1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

NORDETTE 150 µg/ 30 µg sugar- coated tablets

Levonorgestrel and ethinyl estradiol

Contains sugar (active tablets): Lactose monohydrate 32,97 mg, sucrose 22,456 mg

Contains sugar (inactive tablets): Lactose monohydrate 38,006 mg, sucrose 25,686 mg

Read all of this leaflet carefully before you start taking NORDETTE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- NORDETTE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

NORDETTE belongs to a group of medicines called combined oral contraceptive pills (“the Pill”). You take it to prevent you from getting pregnant. Sometimes it is also prescribed for the control of cases of dysfunctional bleeding in the womb and in the symptomatic treatment of primary painful menstruation where contraception is also desired. This contraceptive contains two types of female sex hormones, estrogen and progestogen. These hormones stop you from getting pregnant by working in three ways: by preventing an egg being released from your ovaries; by making the fluid (mucous) in your cervix thicker, which makes it more difficult for sperm to enter the womb; and by preventing the lining of your womb thickening enough for an egg to grow in it.

NORDETTE is a 28-day Pill - you take one each day for 28 days. There are 21 active yellow tablets and 7 inactive red tablets.

NORDETTE needs to be taken as directed to prevent pregnancy.

2. What you need to know before you take NORDETTE

Do not take NORDETTE:

- if you are hypersensitive (allergic) to levonorgestrel and/or ethinyl estradiol or any of the other ingredients of NORDETTE (listed in section 6).
- if you have depression and this is not well controlled with treatment.
- if you have had depression with previous use of hormonal contraceptives.
- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs.
- if you know you have a disorder affecting your blood clotting, for instance protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies.
- if you need an operation or if you are off your feet for a long time (see Blood clots).

- if you have ever had a heart attack or stroke.
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA - temporary stroke symptoms).
- if you have any of the following diseases that may increase your risk of a clot in the arteries:
  - severe diabetes with blood vessel damage,
  - high blood pressure,
  - a high level of fat in the blood (cholesterol or triglycerides),
  - a condition known as hyperhomocysteinaemia (high homocysteine levels which can contribute to arterial damage and blood clots in your blood vessels).
- if you have (or have ever had) a type of migraine called ‘migraine with aura’.
- if you have or have ever had breast cancer.
- If you have a family history of breast cancer.
- if you have or have ever had a severe liver disease and you have been told by your doctor that your liver function test results are not yet back to normal.
- if you have ever had liver tumours.
- if you are also taking medicines containing ritonavir, ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and ofosbuvir/velpatasvir/voxilaprevir.
- if you are known to have inherited genetic changes called "BRCA 1 and/or BRCA 2 genes."
- if you started your menstrual periods (before the age of 12 years).
- if you have a history of non-cancerous breast diseases such as atypical hyperplasia or lobular carcinoma *in situ*.
- if you had any previous treatment using radiation therapy to the chest or breast.
- if you have been treated or exposed while in your mother's womb to a medicine called diethylstilbestrol (DES).

- if you are pregnant or breastfeeding your baby.

General notes

Before you start taking NORDETTE you should read the information on blood clots. It is particularly important to read the symptoms of a blood clot (see section 4).

It's important that you understand the benefits and risks of taking NORDETTE before you start taking it, or when deciding whether to carry on taking it. Although NORDETTE is suitable for most healthy women, it isn't suitable for everyone.

Tell your doctor if you have any of the illnesses or risk factors mentioned in this leaflet.

Warnings and precautions

Take special care with NORDETTE:

CIGARETTE SMOKING

CIGARETTE SMOKING INCREASES THE RISK OF SERIOUS CARDIOVASCULAR SIDE EFFECTS FROM THE USE OF ORAL CONTRACEPTIVES. THE RISK INCREASES WITH AGE AND WITH HEAVY SMOKING (15 OR MORE CIGARETTES PER DAY) AND IS QUITE MARKED IN WOMEN OVER 35 YEARS OF AGE. YOU ARE THEREFORE STRONGLY ADVISED TO STOP SMOKING.

UNDER NO CIRCUMSTANCES SHOULD THE ORAL CONTRACEPTIVE TABLET BE STOPPED WITHOUT HAVING ADOPTED A SATISFACTORY ALTERNATIVE METHOD OF CONTRACEPTION.

