This medicine can be sold with a physician's prescription only

## FLAME®, Tablets

Each tablet contains Ethinylestradiol 0.02 mg and Gestodene 0.075 mg.

Inactive ingredients and allergens in the medicine - see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

### 1. What is the medicine intended for?

Flame is intended for contraception. Therapeutic group: Combined contraceptive pills, a combination of estrogen and progestogen. Each tablet contains two female hormones, estrogen (ethinylestradiol) and progestogen (gestodene).

## Several important things to know about combined hormonal contraceptives:

- When taken correctly, combined hormonal contraceptive pills are one of the most reliable reversible contraceptive methods.
- They slightly increase the risk of thrombosis (blood clots) in the veins and arteries, especially during the first year or upon resuming use after stopping for 4 weeks or more.
- Be vigilant and contact your doctor if you are concerned that you suffer from any symptoms of a blood clot (see section 2, "Flame and thrombosis (blood clots)").

### 2. Before using the medicine

2. Before using the medicine

Before you start taking Flame, you should read the information about thrombosis (blood clots) in section 2. It is especially important to read the part about the symptoms of thrombosis (see section 2, "Flame and thrombosis (blood clots)").

Do not use the medicine if:
You are subject to any of the following conditions. If you have any of the conditions listed below, tell your doctor. Your doctor will discuss with you other contraceptive methods that are more suitable for you. If any of these conditions appears for the first time while using Flame, you should contact your doctor immediately.

• You are hypersensitive (allergic)

- You are hypersensitive (allergic) to the active ingredients (ethinylestradiol or gestodene) or to any of the other ingredients this arms. medicine contains (see section 6).
  You have (or have ever had) a blood clot in a blood had) a blood clot in a blood vessel in the leg (deep vein thrombosis, DVT), lung (pulmonary embolism, PE), eyes or any other organ (see "Flame and thrombosis (blood clots)").
- You know that you suffer from a blood coagulation disorder, for example a protein C deficiency, protein S deficiency, antithrombin III deficiency, factor
- V Leiden mutation or presence of anti-phospholipid antibodies. You are going to have an operation or if you are expected to be in a situation of prolonged immobility (see "Flame and thrombosis"). 'Flame and thrombosis
- "Flame and thrombosis (blood clots)").
  You have ever had a heart attack or stroke (CVA).
  You suffer from a headache or you have (or have ever had) a type of migraine called "migraine with aura" (with an unusual sensation, such as flashes of light) flashes of light). You suffer from heart valve or heart rhythm disorders. You have (or have ever had)
- angina pectoris (a condition that causes severe chest pain and can be an initial sign of a heart attack) or a transient ischemic attack (TIA temporary stroke symptoms). You have one of the following diseases, which may increase the risk of a blood clot
- the risk of a blood clot formation in the arteries: o severe diabetes with blood vessel damage o very high blood pressure high levels of blood fats (cholesterol and triglycerides) o a condition known as hyperhomocysteinaemia

  You have (or have ever had)
- You have (or have ever had) breast cancer, uterine cancer or liver cancer (see "Contraceptive") pills and cancer"). You have severe liver disease.
  You have unexplained vaginal
- bleeding.
  You are pregnant or think you may be pregnant.
  You have or have ever had
- inflammation of the pancreas, which has been linked to a severe increase in the level of

lipids in the blood.

Do not use **Flame** if you have hepatitis C (viral liver inflammation) and are being treated with medicines containing ombitasvir, restions vir. paritaprevir, ritonavir and dasabuvir or glecaprevir/ pibrentasvir (see also "Drug interactions").

Special warnings regarding the use of the medicine: Seek immediate medical

Seek Illinieulate insense.

attention:

If you notice possible symptoms
of a blood clot, which could
indicate that you have a blood
clot in a leg (i.e., deep vein
thrombosis), a blood clot in a lung (pulmonary embolism), a heart attack or stroke (see "Flame and thrombosis (blood For information about the symptoms of these serious side effects, see section 2 "How to recognize

symptoms of a blood clot". If you have one or more of the following conditions, consult your doctor before taking Flame.

If one or more of the following conditions develops or gets worse while you are using Flame, you should consult your doctor.

