B. PACKAGE LEAFLET

Package leaflet: Information for the user

Marynarka 0,075 mg/ 0,020 mg tabletten

Gestodene / Ethinylestradiol

Important things to know about combined hormonal contraceptives (CHCs):

- They are one of the most reliable reversible methods of contraception if used correctly
- They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks
- Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 "Blood clots")

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 or need more advice, ask your doctor, family planning nurse, or pharmacist.
-This medicine has been prescribed for you only. Do not pass it on to others. It may harm them.
-If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this lealfet. See section 4.

What is in this leaflet

1. What Marynarka is and what it is used for

• Marynarka is a contraceptive tablet and is used to prevent pregnancy.
• Each tablet contains a small amount of two different female hormones, namely ethinylestradiol and gestodene.
• Contraceptive tablets as Marynarka that contain two hormones are called "combination" contraceptives.

2. What you need to know before you take Marynarka

General notes

Before you start using Marynarka you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot – see Section 2 "Blood clots"

Before you can begin taking Marynarka, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and depending upon your personal situation, may also carry out some other tests. In this

leaflet, several situations are described where you should stop using Marynarka, or where the reliability of Marynarka may be decreased. In such situations you should either not have intercourse or you should take extra non-hormonal contraceptive precautions, e.g., a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Marynarka alters the monthly changes of the body temperature and of the cervical mucus.

Marynarka, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

When you should not use Marynarka

You should not use Marynarka if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

- 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 section 'Blood clots');
- if you have ever had a heart attack or a 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
  - very high blood pressure
  - a very high level of fat in the blood (cholesterol or triglycerides)
  - a condition known as hyperhomocysteinaemia
- if you have (or have ever had) a type of migraine called 'migraine with aura';
- if you have (had) an inflammation of the pancreas (pancreatitis)
- if you have or have had a liver disease and your liver function is still not normal.
- if you have or have had a tumour in the liver.
- if you have (had) or if you are suspected to having breast cancer or cancer of the genital organs.
- if you have any unexplained bleeding from the vagina.
- if you are pregnant or think you may be pregnant.
- if you are allergic to ethinylestradiol or gestodene, or any of the other ingredients of Marynarka (listed in section 6). This can be recognised by itching, rash or swelling.
- Do not use Marynarka if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir / pibrentasvir (see also in section Other medicines and Marynarka).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking this medicine.

When should you contact your doctor?

Seek urgent medical attention
if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clot' (thrombosis) section below.
For a description of the symptoms of these serious side effects please go to "How to recognise a blood clot".

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

If the condition develops, or gets worse while you are using Marynarka, you should also tell your doctor.

- 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 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 in section 2 '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 Marynarka;
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis);
- if you have varicose veins.
- if a close relative has (had) breast cancer or breast cancer was diagnosed
- if you have a disease of the liver or the gallbladder
- if you have diabetes
- if you have depression
- if you have epilepsy (see section "Other medicines and Marynarka")
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, porphyria (a disease of the blood), gestational herpes (skin rash with vesicles during pregnancy), Sydenham's chorea (a disease of the nerves in which sudden movements of the body occur)
- if you have (had) chloasma (golden brown pigment patches, so called "pregnancy patches", especially on the face). If this is the case, avoid direct exposure to sunlight or ultraviolet light.
- 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. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Marynarka increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems.

Blood clots can develop

- in 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. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to Marynarka is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

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 vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• 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

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

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- 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.
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more
After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive.
When you stop Marynarka your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.
The overall risk of a blood clot in the leg or lung (DVT or PE) with Marynarka is small.

- Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant, about 2 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains

levonorgestrel, norethisterone, or norgestimate about 5-7 will develop a blood clot in a year.
- Out of 10,000 women who are using a combined hormonal contraceptive that contains gestodene such as Marynarka between about 9 and 12 women will develop a blood clot in a year.
- 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" below)

	Risk of developing a blood clot in a year
Women who are **not using** a combined hormonal pill/patch/ring and are not pregnant	About 2 out of 10,000 women
Women using a combined hormonal contraceptive pill containing **levonorgestrel, norethisterone or norgestimate**	About 5-7 out of 10,000 women
Women using Marynarka	About 9-12 out of 10,000 women

Factors that increase your risk of a blood clot in a vein

The risk of a blood clot with Marynarka is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30kg/m2);
- 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). 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 Marynarka may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop Marynarka 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.

