

## Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

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

## FLAME<sup>®</sup>, 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

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) to the active ingredients (ethinylestradiol or gestodene) or to any of the other ingredients this medicine contains (see section 6).
- You have (or have ever 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 (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).
- 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 formation in the arteries:
  - severe diabetes with blood vessel damage
  - very high blood pressure
  - high levels of blood fats (cholesterol and triglycerides)
  - a condition known as hyperhomocysteinemia
- 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, paritaprevir, ritonavir and dasabuvir or glecaprevir/pibrentasvir (see also "Drug interactions").

#### Special warnings regarding the use of the medicine:

##### Seek immediate medical 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 clots)").

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)".
- 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, see "Flame 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 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 non-cancerous growth)
- 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
- 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 (brown spots on the skin called a "mask of pregnancy", particularly on the face). In such a case, you should avoid excessive exposure to the sun or UV rays
- 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)
- If 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 termination 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 taking the conditions which may worsen while using 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.

#### 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

Contact your doctor urgently if you notice one or more of the following symptoms.

| Do you experience one or more of these signs?  | You probably suffer from   |
|--|--|
| <ul style="list-style-type: none"><li>• swelling of one leg or along a vein in the leg or foot, especially when accompanied by:<ul style="list-style-type: none"><li>○ pain or sensitivity in the leg only manifested when standing or walking</li><li>○ sensation of warmth in the same leg</li><li>○ change in color of the skin of the leg, for example turning pale, red or blue</li></ul></li></ul>   | Deep vein thrombosis   |
| <ul style="list-style-type: none"><li>• sudden unexplained shortness of breath or rapid breathing</li><li>• sudden cough without apparent cause, which may contain blood</li><li>• acute chest pain which may increase with deep breathing</li><li>• sensation of light-headedness or dizziness</li><li>• rapid or irregular heartbeat</li><li>• severe stomach pain</li></ul> 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).  | Pulmonary embolism   |
| signs that usually appear in one eye: <ul style="list-style-type: none"><li>• immediate loss of vision or</li><li>• painless blurred vision that can develop into loss of vision</li></ul>   | Retinal vein thrombosis (a blood clot in the eye blood vessel)                               |
| <ul style="list-style-type: none"><li>• pain, discomfort, pressure, heaviness in the chest</li><li>• sensation of tightness or congestion in the chest, arm or under the breastbone</li><li>• sensation of fullness, indigestion or suffocation</li><li>• upper body discomfort radiating to the back, jaw, throat, arm and abdomen</li><li>• sweating, nausea, vomiting or dizziness</li><li>• extreme weakness, anxiety or shortness of breath</li><li>• rapid or irregular heartbeat</li></ul>  | Heart attack   |
| <ul style="list-style-type: none"><li>• sudden weakness or numbness in the face, arm or leg, especially on one side of the body</li><li>• sudden confusion, difficulty speaking or understanding</li><li>• sudden difficulty seeing in one or both eyes</li><li>• sudden difficulty walking, dizziness, loss of balance or coordination</li><li>• severe or prolonged headache that appears suddenly with no known cause</li><li>• loss of consciousness or fainting with or without seizure</li></ul> 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. | Stroke (CVA)   |
| <ul style="list-style-type: none"><li>• swelling and slight bluish coloring of the extremities</li><li>• acute abdominal pain (acute abdomen)</li></ul>  | Blood clots blocking other blood vessels (such as those of the liver, intestines or kidneys) |

#### Venous thrombosis

##### What can happen if a blood clot forms 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).

##### 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 taken previously or a different 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 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).

##### 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:

- if you are very overweight (BMI over 30 kg/m<sup>2</sup>)
- 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 increases with an increasing number of risk factors.

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

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.

#### Arterial thrombosis

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

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

##### 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:

- 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 are overweight
- if you have high blood pressure
- if a member of your immediate family has 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 diabetes

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

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.

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.

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?

##### 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.

##### 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 bleeding
- if you think you may be pregnant
- if your period does not start during the week after stopping the pill

##### Drug interactions

If you are taking or have recently taken any other medicines, including non-prescription 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 (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 perforatum plant (St John's wort)
- modafinil (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.

Do not use **Flame** if you have hepatitis C (viral liver inflammation) and you are taking medicinal products containing ombitasvir, 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 medicines. **Flame** use can be started again. 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.

##### 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?

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 that 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 will start taking **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 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 yet had their first menstrual period or 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 "FR1/1" 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 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 taking 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.

###### 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 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 taking 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.

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You can start taking **Flame** immediately.

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###### 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

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