If you smoke (especially if you are over the age of 35), see "Flame and thrombosis (blood clots)"

- see "Flame and thrombosis (blood clots)"
  If someone in your immediate family has had a disease caused by blood clots, such as deep vein thrombosis, pulmonary embolism, heart attack or stroke, Filame and thrombosis (blood clots)" If you are overweight, see "Flame and thrombosis (blood clots)" If you suffer from migraines If you have (or have ever been and thrombosis (blood clots)" If you have you hav
- If you have (or have ever had) one or more cysts in the breast and someone in your immediate family has had breast cancer
  • If you have uterine fibroids (a benign
- If you have a disease of the liver or gallbladder (gallstones)
  If you have a disease of the liver or gallbladder (gallstones)
  If you have had a biliary disorder while taking contraceptive tablet or during pregnancy.
- pregnancy
  If you suffer from a hypersensitivity reaction called angioedema
  If you suffer or have suffered from severe
- depression If you have (or have ever had) chloasma
- frown spots on the skin called a "mask of pregnancy", particularly on the face). Ir such a case, you should avoid excessive exposure to the sun or UV rays If you suffer from Crohn's disease or
- If you suffer from Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases)
  If you suffer from systemic lupus erythematosus (SLE a disease affecting the immune system)
  If you suffer from hemolytic uremic syndrome (HUS a blood clotting disorder which may cause kidney failure)
  If you suffer from sickle-cell anemia (a hereditary disease of the red blood cells)
- hereditary disease of the red blood cells)
- In you suffer from high levels of fats in the blood (hypertriglyceridemia) or have a family history of this condition. Hypertriglyceridemia has been linked to an increased risk of pancreatitis (inflammation of the pancreas)
  If you have given birth several weeks ago, or if you have undergone a second trimester fermination of pregnancy, you are at an increased risk of blood clot formation. You should ask your doctor how soon you can start using Flame after giving birth or after a second trimester termination of pregnancy
  If you suffer from an inflammation of the veins under the skin (superficial thrombophlebitis)
  If you have varicose veins
  Pay attention to certain conditions which
- If you have varicose veins
  Pay attention to certain conditions which may worsen while taking the pills, such as asthma, epilepsy, herpes occurring during pregnancy (herpes gestationis), hyperprolactinemia, a condition called chorea or "Saint Vitus' Dance" (a disease characterized by rapid, body movements, uncoordinated jerking movements primarily affecting the face, feet and hands) and otosclerosis (a disease of the inner ear).

# Flame, like other contraceptive pills, does not prevent contracting the HIV infection (AIDS) or other sexually transmitted diseases.

Psychiatric disorders Some women have reported depression or a depressed mood while using hormonal contraceptives including Flame. Depression can be severe and can sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms, contact your doctor as soon as possible for further medical advice.

medical advice.

Flame and thrombosis (blood clots)
Using combined hormonal contraceptives
such as Flame increases the risk of
developing blood clots compared to the risk in women not using such contraceptives. In rare cases, a blood clot can block blood vessels and cause serious problems.

- Blood clots can develop:
   in the veins [venous thrombosis, venous thromboembolism (VTE)]
   in the arteries [arterial thrombosis,

arterial thromboembolism (ATE)]. Full recovery is not always achieved following a blood clot. In rare cases, they can cause serious and lasting damage, and in very rare cases they can be fatal.

It is important to remember that the overall risk of a blood clot due to the use of Flame is low.

How to recognize symptoms of a blood clot

one or more of the following sympton		
	Do you experience one or more of these signs?	You probably suffer from
	swelling of one leg or along a vein in the leg or foot, especially when accompanied by:     pain or sensitivity in the leg only manifested when standing or walking     sensation of warmth in the same leg.	Deep vein thrombosis

change in color of the skin of the leg, for example turning pale, red or blue Pulmonary embolism