Your doctor will ask about you and your family's medical problems, check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you, or if you have any

special concerns.

Tell your doctor if any of the following conditions apply to you:

If these conditions develop, or get worse while you are taking NORDETTE, you should also tell your doctor.

- if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Medicines containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.
- if you are on treatment for depression.
- if you have had depression with previous use of hormonal contraceptives.
- if you have a substance abuse problem.
- if you have underlying psychiatric disorder such as post-traumatic stress disorder or bipolar disorder.
- if you have a family history of mental disorders.
- if you have a history of physical or sexual abuse.
- if you suffer from severe kidney impairment. Your dose may need to be adjusted.
- if you have a history of liver disease or consume excessive quantities of alcohol.
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease).
- if you have systemic lupus erythematosus (SLE - a disease affecting your natural defence system).
- if you have haemolytic uraemic syndrome (HUS - a disorder of blood clotting causing failure of the kidneys).
- if you have sickle cell anaemia (an inherited disease of the red blood cells).
- if you have inflammation of the pancreas (pancreatitis).
- if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk

of developing pancreatitis (inflammation of the pancreas).

- if you need an operation, or you are off your feet for a long time (see Blood clots).
- if you have just given birth, you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking NORDETTE.
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis).
- if you have varicose veins.
- if you have diabetes.
- if you or your close family have ever had problems with your heart or circulation, such as high blood pressure.
- if you or your close family have ever had problems with blood clotting.
- if you have the inherited disease called porphyria.
- if you are overweight (obese).
- if you have migraines.
- if you have any illness that worsened during pregnancy or previous use of NORDETTE.
- if you have Dubin Johnson's syndrome.
- if you have Rotor syndrome.
- if you experience irregular vaginal bleeding.
- if you have a history of infrequent or abnormally light periods (oligomenorrhoea) or you miss your period for three or more months after previously having a normal period (secondary amenorrhoea).
- if you notice changes in your period.

Tell your doctor if you notice any of the following:

The following conditions may worsen during pregnancy or previous use of the Pill:

- yellowing of the skin (jaundice),
- persistent itching (pruritus),
- kidney or liver problems,

- gall stones,
- certain rare medical conditions such as systemic lupus erythematosus,
- blister-like rash (herpes gestationis) whilst pregnant,
- an inherited form of deafness (otosclerosis),
- a personal or family history of a form of sickle cell disease,
- swelling of body parts (hereditary angioedema),
- an inherited disease called porphyria,
- cancer of the cervix.

While you are taking NORDETTE

- You will need regular check-ups with your doctor or healthcare provider, usually when you need another prescription of NORDETTE.
- You should go for regular cervical smear tests.
- Check your breasts and nipples every month for changes - tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- If you need a blood test tell your doctor that you are taking NORDETTE, because NORDETTE can affect the results of some tests.
- If you're going to have an operation, make sure your doctor knows about NORDETTE. You may need to stop taking NORDETTE about 4 to 6 weeks before the operation. This is to reduce the risk of a blood clot (see Blood clots). Your doctor will tell you when you can start taking NORDETTE again.

NORDETTE will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Blood clots

Using a combined oral contraceptive such as NORDETTE increases your risk of developing a

blood clot. A blood clot can block vessels and cause serious problems.

Blood clots can develop:

- in the veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE),
- in the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. There may be serious lasting effects, or they may be fatal.

What can happen if a blood clot forms?

- If a blood clot forms in a vein in the leg or foot, it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism.
- A clot may form in a vein in another organ such as the eye (retinal vein thrombosis).
- A clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

What is the risk of developing a blood clot?

The risk of having a blood clot will vary according to your personal medical history (see **Factors that increase your risk of a blood clot**).

When is the risk of developing a blood clot highest?

The risk of developing a blood clot is highest during the first year of taking NORDETTE for the first time. The risk may also be higher if you restart taking NORDETTE (or a different medicine) after a break of 4 weeks or more. After the first year, the risk gets smaller but is always higher than if you were not using NORDETTE.

When you stop NORDETTE your risk of a blood clot returns to normal within a few weeks.

