

<b>LEVONORGESTREL ETHINYL ESTRADIOL</b>
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**NORDETTE<sup>®</sup>  
150 mcg/30 mcg Tablet**

Please read this leaflet carefully before you proceed taking this medication. Keep it in a safe place as you may want to refer to it again. Ask your healthcare provider if you need more information.

**1.0 NAME OF THE PRODUCT**

Nordette

**2.0 DESCRIPTION OF THE PRODUCT**

Levonorgestrel/Ethinyl estradiol (Nordette) tablets are white, shiny, sugar-coated tablets with a smooth surface. The tablets are packed as 21 tablets in PVC/Aluminum blister pack.

**3.0 WHAT IS IN THE MEDICINE?**

This product contains two different female hormones: Levonorgestrel and Ethinyl estradiol.

**4.0 STRENGTH OF THE MEDICINE**

Each tablet contains:

Levonorgestrel -----150 mcg  
Ethinyl estradiol ----- 30 mcg

**5.0 WHAT IS THIS MEDICINE USED FOR?**

Levonorgestrel/Ethinyl estradiol (Nordette) is a combined oral contraceptive pill for the prevention of pregnancy. Combined Oral Contraceptive (COC) products such as Levonorgestrel/Ethinyl estradiol (Nordette) should only be used when medically indicated.

**What does this medicine do to the body?**

Levonorgestrel/Ethinyl estradiol (Nordette) suppress gonadotropins in a manner that inhibits ovulation, which leads to contraception.

**6.0 HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?**

- Use Combined Oral Contraceptive (COC) products, such as Levonorgestrel/Ethinyl estradiol (Nordette) only when prescribed by a doctor;
- Tablets 1-21 contain active ingredients (active tablets);
- Take the tablets in the order directed on the package every day at about the same time;
- Take one active tablet daily for 21 consecutive days, and then follow it up with a 7-day tablet-free interval;
- Start each subsequent pack on the day after the 7-day tablet-free interval;  
You will usually notice a withdrawal bleed on days 2-3, after the last active tablet and it may not have finished before the next pack is started.

**If this is the first time you are using Levonorgestrel/Ethinyl estradiol (Nordette) and you have not used a hormonal contraceptive for the past month**

- Take the first tablet on the first day of menstrual bleeding;
- Starting later than the first day of bleeding (on days 2-7 of the menstrual cycle) will mean you will have to use additional barrier contraception (e.g. condoms, spermicide) for the first 7 days.

### **If you are changing from another contraceptive pill**

- Start Levonorgestrel/Ethinyl estradiol (Nordette) on the day after the last active tablet of your previous contraceptive pill pack has been taken, but no later than the day following the usual tablet-free or inactive tablet interval.

### **If you were using a progestin-only method of birth control (pill, implant, intrauterine device [IUD], injection)**

- When changing from a progestin-only pill, start Levonorgestrel/Ethinyl estradiol (Nordette) the day after stopping the progestin-only pill;
- When changing from a progestin-only implant or a progestin-only IUD, start Levonorgestrel/Ethinyl estradiol (Nordette) on the same day that the implant or IUD is removed;
- When changing from an injectable progestin-only contraceptive, start Levonorgestrel/Ethinyl estradiol (Nordette) on the day that the next progestin-only injection is scheduled;
- In all cases you must use a barrier contraceptive method (e.g. a condom) during the first 7 days of taking Levonorgestrel/Ethinyl estradiol (Nordette).

### **If you are starting Levonorgestrel/Ethinyl estradiol (Nordette) after a miscarriage that occurred during the first trimester (three months) of pregnancy**

- You can start taking Levonorgestrel/Ethinyl estradiol (Nordette) immediately. Additional contraceptive measures are not needed.

### **If you are starting Levonorgestrel/Ethinyl estradiol (Nordette) after giving birth or after a second trimester miscarriage**

- Levonorgestrel/Ethinyl estradiol (Nordette) should not be started sooner than 28 days after giving birth (and you are not breastfeeding) or after a second trimester miscarriage because you are at an increased risk of forming blood clots;
- You are advised to use a barrier contraceptive method during the first 7 days of taking the pill;
- If you have had sex before starting Levonorgestrel/Ethinyl estradiol (Nordette) be sure that you are not pregnant before starting Levonorgestrel/Ethinyl estradiol (Nordette) or wait until your next period before starting Levonorgestrel/Ethinyl estradiol (Nordette).