- sudden unexplained shortness of breath or rapid breathing sudden cough without apparent cause, which may contain blood acute chest pain which may increase with deep breathing sensation of lightheadedness or dizziness rapid or irregular heartbeat severe stomach pain If you are not sure, contact your doctor as some of these symptoms such as coughing or shortness of breath may be mistaken for a mild condition such as a respiratory infection (for example the common cold).
- signs that usually appear in one eye: immediate loss of vision painless blurred vision that can develop into loss of vision
- Stroke (CVA)
- \*sudden weakness or numbness in the face, arm or leg, especially on one side of the body
   \*sudden confusion, difficulty speaking or understanding
   \*sudden difficulty seeing in one or both eyes
   \*sudden difficulty seeing in one or both eyes
   \*sudden difficulty walking, dizziness, loss of balance or coordination
   \*severe or prolonged headache that appears suddenly with no known cause
   \*loss of consciousness
- suddenly with no known cause
  loss of consciousness or fainting with or without seizure
  Sometimes the symptoms of stroke may be very short-lived with an almost immediate full recovery, but you must still seek urgent medical treatment, as you may be at risk of another stroke.

  \* swelling and slight bluish coloring of the
- blocking other blood vessels bluish coloring of the extremities
  acute abdominal pain (such as those of the (acute abdomen) liver, intestines or kidneys) Venous thrombosis What can happen if a blood clot forms in a vein?

When is the risk of developing a venous blood clot 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 increased when you resume taking a combined hormonal contraceptive (the same preparation) after a break of 4 weeks or more. After the first year, the risk is reduced, but it will always be slightly higher compared to a case in which you are not taking a combined hormonal contraceptive. When you stop taking Flame, the risk of developing a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot? The risk depends on your baseline predisposition to venous thrombosis and the type of combined hormonal contraceptive you are taking. The overall risk of a blood clot in a leg or lung (deep vein thrombosis or pulmonary embolism) due to the use of Flame is low.

Of 10,000 women using no combined hormonal contraceptive and who are not

Factors that increase your risk of developing a blood clot in a vein The risk of developing a blood clot with Flame is low but certain conditions will increase the risk. The risk is higher:

The risk of developing a blood clot increases with an increasing number of risk factors.

It is important to tell your doctor if one of the above conditions applies to you, even if you are not sure. Your doctor may decide that you should stop taking **Flame**.

If one or more of these conditions changes while using **Flame**, for example if one of your immediate family members develops thrombosis for an unknown reason or if you've gained a lot of weight, tell your doctor.

# an artery may cause serious problems. For example, it may cause a heart attack or a

Factors that increase your risk of developing a blood clot in an artery it is important to note that the risk of a heart attack or stroke due to the use of Flame is very low, but may increase:

- near attack or stroke due to the use of Flame is very low, but may increase:

   with age (especially beyond 35 years)
   if you smoke. When using a combined hormonal contraceptive like Flame, it is recommended that you stop smoking. If you are unable to stop smoking and are older than 35 years, 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 had a heart attack or stroke at a relatively young age (less than 50 years). If this is the case, you may also have a higher risk of a heart attack or a stroke
   if you, or a member of your immediate family, have high blood lipid levels (cholesterol or triglycerides)
   if you suffer from migraines, especially "migraine with aura"
   if you have a heart problem (heart valve disorders, arrhythmia called atrial fibrillation)
   if you have more than one of these conditions or if one of those is particular.

• If you have more than one of these conditions or if one of them is particularly severe, the risk of developing a blood clot may be even higher. If one of the conditions listed above changes while using Flame, for example, if you start smoking, a close family member develops thrombosis for an unknown reason or if you gain a lot of weight, tell your doctor.

Contraceptive pills and cancer

Retinal vein thrombosis (a blood clot in the eye blood vessel)

Heart attack

mat can develop into loss of vision

pain, discomfort, pressure, heaviness in the chest sensation of tightness or congestion in the chest, arm or under the breastbone sensation of fullness, indigestion or suffocation upper body discomfort radiating to the back, jaw, throat, arm and abdomen sweating, nausea, vomiting or dizziness extreme weakness, anxiety or shortness of breath rapid or irregular heartbeat sudden weakness or supplied to the control of t

Blood clots

in a vein?

The use of combined hormonal contraceptives is associated with an increased risk of developing blood clots in the veins (venous thrombosis). However, this side effect is rare. It can occur more frequently during the first year of using combined hormonal contraceptives.

When a blood clot forms in a vein in the leg or foot it may cause deep vein thrombosis (DVT).

If a blood clot migrates from the leg to the lung, it can cause a pulmonary embolism. In very rare cases a blood clot may form in a vein in another organ, such as the eye (retinal vein thrombosis).

hormonal contraceptive and who are not pregnant, approximately 2 women will develop a blood clot each year.