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 Marynarka needs to be stopped.

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

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery
It is important to note that the risk of a heart attack or stroke from using Marynarka is very small but can increase:

- with increasing age (beyond about 35 years);
- **if you smoke** . When using a combined hormonal contraceptive like Marynarka 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 are overweight;
- 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 then about 50). 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 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.
If any of the above conditions change while you are using Marynarka, 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.

Marynarka and cancer
Breast cancer has been observed slightly more often in women using combined contraceptives, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combined contraceptives because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.
In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in contraceptives users. This can cause internal bleeding leading to severe pain in the abdomen.
Contact your doctor if you have unusual severe abdominal pain. You may need to stop taking Marynarka.

Cervical cancer has been reported to occur more often in women using contraceptives for a long time. This finding may not be caused by the contraceptives, but may be related to sexual behaviour and other factors.

Psychiatric disorders:
Some women using hormonal contraceptives including Marynarka 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 further medical advice as soon as possible.

Bleeding between periods
During the first few months that you are taking Marynarka, you may have unexpected bleeding (bleeding outside the gap week). If this bleeding continues longer than a few months, or if it begins after some months, your doctor must investigate the cause.

What you must do if no bleeding occurs in the gap week
If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.
If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

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

Always tell the doctor, who prescribes Marynarka, which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use Marynarka. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

• Some medicines can have an influence on the blood levels of Marynarka and can make it **less effective in preventing pregnancy**, or can cause unexpected bleeding.
These include medicines used for the treatment of epilepsy (e.g., topiramate, felbamate, lamotrigine, primidone, phenytoin, barbiturates, carbamazepine, oxcarbamazepine) and tuberculosis (e.g. rifampicin), *medicine for the treatment of high blood pressure in the blood vessels in the lungs (bosentan),*, HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efivarenz) or other infectious diseases (griseofulvin,), and the herbal remedy St. John's wort.

• If you want to use herbal products containing St. John's wort while you are already using Marynarka you should consult your doctor first.

• Marynarka may increase efficacy of other medicines, e.g. medicines containing cyclosporine (medicine against infections).

• Marynarka may decrease the efficacy of other medicines, e.g. the anti.epileptic lamotrigine.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not use Marynarka if you have Hepatitis C and are taking the medicinal products containing ombitasvir /paritaprevir /ritonavir and dasabuvir or glecaprevir / pibrentasvir as this 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 medicinal products.
Marynarka can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Marynarka".

Laboratory tests
If you need a blood test, tell your doctor or the laboratory staff that you are taking this medicine, because oral contraceptives can affect the results of some tests.

Pregnancy and breast-feeding
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.
If you are pregnant, you must not take Marynarka. If you become pregnant while taking Marynarka you must stop immediately and contact you doctor.

Use of Marynarka is generally not advisable when a woman is breast-feeding. If you want to take the contraceptive while you are breast-feeding you should contact your doctor.

Driving and using machines
There is no information suggesting that use of Marynarka affects driving or use of machines.

Marynarka contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Marynarka.

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

Take one tablet of Marynarka every day, if necessary with a small amount of water. You may take the tablets with or without food, but should take the tablets every day at approximately the same time.
The strip contains 21 tablets. Next to each tablet the day of the week is printed. If, for example you start on a Wednesday, take a tablet with "WED" next to it. Follow the direction of the arrow on the strip until all 21 tablets have been taken.
Then take no tablets for 7 days. In the course of these 7 tablet-free days (otherwise called a stop or gap week) bleeding should begin. This so-called "withdrawal bleed should occur during this time.
On the 8th day after the last tablet (that is, after the 7-day gap week), start the following strip, even if the bleeding has not stopped. This means that you should start the following strip on the same day of the week and that the withdrawal bleed should occur during this time.
If you use Marynarka in this manner, you are also protected against pregnancy during the 7 days that you are not taking a tablet.