### **How to delay a period**

- You can delay your period by starting a new pack of Levonorgestrel/Ethinyl estradiol (Nordette) without any tablet-free week;
- You may have some spotting or bleeding while taking the second pack;
- You should have a normal bleed after finishing the second course of tablets.

### **If you have vomiting and/or diarrhea**

If you have vomiting or diarrhea within 4 hours of taking the pill, absorption of the tablet may be incomplete. Use of active tablets from a back-up pack is required. Refer to recommendations for management of missed tablets (see section on **WHAT SHOULD YOU DO IF YOU MISS A DOSE?**)

## **7.0 WHEN SHOULD YOU NOT TAKE THIS MEDICINE?**

Do not take Levonorgestrel/Ethinyl estradiol (Nordette) if you have:

- Allergies to the active ingredients Levonorgestrel and Ethinyl estradiol or to any of the inactive ingredients such as lactose, corn starch, povidone, magnesium stearate, talc, sucrose, macrogol, calcium carbonate, white wax, wax carnauba;
- Current or previous heart disease or diseases of the blood vessels;
- A heart rhythm disorder or a heart valve disorder;

- Current or previous blood clot in the legs (deep vein thrombosis);
- Current or previous blocking of a blood vessel by a blood clot dislodged from its site of origin (thromboembolism);
- Any blood disorders;
- Uncontrolled high blood pressure;
- Headache with focal neurological symptoms, such as aura;
- Known or suspected breast cancer, or any known or suspected type of cancer that is sensitive to female sex hormones;
- Vaginal bleeding of unknown cause;
- High levels of sugar in your blood (diabetes) associated with a disease of the blood vessels;
- Known or suspected pregnancy;
- Current or previous benign or malignant tumor of the liver or active liver disease. In these cases your doctor will ask you to stop taking Levonorgestrel/Ethinyl estradiol (Nordette) until your liver is working properly again;
- Current or previous inflammation of the pancreas (pancreatitis) associated with elevated levels of triglyceride;
- Concomitant use of certain anti-viral hepatitis C virus (HCV) medicinal products such as ombitasvir, paritaprevir, ritonavir and dasabuvir.

## **8.0 CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?**

- Consult the section on "WHEN SHOULD YOU NOT TAKE THIS MEDICINE?" to ensure that you do not have a condition which prohibits the use of a Combined Oral Contraceptive (COC). Use COC products, such as Levonorgestrel/Ethinyl estradiol (Nordette) only when prescribed by a doctor.
- Tell your doctor if:
  - You smoke: Cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from oral contraceptive use. This risk increases with age and with the extent of smoking and is quite marked in women over 35 years of age. Women who use combined oral contraceptives should not smoke;
  - Anyone in your family has had blood clots in the deep veins of the legs, a stroke or heart attack;
  - You have a problem with your heart (valve disorder, a disturbance of the heart rhythm);
  - You have high blood pressure, a history of high blood pressure or high blood pressure during pregnancy;
  - You have liver problems;
  - You have gallbladder disease or have problems caused by a blockage of the bile ducts (cholestasis) - this may cause intense itching;
  - You have migraine or other headaches;
  - You have diabetes;
  - A blood test has shown that you have a high level of sugar or a high level of cholesterol and fats;
  - You have a history of depression;
  - You have changes to your eyesight, partial or complete blindness, or double vision, clots in blood vessels of the eye;
  - You have current or previous breast cancer.
- The risk of developing blood clots in the deep veins of the legs in users of combined pills increases:
  - With increasing age;