Of 10,000 women using a combined hormonal contraceptive containing levonorgestrel, norethisterone or norgestimate, approximately 5-7 will develop a blood clot each year.

Of 10,000 women using a combined hormonal contraceptive containing gestodene, like Flame, approximately 9-12 will develop a blood clot each year.

The risk of developing a blood clot will vary according to your personal medical history (see "Factors that increase your risk of developing a blood clot in a vein" below).

if you are very overweight (BMI over 30

• if you are very overweight (BMI over 30 kg/m²)
• if a member 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 50). If this is the case, you might have a hereditary blood coagulation disorder.
• if you need to undergo surgery, or are immobile for a long time due to an injury or illness, or if one of your legs is immobilized (for example in a cast). It may be necessary to stop using Flame several weeks before surgery or while your mobility is reduced. If you need to stop using Flame, ask your doctor when you can start taking Flame again.
• with age (particularly over the age of 35)
• if you have given birth or if you have undergone a second trimester termination of pregnancy several weeks ago

The risk of developing a blood clot

A flight (over 4 hours) may temporarily increase your risk of a blood clot, particularly if you have other conditions that increase the risk.

Arterial thrombosis What can happen if a blood clot forms in an artery? Like a blood clot in a vein, a blood clot in

Established risk factors for the development of breast cancer include age, family history, obesity, no childbirth in the past and first pregnancy and childbirth at an older age.

pregnancy and childbirth at an older age. Breast cancer has been diagnosed at a slightly higher incidence in women taking pill compared to women of the same age not taking pill. This moderate increase in the number of breast cancer diagnoses gradually disappears 10 years after discontinuing the pill. It is not known if this difference is caused by the use of the pill. It is possible that women taking pill are examined more carefully and more often, so that breast cancer is detected at an earlier stage.

Taking the pill may also increase the risk of cervical cancer, but this has not been scientifically proven.

with the necessary explanations.

Contact your doctor immediately in the following cases:

if you experience any signs of thrombosis (see "How to recognize symptoms of a blood clot" above)

if you feel a lump in or near the breast contact your doctor at least four weeks in advance if you are going to have an operation or if you are expected to be in a situation of prolonged immobility (see "Flame and thrombosis (blood clots"))

if you have given birth or if you have undergone a second trimester termination of pregnancy several weeks ago (see "Flame and thrombosis (blood clots"))

if you experience unusual heavy vaginal

In rare cases, benign liver tumors, and even more rarely, malignant liver tumors have been reported in women taking the pill. The risk of developing such tumors increases with the duration of taking the pill, but remains low nevertheless.

When should you contact your doctor?

When should you contact your doctor? Tests and follow up Your doctor will instruct you to arrive for regular medical examinations. In general, the frequency and nature of these examinations will depend on individual medical factors. Your doctor will assess the information obtained and provide you with the necessary explanations.

clots)")
• if you experience unusual heavy vaginal bleeding
• if you think you may be pregnant
• if your period does not start during the week after stopping the pill

wéek after stopping the pill

Drug interactions
If you are taking or have recently taken
any other medicines, including nonprescription medicines and nutritional
supplements, tell your doctor or
pharmacist.

When your doctor, including your dentist,
wants to prescribe you a new medicine,
you should inform them that you are
taking Flame. In certain cases, your
doctor will advise you to use another
contraceptive for a certain period while
taking this medicine.
Certain medicines may decrease the
effectiveness of the pill in pregnancy
prevention; these include:

• certain medicines for treatment of epilepsy

certain medicines for treatment of epilepsy

certain medicines for treatment of epilepsy (primidone, phenytoin, barbiturates, topiramate, phenylbutazone, carbamazepine or felbamate) griseofulvin (a medicine for treatment of fungal infections) some medicines for treatment of HIV/AIDS (protease inhibitors) and other viral infections (ritonavir) rifampicin (for treatment of tuberculosis) preparations containing the Hypericum

Interpolar (or readment of updercuosis) preparations containing the Hypericum perforatum plant (St John's wort) modafini (a medicine for treatment of sleep disorders)
 dexamethasone (a medicine for treatment of certain inflammatory and autoimmune diseases)

Oral contraceptives can influence the results of certain laboratory tests. Inform your doctor that you are taking **Flame** if you are going to have a blood test.

you are going to have a blood test.

