

**PATIENT INFORMATION LEAFLET**

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

### **FAMY-POP 30 µg Tablets<sup>1</sup>**

International Nonproprietary Name (INN):

levonorgestrel

**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, ask your health care provider.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet**

1. What FAMY-POP is and what it is used for
2. What you need to know before you take FAMY-POP
3. How to take FAMY-POP
4. Possible side effects
5. How to store FAMY-POP
6. Contents of the pack and other information

#### **1. WHAT LEVONORGVFESTREL 30 µg TABLETS IS AND WHAT IT IS USED FOR**

FAMY-POP is a hormonal contraceptive from the group of so-called minipills. In contrast to "combined pills" (combined oral contraceptives), that contain two hormones, an estrogen and a progestogen (gestagen), minipills contain only one progestogen in a low dose.

FAMY-POP is used for prevention of pregnancy.

#### **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FAMY-POP**

##### **Do not take FAMY-POP:**

- if you are allergic to levonorgestrel or any of the other components of this medicinal product listed in section 6,
- if you are pregnant or suspect you are,
- if there is a blood clot in the veins, e.g. in a leg (deep venous thrombosis) or in the lungs (pulmonary embolism) (see also "FAMY-POP and thrombosis"),
- if arterial vascular disease is present or ever occurred, e.g. myocardial infarction, stroke or ischemic heart disease (angina pectoris) (see also "FAMY-POP and thrombosis"),
- if you have sugar diabetes which has caused vascular changes,
- if you now have or have a history of severe hepatic disease and your liver values have not yet returned to normal,
- if you have or have had a benign or malignant liver tumor,
- if you have or have had a sex hormone-dependent malignancy, such as breast cancer or genital cancer, or if you suspect that you have any of these diseases,

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<sup>1</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

- if you have undiagnosed vaginal bleeding,

If any of the above cases occurs while you are taking FAMY-POP, you must stop taking the drug immediately and see your health care provider. In the meantime, you should use a different, non-hormonal contraceptive method. For further information, see also "Warnings and precautions".

### **Warnings and precautions**

Please talk to your health care provider before taking FAMY-POP.

This section describes when you must immediately stop taking FAMY-POP or when the reliability of FAMY-POP might be impaired. In these cases, you are advised either not to have sexual intercourse or to use other, non-hormonal contraceptive methods, such as condoms or another barrier method. However, do not use the calendar or temperature methods. These methods can fail, because taking FAMY-POP alters the monthly fluctuations in body temperature and the uterine mucosa.

Like all oral contraceptives, FAMY-POP does not offer any protection against HIV infection (AIDS) or other sexually transmitted diseases.

### **Medical examination/checkup**

Before you start or resume taking FAMY-POP, a full history must be taken of the diseases you and your close relatives have had, and pregnancy must be ruled out. The medical examination (including pelvis and breast) should reflect this medical history, as well as the contraindications and warnings relevant to this medicinal product. During the course of treatment, regular check-ups are recommended, the frequency and nature of which should be adapted to your individual state of health. These investigations, including your breasts (mammography), are to be conducted in line with current preventive care and according to your personal health status.

### **Special medical monitoring is required, if**

- you have only one fallopian tube, have or have had an inflammation of the fallopian tubes or a tubal (ectopic) pregnancy (see "FAMY-POP and tubal (ectopic) pregnancy"),
- you smoke (see "FAMY-POP and thrombosis"),
- you have sugar diabetes (see "FAMY-POP and other diseases"),
- you are seriously overweight (body mass index above 30 kg/m<sup>2</sup>; see "FAMY-POP and thrombosis"),
- you or a close relative had a venous occlusion (at an early age) (see "FAMY-POP and thrombosis"),
- you have high blood pressure (see "FAMY-POP and other diseases"),
- breast cancer occurred in close relatives (see "FAMY-POP and cancer"),
- you have a liver condition (see "FAMY-POP and cancer" and "FAMY-POP and other diseases"),
- you have a tendency toward pigmentation spots (see "FAMY-POP and other diseases").

### **FAMY-POP and thrombosis**

The term thrombosis refers to the formation of a thrombus (blood clot) that is capable of blocking a blood vessel. Thromboses occur in such places as the deep veins of the lower leg (deep venous thrombosis of the leg). If one of these blood clots becomes dislodged, it can be carried through the bloodstream into the lung arteries, obstructing a blood vessel there (pulmonary embolism). Deep venous thromboses in the legs are rare. They can occur regardless of whether you are taking FAMY-POP or not. They can also occur during pregnancy.