When can you start with the first strip

• *If you have not used a contraceptive with hormones in the previous month.* Begin with Marynarka on the first day of the cycle (that is the first day of your menstruation). If you start Marynarka on the first day of your menstruation you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

• *Changing from another combined hormonal contraceptive, or combined contraceptive* vaginal *ring or patch.*
You can start Marynarka on the day after the tablet-free period of your previous contraceptive finishes (or after the last inactive tablet of your previous contraceptive). When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.

• *Changing from a preparation containing only a progestogen (progestogen-only tablet, injection, implant or a progestogen-releasing IUD).*You may switch any day from an injectable when the next injection would be due from the progestogen-only tablet and from an implant or the IUD on the day of its removal. But in all of these cases you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.

• *After a miscarriage.* Follow the advice of your doctor.

• *After having a baby.* After having a baby, you can start with Marynarka between 21 and 28 days later. If you start later than day 28, you must use a so-called barrier method (for example, a condom) during the first seven days of Marynarka use.
If, after having a baby, you have had intercourse before starting Marynarka (again), you must first be sure that you are not pregnant otherwise you must wait until the next menstrual bleed.
Ask your doctor for advice in case you are not sure when to start taking Marynarka

*If you are breastfeeding and want to start Marynarka (again) after having a baby.*Marynarka should not be used during breast feeding. Read the section 2. "Pregnancy and breast feeding".

If you take more Marynarka than you should. There are no reports of serious harmful results of taking too many Marynarka tablets.
If you take several tablets at once then you may have symptoms of nausea, dizziness, abdominal pain, drowsiness/fatigue or vomiting. Young girls may have bleeding from the vagina.
If you have taken too many Marynarka tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take Marynarka

- If you are **less than 12 hours** late taking a tablet, the protection from pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- If you are **more than 12 hours** late taking a tablet, the protection from pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk that the protection from pregnancy is reduced.

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or the end of the strip. Therefore, you should adhere to the following rules (see also the diagram below):
• **If you forgot more than one tablet in this strip**.
Contact your doctor.

• If you forgot one tablet in week 1
Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time and use **extra precautions** for the next 7 days, for example, a condom. If you have had intercourse in the week before the oversight or you have forgotten to start a new strip after the tablet-free period, you must realize that there is a risk of pregnancy. In that case, contact your doctor.