Do not use Flame if you have hepatitis C (viral liver inflammation), and you are taking medicinal products containing ombifasvir, paritaprevir, ritonavir and dasabuvir or glecaprevir/pibrentasvir as this may cause an increase in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraception before starting treatment with these medicinal products. Approximately two weeks after the end of treatment with they medicine starting treatment with they medicine if see section "Do not use the medicine if". Use of the medicine and food Flame can be taken with food or drinks

Pregnancy, breastfeeding and fertility
Pregnancy
Do not use the medicine if you are pregnant
or if pregnancy is suspected.
If you are planning to become pregnant,
consult your doctor or pharmacist.
Breastfeeding
Do not use the medicine if you are
breastfeeding.

Driving and using machines
The effect on the ability to drive or use
machines while using Flame has not been
studied.

studied.

Important information about some of the ingredients of the medicine
Flame contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains less than 1 millimole sodium (23 mg) per tablet, that is to say essentially "sodium free".

3. How should you use the

medicine?

medicine?

Always use the medicine according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only. Each blister pack of Flame contains 21 tablets. For each tablet, the day of the week when it should be taken is indicated on the pack. The usual recommended dosage is: one tablet each day, at the same time, in the order indicated by the arrows on the blister pack, for 21 days. Do not take any pills for 7 days following the period of 21 days on which you have taken Flame. Your menstrual period will start during the 7 days on which you don't take the pill (usually on the third day after taking the last tablet in the blister pack). After the 7 day break, start a new pack on the eight had we whether the proserver. After the 7 day break, start a new pack on the eighth day, whether the menstrual period has ended or not. This way, you will always start a new blister pack on the same day of the week and your menstrual period will start around the same day every four weeks. Taking the pill is not indicated for women who have not you had they first menstrual period or have not yet had their first menstrual period or

The restrict of the first mensual period of for post-menopausal women.

Swallow the tablet with some water. Do not crush/halve/chew the pill as these actions may interfere with the absorption of the active ingredients of the tablet and thus impair its efficacy. Starting the first pack
How to start your first pack if you have
not used hormonal contraceptives in

the last month?

Take the first tablet on the first day of your menstrual period in accordance with the day of the week marked on the blister pack. For example, if your menstrual period starts on a Friday, take a tablet marked "FRI/" on the blister pack.

Switching to Flame from other combined contraceptive pills
Take Flame the day after taking the last active pill from the blister pack of the previous pills. Switching to Flame from a pill containing

Switching to Flame from a pill containing progesterone only If you are switching to Flame from a pill containing progesterone only, you can stop taking the pill containing progesterone only on any day and start taking Flame the day after you stop talking the progesterone only pill. You must use an additional non-hormonal method of contraception (such as a condom or spermicide) during the first 7 days of taking the first blister pack.

Switching to Flame from injectable or implanted contraceptives or an IUD If you are switching to Flame from an injectable contraceptive, an implant or an IUD, you can start using Flame on the day the implant or IUD is removed or on the day that was scheduled for your next injection. You must use an additional non-hormonal method of contraception (such as a condom or spermicide) during the first 7 days of taking the first blister pack. If you have undergone a first trimester termination of pregnancy You can start taking **Flame** immediately.

If you have given birth or if you have undergone a second trimester termination of pregnancy

Your doctor may advise you to start taking Flame from the 28th day after childbirth or after a second-trimester termination of pregnancy. You must use an additional non-hormonal, method of contraception (such as a condom or spermicide) during the first 7 days of taking the first blister pack. If you have already had sexual intercourse during this period, you must make sure that you are not pregnant before you start taking Flame or wait until the menstrual period begins. Unexpected bleeding occurs
Unexpected bleeding (staining) may occur between menstrual periods, especially during the first months of use. In general, this irregular bleeding stops once your body has become used to the pill (after about three blister packs). Nevertheless, if the unexpected bleeding persists or appears for the first time after prolonged use of Flame, contact your doctor immediately. If unexpected bleeding occurs
Unexpected bleeding (staining occur between menstrual

If no bleeding occurs after completing If no bleeding occurs after completing the blister pack If menstrual bleeding has not started after 7 days of discontinuing the pill and you have taken all the pills properly, you are unlikely to be pregnant. Start the next blister pack on the eighth day. However, if the menstrual period has not started after taking two complete blister packs, contact your doctor immediately and do not start the next blister pack before you have their approval. approval.