- If you are overweight;
  - If one of your close relatives has developed a blood clot in a vessel at an early age;
  - With prolonged immobilization (when you have your leg or legs in plaster or splints or are on prolonged bedrest), major surgery, any surgery to the legs, major trauma. In these situations it is better to stop taking Levonorgestrel/Ethinyl estradiol (Nordette). If you have a planned surgery, you should stop the medicine at least four weeks beforehand and you can resume it two or more weeks after you are fully on your feet again;
  - Directly after giving birth or after suffering a 2<sup>nd</sup> trimester miscarriage, women are at an increased risk of blood clots so you should ask your doctor how soon you can start taking a combined pill.
- The risk of heart attack or stroke in users of combined pills increases:
    - If you smoke: You are strongly advised to stop smoking when you use Levonorgestrel/Ethinyl estradiol (Nordette);
    - With increasing age even if you do not smoke;
    - If you have an increased fat content in your blood (cholesterol or triglycerides);
    - If you are overweight;
    - If one of your close relatives has had a heart attack or stroke at a young age;
    - If you have high blood pressure;
    - If you have migraine

Levonorgestrel/Ethinyl estradiol (Nordette) and cancer: Breast cancer has been detected slightly more often in women using combination pills, but it is not known whether this is caused by the pill. It is possible that these women were simply examined more thoroughly and more frequently, meaning that the breast cancer was detected earlier.

Studies have reported cases of cervical cancer or precancer in women using combination pills. It is currently unknown whether it is caused by the pill or connected with sexual behavior (e.g. more frequent changes of partner) and other factors. In rare cases, benign liver tumors, and in even fewer cases malignant liver tumors have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

If you have hereditary angioedema, products containing estrogens may cause or worsen the symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing.

During the first few months, especially during the first three months, that you are taking Levonorgestrel/Ethinyl estradiol (Nordette), you may have unexpected bleeding (bleeding or spotting outside the tablet-free week). If this bleeding persists, or if it recurs, you must consult your doctor in order to investigate the cause.

If you are using medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir, with or without ribavirin, inform your doctor immediately. You must switch to an alternative method of contraception prior to starting therapy with anti-viral HCV medicinal products such as ombitasvir, paritaprevir, ritonavir, dasabuvir. Consult your doctor for alternative methods of contraception. Once you have completed the course of anti-viral HCV treatment, consult your doctor if and when you can resume taking Combined Oral Contraceptive (COC) products.

### **Pregnancy and lactation**

Do NOT take Levonorgestrel/Ethinyl estradiol (Nordette) if you are pregnant. If you think you may have become pregnant while using Levonorgestrel/Ethinyl estradiol (Nordette), tell your doctor immediately. There is no conclusive evidence that the estrogen and progestin

contained in the medicine will damage the developing child if conception accidentally occurs during Levonorgestrel/Ethinyl estradiol (Nordette) use.

Taking Combined Oral Contraceptive pills such as Levonorgestrel/Ethinyl estradiol (Nordette) while you are breastfeeding is NOT recommended as the hormones can affect the amount and composition of your milk. If you wish to breastfeed, your doctor will be able to advise you on suitable alternative methods of contraception.

## **9.0 UNDESIRABLE EFFECTS OF THIS MEDICINE**

Use of birth control pills has been associated with increased risk of blood clot formation in arteries and veins (including heart attack, stroke, venous thrombosis and pulmonary embolism); cervical cancer or pre-cancer; breast cancer diagnosis and benign liver tumors.

### **Very common side effects (affect 1 in 10 women or more) include:**

- Headache, including migraines;
- Breakthrough bleeding/spotting.

### **Common side effects (affect less than 1 in 10 women) include:**

- Inflammation of vagina resulting in discharge, itching and pain (vaginitis), vaginal thrush (candidiasis);
- Mood changes, including depression, changes in sex drive;
- Nervousness, dizziness;
- Nausea, vomiting, abdominal pain;
- Acne;
- Breast pain, tenderness, enlargement, secretion; painful periods, missed periods, changes in menstrual bleeding patterns, changes in the cervix (lower part of the womb) and cervical secretion;
- Swelling of the hands, ankles or feet, fluid retention;
- Weight changes (increase or decrease).