Factors that increase your risk of a blood clot

- **If you smoke.** When using NORDETTE, you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive.
- If you have high blood pressure.
- If a member of your immediate family has had a heart attack or stroke at a young age (less than about 50 years). In this case you could also have a higher risk of having a heart attack or stroke.
- If you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides).
- If you get migraines, especially migraines with aura.
- If you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation).
- If you have diabetes.
- If you are overweight (body mass index or BMI over 30 kg/m^2).
- If one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50 years). In this case you could have a hereditary blood clotting disorder.
- If you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of NORDETTE may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop NORDETTE, ask your doctor when you can start using it again.
- As you get older (particularly above about 35 years).
- If you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have. If you have more than one of these conditions or if any of them are particularly severe, the risk of developing a blood clot may be increased even more.

Air travel (> 4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.

It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that NORDETTE needs to be stopped.

If any of the above conditions change while you are using NORDETTE, for example you start smoking, a close family member experiences a thrombosis for no known reason, or you gain a lot of weight, tell your doctor.

NORDETTE and cancer

Oral contraceptives such as NORDETTE increase your risk of cancer of the cervix. All women should have regular smear tests.

NORDETTE and breast cancer

If you have breast cancer, or have had it in the past, you should not take NORDETTE. Oral contraceptives, such as NORDETTE increase your risk of breast cancer.

Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill.

When you are using NORDETTE, you must perform monthly breast self-examinations. Your doctor will advise you on when to report for breast examinations and any appropriate investigations.

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.

See a doctor as soon as possible if you notice any changes in your breasts, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

NORDETTE has also been linked to liver diseases, such as jaundice and non-cancerous liver tumours. Oral contraceptives have also been linked with some forms of liver cancer in women

who have taken them for a long time.

See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice). You may need to stop taking NORDETTE.

Other medicines and NORDETTE

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

If you ever need to take another medicine at the same time as being on NORDETTE, always tell your doctor, pharmacist or other healthcare provider that you're taking NORDETTE. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can have an influence on the blood levels of NORDETTE and can stop it from working properly - for example:

- some medicines used to treat epilepsy e.g. phenytoin, carbamazepine, oxcarbazepine, topiramate, felbamate,
- some medicines used to treat HIV such as ritonavir, nelfinavir and nevirapine, and hepatitis C virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors),
- griseofulvin, itraconazole, voriconazole, fluconazole (anti-fungal medicines),
- certain antibiotics, e.g. ampicillin, penicillin v, tetracycline, rifampicin, neomycin, chloramphenicol, sulphonamides, nitrofurantoin, erythromycin,
- certain sedatives (called barbiturates i.e. phenobarbitone primidone),
- St. John's Wort (a herbal remedy),
- etoricoxib (medicine used to reduce pain and swelling in the joints and muscles)

If you do need to take one of these medicines, NORDETTE may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or other healthcare provider can tell you if this is necessary and for how long.

Do not use NORDETTE if you have hepatitis C and are taking medicines containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir and sofosbuvir/velpatasvir/voxilaprevir, as these medicines may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicines. NORDETTE can be restarted approximately 2 weeks after completion of this treatment. See section “Do not use NORDETTE”.

NORDETTE can also affect how well other medicines work. NORDETTE can either increase or decrease the blood levels of the following medicines:

- Ciclosporin: used to treat inflammatory diseases.
- Theophylline: used to treat breathing problems such as asthma.
- Lamotrigine: used to treat epilepsy.

Your doctor may need to adjust the dose of your other medicine.

In addition, NORDETTE can also interfere with the results of some blood tests, so always tell your doctor that you are taking NORDETTE if you have a blood test.

NORDETTE with food and drink

There are no special instructions about food and drink while taking NORDETTE.

Pregnancy, breastfeeding and fertility

You should not take NORDETTE if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machinery

NORDETTE is not expected to influence your ability to drive. However, you should not drive, use machinery or perform any tasks that require concentration until you are certain that NORDETTE does not adversely affect your ability to do so safely (see section 4).

NORDETTE contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking NORDETTE.

3. How to take NORDETTE

Do not share medicines prescribed for you with any other person.

Always take NORDETTE exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

To prevent pregnancy, always take NORDETTE as described below. Check with your doctor or healthcare provider if you are not sure.