A thrombosis does not always heal completely and sometimes results in lasting disabilities. A thrombosis can even be fatal.

Large-scale investigations point to a correlation between the use of "combined pills" and a more frequent occurrence of deep venous thromboses of the leg, other deep venous thromboses and pulmonary embolisms. The thrombosis risk is higher in women taking these drugs than in women who do not use the "combined pill" for contraception. The significance of these findings for minipills like FAMY-POP is not clear.

It is known that the risk of suffering a venous thromboembolism increases with age. Moreover, the risk increases, if you are seriously overweight (body mass index above 30 kg/m<sup>2</sup>) or if you or a close relative of yours (sibling or parents at a relatively early age) had a venous thromboembolic disorder.

The risk of deep venous thrombosis of the leg may be temporarily enhanced if you undergo surgery, are strictly confined to bed or immobilized (e.g. if a leg is in a cast). In this event, you should inform your health care provider as early as possible that you are taking FAMY-POP. Your health care provider will then advise you to stop taking FAMY-POP at least four weeks prior to the operation, at the start of bed rest or immobilization. Your health care provider will also tell you when you can resume taking FAMY-POP after remobilization.

Equally, the risk of a blood clot occurring may increase following childbirth.

A thrombosis can also occur in an artery (arterial thrombosis), e.g. in the coronary arteries or the arteries supplying the brain, and consequently result in myocardial infarction or stroke. Clinical observation studies showed very few signs of any link between the use of FAMY-POP and an enhanced risk of suffering a myocardial infarction or stroke. Known risk factors for the occurrence of such conditions are increasing age, hypertension and smoking. The risk of suffering a stroke might be slightly higher in women with high blood pressure taking FAMY-POP.

If high blood pressure occurs while you are taking FAMY-POP, you might be advised to stop taking the drug and possibly to use a different contraception method.

The following symptoms can be signs of venous or arterial thrombosis. If you notice any of these symptoms in yourself, stop taking the tablets immediately and see a health care provider right away:

- unusual pain or swelling in a leg,
- pain and tightness in the chest, possibly radiating into the left arm,
- sudden difficulty in breathing,
- sudden, severe coughing,
- unusual, severe or persistent headaches,
- sudden partial or complete loss of vision,
- seeing double,
- indistinct speech or problems with speaking,
- dizziness,
- collapse, possibly in connection with an epileptic seizure,
- sudden weakness or numbness on one side of the body or in one part of the body,
- problems with movement (motor disturbances),
- severe, intolerable abdominal pain.

## **FAMY-POP and cancer**

### Breast

Breast cancer is diagnosed slightly more often in women who take the "combined pill" than in women of the same age who do not use the "combined pill". It is not known whether this is caused by the "combined pill". The difference may be due to the fact that women who take the "combined pill" get examined more frequently and thoroughly, so that breast cancer is discovered earlier. The difference can also be the result of a combination of both.

Because breast cancer is rare in women under 40 years of age, the excess number of breast cancer diagnoses in current and recent users of "combined pills" is small in relation to the overall risk.

This number of breast cancer diagnoses gradually levels out, and after 10 years there is no ascertainable difference between previous "combined pill" users and other women. This risk for women taking FAMY-POP is possibly about the same as for those taking "combined pills", even though the data situation for FAMY-POP is less conclusive.

The breast cancers diagnosed in ever-users of oral contraceptives tend to be less advanced clinically than the cancers diagnosed in never-users.

### Liver

In rare cases, benign liver tumors, and even more rarely, malignant liver tumors have been reported in users of "combined pills". In isolated cases, these tumors have led to life-threatening intra-abdominal hemorrhages. If you suddenly have severe abdominal pain, you must see your health care provider right away.

### **FAMY-POP and other diseases**

FAMY-POP generally does not appear to affect blood pressure in healthy women. However, if a sustained hypertension develops during the use of FAMY-POP, it is advisable to discontinue FAMY-POP.

Occurrence of full-body itching (cholestatic pruritus) or blockage of bile drainage (cholestatic icterus) necessitates the discontinuation of FAMY-POP. Particular caution is required, if these disorders have already occurred during pregnancy or previous use of hormones.