### **Uncommon side effects (affect less than 1 in 100 women) include:**

- Changes in appetite (increase or decrease);
- Stomach cramps, bloating;
- Rash, brown patches on your face (chloasma) which may persist, unwanted male-pattern hair growth in women (hirsutism), hair loss;
- Increase in blood pressure;
- Changes in the fat levels in your blood (e.g. high triglyceride levels);

### **Rare side effects (affect less than 1 in 1000 women) include:**

- Serious allergic reaction which causes difficulty in breathing or dizziness including swelling of the skin and its underlying tissues;
- Increase in blood sugar (glucose intolerance);
- Contact lenses may feel uncomfortable;
- Yellowing of the skin or whites of the eyes caused by high levels of bile pigments (cholestatic jaundice);
- Painful red lumps on skin (erythema nodosum);
- Decrease in the folic acid levels in blood.

### **Very rare side effects (affect less than 1 in 10,000 women) include:**

- Liver cancer;

- Worsening of systemic lupus erythematosus (an autoimmune disease in which the body's immune system mistakenly attacks healthy tissue. It can affect the skin, joints, kidneys, brain, and other organs);
- Worsening of porphyria (a rare disease of the blood pigments);
- Worsening of chorea (a disease of the nervous system causing sudden movements of the body);
- Inflammation of the nerve to the eye (optic neuritis) which may cause partial or complete loss of vision, problems with the vein at the back of your eye which may cause partial or complete loss of vision (retinal vascular thrombosis);
- Worsening of varicose veins;
- Inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis); pain and diarrhea due to restricted blood supply to the large intestine or colon (ischemic colitis);
- Gallstones and gallbladder disease;
- Pink-red blotches on skin (erythema multiforme);
- Anemia due to abnormal premature destruction of red blood cells with kidney injury (hemolytic-uremic syndrome).

**Side effects with unknown frequency include:**

- Liver injury (e.g. hepatitis, abnormal liver function tests)
- Ulcerative colitis or Crohn's disease (inflammation of the bowels which causes pain in the abdomen, frequent diarrhea and tiredness)

**10.0 WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?**

Please consult your doctor for instructions if you need to take any of these:

- Medicines used for the treatment of tuberculosis (such as rifabutin, rifampicin);
- Medicines used for the treatment of epilepsy and other conditions (barbiturates, primidone, phenytoin, topiramate, some protease inhibitors and lamotrigine);
- Medicines used to reduce inflammation (corticosteroids, such as dexamethasone);
- Modafinil (used to treat excessive daytime sleepiness);
- Medicines used for treatment of HIV infections, such as ritonavir, indinavir;
- St. John's Wort (medicinal herb used for certain types of depression);
- Antifungal medicines (such as griseofulvin, fluconazole);
- Atorvastatin (used to treat high cholesterol level);
- Medicines used for fever and pain relief (such as paracetamol and phenylbutazone);
- Cyclosporine (used to prevent organ rejection);
- Theophylline (used for asthma and other breathing difficulties);
- Vitamin C;
- Medicines used to treat migraine, such as flunarizine;
- Medicines containing ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribavirin (anti-viral Hepatitis C virus (HCV) medications): you must use a different method of contraception while you are taking this type of medicine

There have been reports of pregnancy when COCs were co-administered with certain antibiotics (e.g., ampicillin and other penicillins, tetracyclines).

Consult your doctor if you need to take other medications together with Levonorgestrel/Ethinyl estradiol (Nordette) as drug interactions may occur.

If you are scheduled for any laboratory tests, tell your doctor you are taking Levonorgestrel/Ethinyl estradiol (Nordette). Some blood tests may be affected by taking Levonorgestrel/Ethinyl estradiol (Nordette).

### **11.0 WHAT SHOULD YOU DO IF YOU MISS A DOSE?**

- **Contraceptive protection may be reduced if active tablets are missed, particularly if the missing of tablets extends the tablet-free interval.**
- If you forget one Levonorgestrel/Ethinyl estradiol (Nordette) tablet but you remember within 12 hours of the usual dose, take the missed tablet immediately. Take the next tablet at your usual time;
- If one Levonorgestrel/Ethinyl estradiol (Nordette) tablet is missed and is remembered more than 12 hours after the usual dose or if two or more tablets are missed, your contraceptive protection may be reduced so you must use extra protection for the next 7 days. Take the last missed tablet as soon as you remember, even if this means taking two tablets in one day. Continue to take subsequent tablets at your usual time but you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature method) for the next 7 days.
- If you take the last Levonorgestrel/Ethinyl estradiol (Nordette) tablet before the 7-day interval (during which the use of an additional non-hormonal method of contraception is required) has ended, you must begin a new Levonorgestrel/Ethinyl estradiol (Nordette) pack immediately (no tablet-free interval between packs). Withdrawal bleeding is unlikely until the end of the new pack, but there may be some spotting, or breakthrough bleeding, on the days you are taking tablets. If you do not get a withdrawal bleeding after all the tablets in the new pack are used, the possibility of pregnancy must be considered and you must consult your doctor.