Take NORDETTE every day for 28 days

NORDETTE comes in strips of 28 tablets. There are 21 active yellow tablets, and 7 inactive red tablets.

- Take your tablet at the same time every day, no longer than 24 hours apart, preferably after the evening meal or at bedtime.
- Swallow each tablet whole, with water if necessary. Do not chew the tablet.
- If it is the first time you take NORDETTE, take one yellow tablet daily for 21 uninterrupted days, beginning on Day 1 of your menstrual cycle, i.e. the first day of bleeding.
- One red inactive tablet is taken daily for the next 7 continuous days.
- Withdrawal bleeding should usually occur 2 to 4 days after the last yellow tablet is taken.

- During this first cycle, an alternative method of contraception, such as a condom, should be used together with NORDETTE until 14 tablets have been taken. If the tablets are begun after day 5 of your menstrual cycle, or after giving birth, it must be considered that ovulation and conception may have occurred before the tablets were started.

Then start your next strip

The next and all the following courses will begin on the day after the last package was completed, even if withdrawal bleeding has not occurred or is still in progress. Each course of NORDETTE is therefore begun on the same day of the week and follows the same schedule (21 days of yellow tablets, 7 days of red inactive tablets) as the first course.

Changing to NORDETTE from another contraceptive Pill

If you are changing from another oral contraceptive product to NORDETTE, start NORDETTE on the day you would usually start a new package of the other medicine. During the first NORDETTE cycle, an alternative method of contraception, such as a condom, should be used until 14 uninterrupted tablets have been taken. If temporary spotting or breakthrough bleeding occurs, continue the treatment since such bleeding is usually without significance. If the bleeding is persistent or prolonged, contact your doctor.

- **If you are currently taking a 21-day Pill or a 28-day Pill:**

Start NORDETTE the next day after the end of the previous strip.

- **Or, if you are taking a progestogen-only Pill (POP or 'mini Pill'):**

Start NORDETTE on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. The remaining progestogen-only tablets should be discarded (see How to store NORDETTE).

Starting NORDETTE after a miscarriage or abortion

If you have had a miscarriage or an abortion **during the first three months** of pregnancy, your doctor may tell you to start taking NORDETTE straight away. Discuss this with your healthcare provider.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby and you are breastfeeding, your doctor may advise you that you should start with an alternative oral contraceptive 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start the oral contraceptive your doctor has prescribed and for the first 7 days of pill taking.

If you are sick or have diarrhoea

If you are sick (vomit) or have very bad diarrhoea within 4 hours of taking NORDETTE, your body may not get its usual dose of hormones from that tablet. Take another tablet and continue with the pack.

Talk to your doctor if your stomach upset carries on or gets worse. He or she may recommend another form of contraception.

Missed a period - could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test.

You can buy these from the pharmacy. If you are pregnant, stop taking NORDETTE and see your doctor.

When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping NORDETTE until you have had a proper period. Your doctor relies on the date of your last natural period to tell you when your baby is due.

Your doctor will tell you how long your treatment with NORDETTE will last (see **If you forget to take NORDETTE**).

If you have the impression that the effect of NORDETTE is too strong or too weak, tell your

doctor or pharmacist.

If you take more NORDETTE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to take NORDETTE

Take a missed yellow tablet as soon as you remember. If two consecutive yellow tablets are missed, they should both be taken as soon as you remember. In either case, the next tablet should be taken at its usual time. Each time you miss one or two consecutive yellow tablets, a mechanical method of contraception, such as a condom, should be supplemented until 14 consecutive daily tablets have been taken or until the package is finished if less than 14 yellow tablets remain.

If you miss one or more red inert tablets, you are still protected against pregnancy, provided you begin the yellow tablets on the proper day. If three consecutive yellow tablets are missed, NORDETTE should be discontinued, and the remainder of the package discarded. A new package should be started on the eighth day after the last tablet was taken.

A mechanical method of contraception, such as a condom, should be used until 14 consecutive daily tablets have been taken.

If withdrawal bleeding does not occur and NORDETTE has been taken according to directions, it is unlikely that you could be pregnant. Begin a second course of NORDETTE on the usual day. If bleeding does not occur at the end of this second cycle, you should not take NORDETTE until you are certain that you are not pregnant, by consulting your doctor and having a pregnancy test done.