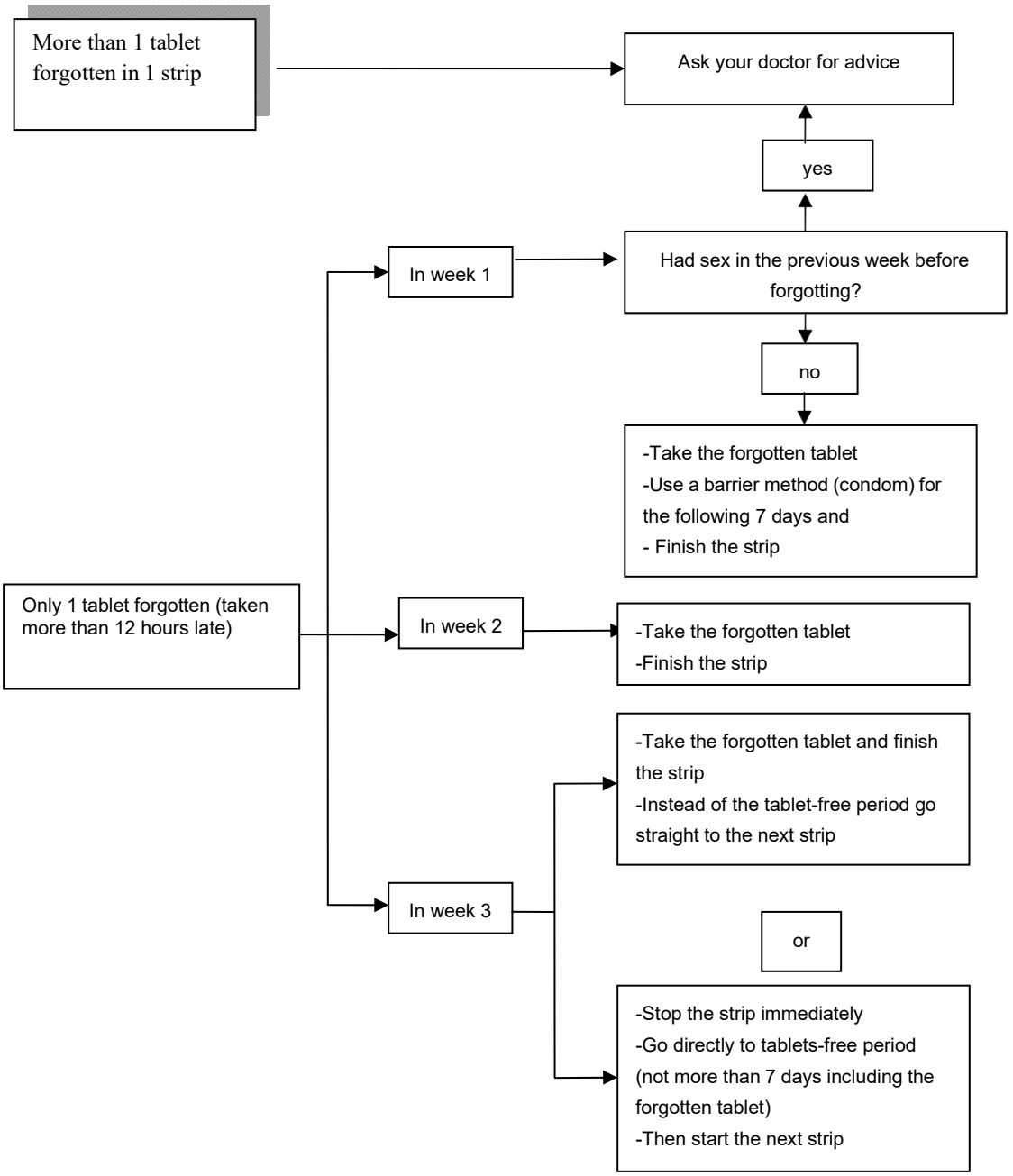
• If you forgot one tablet in week 2
Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time. The protection from pregnancy is not reduced, and you do not need to take extra precautions.

•If you forgot one tablet in week 3
You can choose between two possibilities:

1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time. Instead of the tablet-free period go straight on to the next strip.
Most likely, you will have a period (withdrawal bleed) at the end of the second strip but you may also have spotting or breakthrough bleeding during the second strip.

2. You can also stop the strip and go directly to the tablet-free period of 7 days **(record the day on which you forgot your tablet).** If you want to start a new strip on your fixed start day, make the tablet-free period less than 7 days.
If you follow either of these two recommendations, you will remain protected against pregnancy.

• If you have forgotten any of the tablets in a strip, and you do not have bleeding in the first tablet-free period, this may mean that you are pregnant. You must contact your doctor before you go on to the next strip.



What you must do in the case of gastro-intestinal disturbances
In case of severe gastro-intestinal disturbances (e.g., vomiting or diarrohoea), absorption may not be complete and additional contraceptive measures should be taken. If you vomit within 3-4 hours of taking a tablet or you have severe diarrhoea, the situation is similar to if you forget a tablet. After vomiting or diarrhoea, you must take another tablet from a reserve strip as soon as possible. If

possible take it *within 12 hours* of when you normally take your tablet. If this is not possible or 12 hours have passed, you should follow the advice given under "If you forget to take Marynarka".

Delay of menstrual period: what you must know
Even if not recommended, delay of your menstrual period (withdrawal bleed) is possible. This can be done by going straight on to a new strip of Marynarka instead of the tablet-free period, after the first strip. You may experience spotting (drops or flecks of blood) or breakthrough bleeding while using this second strip. After the usual tablet-free period of 7 days, *continue with* the following strip.
You might ask your doctor for advice before deciding to delay your menstrual period.