If you have accidentally taken a higher dosage of Flame
There are no known cases of serious harm after taking too many Flame tablets. Taking too many Flame tablets may cause nausea, vomiting, abdominal pain, dizziness, drowsiness/tiredness, breast tenderness, or slight vaginal bleeding. Special treatment is probably unprecessary dizziness, drowsiness/irredness, breast tenderness, or slight vaginal bleeding. Special treatment is probably unnecessary. If a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

the package of the medicine with you.

If you forgot to take Flame
The contraceptive efficacy of the pill is maintained only if less than 12 hours have passed since the time at which you should have taken the tablet. Take the tablet as soon as you remember and continue taking the next tablets at the usual time. If more than 12 hours have passed since the time at which you should have taken the tablet, or if you have missed more than one tablet, the contraceptive efficacy of the pill may be reduced. In such case:

 Take the last forgotten tablet immediately when you remember and continue taking the rest of the tablets at the usual time, even if that means taking 2 tablets time, ever in that means taking 2 tablets on the same day.

Continue taking **Flame** until the end of the blister pack.

In addition, use an additional non-hormonal method of contraception of devia Information the control of contraception (sold) as a condom or a spermicide) for 7 days. If the 7-day period requiring the use of an additional method of contraception extends beyond the day on which you take the last tablet in the current blister.

pack, start the next blister pack on the day after taking the last tablet of the current blister pack (i.e. with no break).

In any case, consult your doctor.

doctor.

can develop into loss of vision, that usually appear in one eye sensation of pain, discomfort, pressure, heaviness in the chest sensation of tightness or congestion in the chest, arm or under the breastbone sensation of fullness, indigestion or suffocation sensation of discomfort in the upper body, radiating to the back, jaw, throat, arm and abdomen

abdomen sweating, nausea or vomiting extreme weakness, anxiety or shortness of breath sudden weakness or numbness in the face, arm or leg, especially on one side of the body sudden confusion, difficulty

if you feel a lump in or near your breast

Common side effects – effects that occur in 1-10 in 100 users:

• Vaginal infection including vaginal fungal infection.

Acne Pain, tension, enlargement and secretion

Uncommon side effects - effects that occur in 1-10 in 1,000 users:

Changes in appetite
 Abdominal cramps, bloating
 Rash, appearance of dark spots on the face which may persist, excessive hair growth, hair loss

lipid levels in the blood Rare side effects – effects that occur in

face (angioedema), severe respiratory

and circulatory disorders

• Glucose intolerance
• Intolerance to contact lenses A blood clot in a vein or an artery, for

example:

 mini-stroke or temporary stroke-like symptoms, known as a transient ischemic attack in very rare cases, blood clots in the liver, stomach/intestine, kidneys or one

blood clots). Jaundice due to obstruction of

Jaundice due to obtain bile ducts
 Nodular erythema (erythema nodosum)
 A decrease in folic acid levels in the blood (This is very important if you become pregnant immediately after discontinuing

(accumulation of porphyrin in the tissues)

Aggravation of chorea (a movement disorder)

Inflammation of the optic nerve (may lead to partial or complete blindness)

Aggravation of varicose veins

Inflammation of the pancreas, inflammation of the colon due to hypoxia

Gallstones, decreased bile secretion (Flame may aggravate existing gallbladder disorders or lead to the onset of such disorders)

Side effects with unknown frequency
- effects for which a frequency has not
yet been determined:
• Inflammatory bowel disease (Crohn's
disease, ulcerative colitis)
• Liver damage (for example liver
inflammation, abnormal liver function)

inflammation, abnormal liver function) If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיוו על הופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: https://sideeffects.health.gov.il

# Avoid poisoning! This medicine, and any other medicine, should be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

5. How to store the medicine?

unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (תאריך תפוד) stated on the package. The expiry date refers to the last day of that month.

Storage conditions: store in the original package, below 25°C.

Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

What the medicine looks like and what the package contains: Yellow, round, biconvex tablets. The tablets come in trays (blisters) of 21 tablets. Each package contains 1, 3 or 4

Manufacturer and registration holder:

Dexcel® Ltd.

1 Dexcel St., Or Akiva 3060000, Israel

When you stop taking **Flame**, your menstrual period may not return spontaneously (post-treatment amenorrhea). You must consult your amenorrhea). You mus doctor in such a case.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take a medicine. Wear glasses if you need them.

If you experience diarrhea or vomiting If you experience diarrhea or vomiting within 3 to 4 hours after taking the tablet, the active ingredients in Flame may have not been absorbed adequately by your body. This situation is similar to forgetting to take a tablet. Therefore, after vomiting or diarrhea, take an additional tablet from a spare blister pack. If your diarrhea or vomiting persists, consult your doctor.

If you want to stop taking Flame

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

4. Side effects
Like any medicine, the use of Flame may cause side effects in some users. Do not be alarmed when reading the list of side effects; you may not suffer from any of them. them. If one or more of the side effects occur, especially if it is severe or prolonged, or if there is a change in your health that you think may be due to **Flame**, inform your

doctor.

An increased risk of blood clots in the veins (venous thromboembolism) or blood clots in the arteries (arterial thromboembolism) exists in all women using combined hormonal contraceptives. For more detailed information, see section 2 "Before using the medicine".

The serious side effects associated with the use of the pill are described in the sections "Flame and thrombosis (blood clots)" and "Contraceptive pills and cancer". Read these sections for more information

# Contact your doctor immediately if you experience any of the following symptoms:

- symptoms:

   swelling of one leg or along the length of a vein in the leg or foot

   sudden, unexplained shortness of breath or rapid breathing

   sudden cough without apparent cause, which may contain blood

   acute pain in the chest, which may be exacerbated by deep breathing

   sensation of light-headedness or dizziness rapid or irregular heartbeat

   intense pain in the abdomen, acute pain in the abdomen (acute abdomen)

   immediate loss of vision or painless blurred vision which can develop into loss of vision, that usually appear in one eye
- abdomen
- sudden confusion, difficulty speaking or understanding sudden difficulty seeing in one or sudden difficulty seeing in one or both eyes sudden difficulty walking, loss of balance or coordination severe or prolonged headache with no known cause loss of consciousness or fainting, with or without seizure swelling and slight cyanosis of the extremities
- Additional side effects:
  Very common side effects effects that occur in more than 1 in 10 users:

  + Headache, migraine

   Bleeding between menstrual periods (staining)
- infection
  Changes in mood (e.g. depression) or changes in sexual drive
  Nervousness or dizziness
  Nausea, vomiting or abdominal pain
- Paint, tension, enlargement and secretion from the breasts
  Painful menstrual bleeding or changes in the menstrual blood flow, absence of menstrual periods
  Changes in cervical secretions
  Fluid retention or edema
  Weight gain or loss
- 1-10 in 10.000 users: Allergic reactions, including very rare cases of urticaria, allergic edema of the
- in a leg or foot (deep vein thrombosis)
   in a lung (pulmonary embolism)
   heart attack stroke
- eye The risk of developing a blood clot may be higher if you have other conditions that increase the risk (see section 2 for more information on factors that increase the risk of blood clots and the symptoms of blood lette).
- Very rare side effects effects that occur in less than 1 in 10,000 users:
  Increased risk of benign liver tumor, malignant liver tumor
  Aggravation of lupus erythematosus
  Aggravation of porphyria (accumulation of porphyrin in the tissues)
- disorders)
  Blistering rash (erythema multiforme)
  Hemolytic uremic syndrome (a condition of renal failure caused by blood clots)

- triis medicine also contains: Lactose monohydrate, sucrose, maize starch, calcium carbonate, talc, macrogol 6000, povidone, titanium dioxide (E171), silica colloidal anhydrous, magnesium stearate, sodium calcium edetate, quinoline yellow (E104).

guidelines.

Drug registration number at the national drug registry of the Ministry of Health: 140-58-31529-00

6. Additional information In addition to the active ingredients, this medicine also contains:

Flame PIL PB0522-11

blisters Not all pack sizes may be marketed. Revised in April 2022 according to MOH