If you have missed one or more yellow tablets or started taking them on a day later than recommended, the probability of pregnancy should be considered at the time of the first missed period before NORDETTE is restarted.

4. Possible side effects

NORDETTE can have side effects.

Not all side effects reported for NORDETTE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NORDETTE, please consult your healthcare provider for advice.

If any of the following happens, stop taking NORDETTE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are very serious side effects. If you have them, you may have had a serious reaction to NORDETTE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Are you experiencing any of these signs?	**What are you possibly suffering from?**

- swelling of one leg or along a vein in the leg or foot especially when accompanied by:
  - pain or tenderness in the leg which may be felt only when standing or walking
  - increased warmth in the affected leg
  - change in colour of the skin on the leg e.g. turning pale, red or blue
	Deep vein thrombosis

- sudden unexplained breathlessness or rapid breathing - sudden cough without an obvious cause, which may bring up blood - sharp chest pain which may increase with deep breathing - severe light headedness or dizziness - rapid or irregular heartbeat - severe pain in your stomach If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	Pulmonary embolism
Symptoms most commonly occur in one eye: - immediate loss of vision or painless blurring of	Retinal vein thrombosis (blood clot in the eye)

vision which can progress to loss of vision	
- chest pain, discomfort, pressure, heaviness - sensation of squeezing or fullness in the chest, arm or below the breastbone - fullness, indigestion or choking feeling - upper body discomfort radiating to the back, jaw, throat, arm and stomach - sweating, nausea, vomiting or dizziness - extreme weakness, anxiety, or shortness of breath, rapid or irregular heartbeats	Heart attack
- sudden weakness or numbness of the face, arm or leg, especially on one side of the body - sudden confusion, trouble speaking or understanding - sudden trouble seeing in one or both eyes - sudden trouble walking, dizziness, loss of balance or coordination - sudden, severe or prolonged headache with no known cause - loss of consciousness or fainting with or without seizure Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Stroke
- swelling and slight blue discolouration of an extremity, severe pain in your stomach (acute abdomen)	Blood clots blocking other blood vessels

- Signs of breast cancer include:

  -dimpling of the skin,

  -changes in the nipple,

  -any lumps you can see or feel.

- Signs of cancer of the cervix include:

  - vaginal discharge that smells and/or contains blood,
  - unusual vaginal bleeding,
  - pelvic pain, painful sex.

- Signs of severe liver problems include:

- severe pain in your upper abdomen,
- yellow skin or eyes, light-coloured stools and dark urine (*jaundice or obstructive jaundice*,
- inflammation of the liver (*hepatitis*),
- your whole body starts itching.

- suicidal thoughts/ behaviour and suicide,
- inflammatory disease caused when the immune system attacks its own tissues (Systemic Lupus Erythematosus),
- hypertension, venous thromboembolism (VTE), arterial thromboembolism (ATE). An increased risk of arterial and venous thrombotic and thrombo-embolic events, including myocardial infarction, stroke (e.g. ischaemic stroke, haemorrhagic stroke), transient ischaemic attacks, venous thrombosis and pulmonary embolism has been observed in women using combined oral contraceptives (COCs),
- inflammation of the pancreas (may have symptoms of upper stomach pain, stomach pain that feels worse after eating, fever, rapid pulse),
- erythema multiforme (skin reaction),
- Crohn's disease (can lead to abdominal pain, severe diarrhoea, fatigue, weight loss),
- precipitation of acute attack of porphyria,

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- depressive moods,
- changed moods, mood swings, nervousness
- headache,
- nausea (feeling sick),

- abdominal pain (stomachache),
- breast pain (sore or painful breasts),
- breast tenderness,
- acne,
- bleeding and spotting between your periods can sometimes occur for the first few months but this usually stops once your body has adjusted to NORDETTE. If it continues, becomes heavy or starts again, contact your doctor (see **Bleeding between periods should not last long**),
- vaginal candidiasis (fungal infection that causes irritation, discharge and intense itchiness of the vagina and the vulva),
- vaginitis (inflammation of the vagina).

