- uncontrolled cholesterol levels or if you are under treatment for high cholesterol
- had severe depression

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Do not use Nordette 21 if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir and dasabuvir. Your doctor will prescribe another type of contraceptive before starting the treatment with these medicinal products.

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

- some anti-hepatitis medicines (ombitasvir, paritaprevir, ritonavir and dasabuvir)
- some medicines used to treat epilepsy (such as phenytoin, primidone, lamotrigine and topiramate)
- some medicines used to treat tuberculosis (rifampicin and rifabutin)

- some medicines used to treat HIV or AIDS (ritonavir)
- certain antibiotics (ampicillin, troleandomycin, other penicillins and tetracyclines)
- certain sedatives (called 'barbiturates')
- St. John's wort (a herbal remedy).
- corticosteroids such as dexamethasone
- modafinil used to treat excessive daytime sleepiness
- atorvastatin used to treat high cholesterol
- paracetamol and ascorbic acid (Vitamin C)
- anti-fungal agents such as fluconazole
- cyclosporin used to prevent organ rejection
- theophyllines used for asthma and other breathing difficulties
- corticosteroids
- flunarizine
- metyrapone test

If you do need to take any one of these medicines, Nordette 21 may not be suitable for you or you may need to use extra contraception for a while.

How to use Nordette 21

- How much to use

To prevent pregnancy, always take Nordette 21 as described below:

- Take Nordette21 every day for 21 days. Nordette 21 comes in strips of 21 tablets, each marked with a day of the week.
- Take your tablet at the same time every day.
 - Start by taking a tablet marked with the correct day of the week and continue one tablet each day, until you have finished all 21 tablets.
 - Swallow each tablet whole, with water if necessary. Do not chew the tablet.

After you have taken all 21 tablets in the strip, you have seven days when you are not required to take any tablets.

Within a few days of taking the last tablet from the strip, you should have a withdrawal bleed like a period. This bleed may not have stopped when it is time to start your next strip of tablets.

You do not need to use extra contraception during these seven tablet-free days as long as you have taken your tablets correctly and start the next strip of tablets on time.

Start taking your next strip of Nordette 21 after the seven tablet-free days.

Starting Nordette 21 as a new user or starting the tablet again after a break

You should begin taking Nordette 21 on Day 1 of your menstrual cycle. You can also start taking Nordette 21 on days 2-7 of your period. You must also use extra contraception, such as condoms during the first seven days.

Changing to Nordette 21 from another contraceptive Tablet

Start Nordette 21 the next day after the end of the previous strip if you are on a 21-day Tablet or after your last active tablet if you are on a 28 day Tablet. You will have contraceptive protection with your first tablet.

If you are taking a progestogen-only Tablet implant, intrauterine device [IUD] or injection

Start Nordette 21 on the first day of bleeding, even if you have already taken the progestogen-only Tablet for that day. You will have contraceptive cover straight away.

Starting Nordette 21 after a first-trimester miscarriage or abortion

Your doctor may tell you to start taking Nordette 21 straight away. This means that you will have

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contraceptive protection with your first tablet.

Contraception after having a baby or second trimester abortion

You can start using Nordette 21 after 28 days if you are not breast-feeding or had an abortion after three months of pregnancy.

If the tablet is started later than 28 days after delivery, then alternative contraception, such as condoms, should be used for the first 7 days of tablet taking. If unprotected intercourse has already occurred, then oral contraception should not be started until the first period after childbirth.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Nordette 21 for as long as your doctor recommends. Your doctor may prescribe Nordette for long periods, until you no longer need or want contraception.

- If you forget to use it

If you miss a tablet, follow these instructions:

If you miss a tablet and remembered it within 12 hours of usual dose, take the delayed tablet straight away, and further tablet as usual. This may mean taking two tablets in one day.

If you miss a tablet and remembered it after 12 hours of usual dose or if you have missed more than one tablet:

- Take the most recently missed tablet straight away.
- Leave any earlier missed tablet in the strips.

- Take your further tablet as usual. This may mean taking two tablets in one day.

- Use extra precaution (condoms, for instance) for the next 7 days.

Check how many tablets are left in the strips after most recently missed tablets.

- If 7 or more tablets are left in the pack, don't forget to use extra precaution for the next 7 days. When you have finished the strip, leave the usual 7-days break before that next strip.
- If fewer than 7 tablets are left in the pack, don't forget to use precaution for the next 7 days. When you finish the strip of tablets, start the next strip the next day without a break. If you do not have a withdrawal bleed after you have finished the second strip, do a pregnancy test before starting another strip.

If you missed one or more tablets in the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraceptive.

If you have missed any of the tablets in a strip, and you do not bleed in the first tablet-free break, you may be pregnant. Contact your doctor or pharmacist, or do a pregnancy test yourself.

If you start a new strip of tablets late, or make your 'week off' longer than seven days, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception.

If you are sick or have diarrhea:

If you are sick (vomit) or have very bad diarrhoea, your body may not get its usual dose of hormones from

that tablet. Continue to take your next tablets at your usual time. Use extra contraception, such as condoms, while you are ill and for the next seven days after you are better.

- If you use too much (overdose)

It is unlikely that taking more than one tablet will do you any harm, but you may feel sick or vomit; have breast tenderness or abdominal pain; feel dizzy, drowsy or tired; or you may have some vaginal bleeding. You should talk to your doctor as soon as possible if you have any of these symptoms.

While you are using it

- Things you must do

- You should go for regular check-ups including pap smear tests.
- Check your breasts and nipples every month for changes.
- If you need a blood test tell your doctor that you are taking the tablet, because the tablet can affect the results of some tests.
- If you're going to have an operation, make sure your doctor knows about it. You may need to stop taking the tablet about 4–6 weeks before the operation.

- Things you must not do

Do not take Nordette 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.

- Things to be careful of

Driving and using machines

Nordette 21 has no known effect on the ability to drive or use machines.

Nordette 21 contains lactose and sucrose

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If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Nordette 21.

Side effects

Like all medicines, Nordette 21 can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you are worried about any side effects which you think may be due to Nordette 21.

Serious side effects

If you think you may have any of the following, see a doctor straight away. You may need to stop taking Nordette 21 if you have signs of the following side effects:

- Blood clot in a vein
- Heart attack or stroke
- Severe allergic reaction
- Breast cancer
- Cervical cancer
- Severe liver problems

The most common side effects are

- headache including migraines
- weight gain or weight loss
- breast pain, tenderness, enlargement, possible milk secretion
- changes in bleeding patterns, including breakthrough bleeding/spotting
- depression or low mood
- lower sex drive
- stomach problems, such as nausea, vomiting, stomach pain
- vaginal thrush (candida)
- nervousness, dizziness
- acne
- painful periods, absence of periods or change in menstrual flow
- fluid retention/edema

Tell your doctor or pharmacist if you are worried about any side effects which you think may be due to Nordette 21. Also tell them if any existing conditions get worse while you are taking Nordette 21.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Nordette 21

- Storage

Store below 30°C

Keep out of the reach of children.

Do not use Nordette 21 after the expiry date shown on the strip.

- Disposal

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

Product Description

- What it looks like

Nordette 21 are white, sugar coated tablets

- Ingredients

Active ingredients:
levonorgestrel and estrogen
ethinylestradiol.

- MAL number:

MAL20013009AZ

Manufacturer

Pfizer Ireland Pharmaceuticals
Unlimited Company
Little Connell, Newbridge,
W12 HX57
Ireland

Product Registration Holder

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