Change of the first day of your menstrual period: what you must know
If you take the tablets according to the instructions, then your menstrual period/withdrawal bleed will begin in the tablet-free period. If you have to change this day, you do this by making the tablet-free period shorter (**but never longer than 7 days!**). For example, if your tablet-free period begins on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. If you make the tablet-free period very short (for example, for 3 days or less) then it may be that you do not have any bleeding during this tablet-free period. You may then experience spotting (droplets or flecks or blood) or breakthrough bleeding.

If you are not sure how to proceed, contact your doctor for advice.

If you stop taking Marynarka
You can stop taking Marynarka whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Marynarka can cause side effects, although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Marynarka, please talk to your doctor.
An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 "What you need to know before you use Marynarka".

- harmful blood clots in a vein or artery for example:
  - in a leg or foot (i.e. DVT)
  - in a lung (i.e. PE)
  - heart attack
  - stroke
  - mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA)
  - blood clots in the liver, stomach/intestine, kidneys or eye.

The chance of having a blood clot may be higher if you have any other conditions that increase this risk (See section 2 for more information on the conditions that increase risk for blood clots and the symptoms of a blood clot)

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section "Warnings and precautions").

The following is a list of the side effects that have been linked with the use of Marynarka:

- **Common** (may affect up to 1 in 10 women):
    - headaches,
    - nervousness,
    - poor tolerance of contact lenses,
    - visual disturbances,
    - nausea,
    - acne,
    - migraine,
    - increase in weight,
    - fluid retentions,
    - bleeding and spotting between your periods can sometimes occur for the first few months but this usually stops once your body has adjusted to Marynarka. If it continues, becomes heavy or starts again, contact your doctor.
    - absence of menstruations,
    - sore breasts,
    - loss of interest in sex,
    - depressive moods,
    - irritability.
- **Uncommon** (may affect up to 1 in 100 women):
    - excess of lipids in blood,
    - vomiting,
    - hypertension.
- **Rare** (may affect up to 1 in 1,000 women):
    - liver disease,
    - skin and subcutaneous tissue disorder (lupus erythematosus),
    - middle ear disorders,
    - gallstones,
    - thrombosis (the formation of a clot in blood vessels),
    - pigmentation disorders. This may happen even if you have been using Marynarka for a number of months. This may be reduced by avoiding too much sunlight.
    - changes in vaginal secretion.
- **Very rare** (may affect up to 1 in 10,000):
    - movement disorders,
    - affection of the pancreas.

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. You can also report side effects directly via <To be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Marynarka

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 strip and carton after EXP. The expiry date refers to the last day of that month..
Do not store above 30°C. Keep the strip in the outer carton, in order to protect from light.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to

throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Marynarka contains
The active substances are gestodene and ethinylestradiol.

- Each tablet contains 0,075 mg gestodene and 0,020 mg ethinylestradiol
- The other ingredients are: lactose monohydrate, microcrystalline cellulose, povidone K-30, magnesium stearate and polacrilin potassium.

What Marynarka looks like and contents of the pack
Marynarka tablets are round, white tablets, with a diameter of 5.7 mm approximately and debossed with a '*C'* on one side and '*34'* on the other side.

Marketing Authorisation Holder
Laboratorios León Farma, S.A.
Pol.Ind. Navatejera; C/La Vallina s/n; 24008-León,
Spanje

Manufacturer
Laboratorios León Farma, S.A.
Pol.Ind. Navatejera; C/La Vallina s/n; 24008-León,
Spanje

In het register ingeschreven onder:
RVG114158

This product is commercialized in other countries with the following names:

Netherlands	Marynarka 0.075 mg / 0.020 mg tabletten
Czech Republic	Lucienne 0,075 mg/ 0,020 mg tablety
Slovakia	Marynarka 0,075 mg/ 0,020 mg tablety
Spain	Gesdine 20 comprimidos EFG

Deze bijsluiter is voor het laatst goedgekeurd in november 2021.