Less frequent side effects

- hypersensitivity,
- exacerbation of hereditary angioedema (recurrent episodes of severe swelling),
- fluid retention,
- hypertriglyceridaemia (elevated levels of fat),
- increase or decrease in weight,
- changes in appetite,
- decreased or increased interest in sex,
- premenstrual-like syndrome (PMS),
- migraine,
- dizziness,
- changes in corneal curvature (steepening),
- intolerance to contact lenses,
- cataracts,
- vomiting,

- diarrhoea,
- abdominal cramps,
- bloating,
- gastrointestinal irritation,
- liver function disturbances,
- gallbladder disease,
- urticarial erythema nodosum (type of skin inflammation),
- skin pigmentation,
- breast hypertrophy (overgrowth of breast tissue),
- vaginal discharge,
- breast secretion,
- change in cervical erosion or cervical secretion,

Side effects with an unknown frequency

- hirsutism (abnormal growth of hair on a woman's face and body),
- loss of scalp hair,
- haemorrhagic eruption (bleeding),
- cystitis like syndrome (is a chronic condition causing bladder pressure, bladder pain and sometimes pelvic pain),
- haemolytic uremic syndrome (vessels in the kidney become damaged),
- ulcerative colitis (causes long-lasting inflammation and ulcers (sores) in your digestive tract),
- reduced menstrual flow,
- post pill amenorrhoea (missing of menstrual period),
- exacerbation of chorea (movement disorder),
- chloasma or melasma which may be persistent. Chloasma is yellow brown patches on the skin. This may happen even if you have been using NORDETTE for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking NORDETTE, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking NORDETTE as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

Make an appointment to see your doctor if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking NORDETTE for a while
- carries on even after you've stopped taking NORDETTE.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to **SAHPRA:** via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/+27 (0) 11 239-6200

By reporting side effects, you can help provide more information on the safety of NORDETTE

5. How to store NORDETTE

Store all medicines out of reach of children

Store at or below 25 °C.

Protect from light.

Keep the blisters in the carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NORDETTE contains

The active substances in each yellow active sugar-coated tablet of NORDETTE are levonorgestrel 150 µg and ethinyl estradiol 30 µg.

The other ingredients are:

Active tablets

Calcium carbonate, iron oxide yellow (C.I. 77492), lactose monohydrate, magnesium stearate, maize starch, methyl parahydroxybenzoate, polyethylene glycol, Povidone, Povidone 25, Povidone 90F, propyl parahydroxybenzoate, purified talc, sucrose refined white H1, titanium dioxide (C.I. 77891), waradur XE.

Preservative

Methyl parahydroxybenzoate 0,001 % *m/m*

Propyl parahydroxybenzoate 0,00076 % *m/m*

Contains sugar: Lactose monohydrate 32,97 mg, sucrose 22,456 mg

Each red inactive sugar-coated tablet contains:

Calcium carbonate, colour FD&C Red No.3 aluminium lake (C.I. 45430), FD&C yellow # 6/sunset yellow FCF (C.I. 15985), magnesium stearate, microcrystalline cellulose PH 102, polyethylene glycol, Ponceau 4R aluminium lake (C.I. 16255), povidone, quinoline yellow aluminium lake (C.I. 47005), purified talc, Povidone 90F, sodium benzoate, sucrose refined white H1, Tablettose 80, waradur XE.

Preservative

Sodium benzoate 0,0018 % *m/m*

Contains sugar: Lactose monohydrate 38,006 mg, sucrose 25,686 mg

What NORDETTE looks like and contents of the pack

21 active yellow tablets: NORDETTE is a yellow, lustrous, round, biconvex sugar-coated tablet.

7 red inert tablets: NORDETTE is a red, biconvex, sugar-coated tablet.

28 tablets consisting of 21 yellow active tablets and 7 red inert tablets. The tablets are packed in clear polyvinyl chloride blister strips sealed with an aluminium foil backing. One blister strip is packed into a pre-printed cardboard carton together with a leaflet.

28 tablets consisting of 21 yellow active tablets and 7 red inert tablets. The tablets are packed in clear polyvinyl chloride blister strips sealed with an aluminium foil backing. 100 strips together with 100 leaflets are packed into a shipper carton.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912/ +27 (0) 11 239-6200 (South Africa)

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Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

Botswana: B9319920 S2

Namibia: NS2 90/18.8/001077

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