#### **Alternative Management of Missed dose**

- If one active tablet is missed, it should be taken as soon as it is remembered. Subsequent tablets should be taken at the usual time.
- If two consecutive active tablets are missed during Week 1 or Week 2, two tablets should be taken on both the day remembered and the following day. Subsequent tablets should be taken at the usual time. A nonhormonal back-up method of birth control must be used for the next 7 days.
- If two consecutive active tablets are missed during Week 3 or if three or more consecutive active tablets are missed during weeks 1-3, the following apply:
  - Day 1 starters should discard any tablets remaining in the current pack and start a new pack the same day.
  - Sunday starters should continue taking one tablet every day until the following Sunday. On Sunday, any tablets remaining in the current pack should be discarded, and a new pack should be started the same day.
  - Both Day 1 and Sunday starters must use a nonhormonal back-up method of birth control for the next 7 days. The user may not have a withdrawal bleed until all tablets in the new pack have been taken. If the user does not have a withdrawal bleed after all tablets in the new pack have been taken, pregnancy must be ruled out before tablet-taking is resumed.

## **12.0 SIGNS AND SYMPTOMS OF OVERDOSE**

Taking too many tablets may cause nausea, vomiting, breast tenderness, dizziness, abdominal pain, drowsiness/fatigue and withdrawal bleeding in some cases.

## **13.0 WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?**

There is no specific antidote and further treatment of overdose, if necessary, is directed to the symptoms. Seek the advice of your physician.

## **14.0 HOW SHOULD YOU KEEP THIS MEDICINE?**

Keep out of the reach of children.

Store at temperatures not exceeding 30°C.

Protect from light and moisture.

## **15.0 WHEN SHOULD YOU CONSULT YOUR DOCTOR?**

Tell your doctor immediately if you notice any of the following:

- Sharp chest pain, coughing of blood or sudden shortness of breath (indicating a possible clot in the lungs);
- Pain in the calf muscle area;
- Crushing chest pain or heaviness in the chest (indicating a possible heart attack);
- Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg (indicating a possible stroke);
- Sudden changes or loss of vision (indicating a possible clot in the eye);
- Breast lumps (indicating possible breast cancer or fibrocystic disease of the breast; ask your healthcare provider to teach you how to examine your breasts);
- Severe pain or tenderness in the stomach area (indicating a possible ruptured liver tumor);
- Difficulty in sleeping, weakness, lack of energy, fatigue, or change in mood (possibly indicating severe depression);
- Yellowing of the skin or eyeballs, often with fever, fatigue, loss of appetite, dark colored urine or light colored bowel movements (indicating possible liver problems);
- Migraine headaches for the first time;
- More frequent migraines if you already suffer from them;
- Severe pain and/or swelling in one of your legs;
- Sudden changes to your hearing, sense of smell or taste;
- Itchy rash;
- 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 around eyes or mouth;
- Bloody diarrhea, abdominal pain or tenderness, fever, nausea or vomiting.

## **16.0 FDA REGISTRATION NUMBER**

Levonorgestrel 150 mcg/Ethinyl estradiol 30 mcg (Nordette) Tablet: DR-XY23241.

## **17.0 DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION**

Levonorgestrel 150 mcg/Ethinyl estradiol 30 mcg (Nordette) Tablet: 7 July 2003.

**For suspected adverse drug reaction, report to the FDA: [www.fda.gov.ph](http://www.fda.gov.ph)**



**Seek medical attention immediately at the first sign of any adverse drug reaction.**

**Caution:** Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription

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Under the Authority of PFIZER, INC., New York, NY, U.S.A.

Revision No.: 3.0 Revision Date: 17 January 2023 Reference: LPD revision 3.0 Reference Date: 16 January 2023
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