If you are diabetic, the required dose of the medicinal products used to treat your diabetes (diabetes mellitus) may change while taking FAMY-POP. Diabetic women, also those with a history of diabetes in an earlier pregnancy, should therefore be carefully observed while taking FAMY-POP, especially during the initial stages of use.

Yellowish-brown pigmentation spots (chloasma) may occasionally occur, especially in women with a history of chloasma gravidarum. Women with this tendency should avoid direct exposure to the sun or ultraviolet radiation (e.g. sun tanning equipment) while taking FAMY-POP.

### **FAMY-POP and tubal (ectopic) pregnancy**

In those exceptional cases when a woman becomes pregnant while taking FAMY-POP, the pregnancy is more likely to be tubal (ectopic) than are pregnancies among users of the "combined pill".

Therefore, in women with a history of tubal (ectopic) pregnancy, of inflammation in an ovary or who have only one fallopian tube, FAMY-POP should be used only after careful risk/benefit assessment by a health care provider.

If unexplained lower abdominal complaints occur together with an irregular cycle pattern (no bleeding or a stretch of time without bleeding (amenorrhea) followed by persistent bleeding), the possibility of an extrauterine pregnancy must be considered. If this happens, you must see your health care provider at once.

### **FAMY-POP and persistent ovarian cysts**

Persistent ovarian follicles (persistent follicles are often referred to as functional ovarian cysts) may occur during the use of FAMY-POP. Most of these follicles do not cause symptoms, although some may lead to pain in the lower abdomen or painful sexual intercourse (dyspareunia). In most cases, the enlarged follicles disappear spontaneously over two to three months of observation.

### **In the following cases you should see your health care provider as soon as possible**

- changes in your health, e.g. occurrence of conditions described elsewhere in these instructions for use (see "Do not take FAMY-POP ", and "Warnings and precautions", also consider any disorders that have occurred in your close relatives),
- lumps in the breast,
- persistent or increasing irregular bleeding,
- if you forgot to take tablets or took them late and had sexual intercourse,
- if your menstrual bleeding does not occur within six weeks after your last menstrual bleeding (only start a new blister pack when it is certain that you are not pregnant),
- if you have unexplained lower abdominal complaints together with an irregular cycle pattern (menstrual bleeding does not occur (amenorrhea) or if bleeding fails to occur followed by irregular bleeding, see "FAMY-POP and tubal (ectopic) pregnancy"),
- if you notice possible signs of a thrombosis (see "FAMY-POP and thrombosis").

### **Reduced efficacy**

The efficacy of FAMY-POP can be impaired, if

- one or several tablets are missed or taken late (see "If you forgot to take FAMY-POP "),
- you vomit and/or have severe diarrhea (see "If you suffer from vomiting and/or diarrhea"),
- you are taking other medicines at the same time (see "Taking FAMY-POP with other medicines").

If FAMY-POP and products containing St. John's wort are taken at the same time, it is advisable to use an additional barrier contraceptive method (see "Taking FAMY-POP with other medicines").

### **Disturbed cycle**

#### Menstrual bleeding

While FAMY-POP is being taken, menstrual bleeding mostly occurs at normal intervals and is of normal duration and intensity. However, both shortened and lengthened intervals between menstruations are observed.

These changes mainly occur in the initial months of use. The bleeding pattern then becomes steady during the course of further use, establishing a personal menstrual rhythm in most cases. You should always record bleeding in a calendar.

#### Procedure in the event of intermenstrual bleeding

Intermenstrual bleeding of varying intensity may occur, particularly during the first few months. This is not a medical reason to stop taking FAMY-POP. You should, however, inform your health care provider so that organic causes for such bleeding can be ruled out.

#### Absence of menstrual bleeding

Absence of menstrual bleeding may occur, but in most cases this is only for one or two menstrual cycles. In rare cases, bleeding may fail to occur for longer periods of time.

If no menstrual bleeding has occurred within 6 weeks after the last menstrual bleeding, you must see your doctor so that pregnancy can be excluded before tablet-taking is continued.

#### Children

FAMY-POP must not be used before the first menstruation occurs.

### **Taking FAMY-POP with other medicines**

Please inform your health care provider if you are taking/using or have recently taken/used any other medicines or are planning to take/use any other medicines, even those not requiring any prescription.

Please note that this information can also apply to medicines that you have used recently.

The efficacy of FAMY-POP may be reduced by simultaneous treatment with the following active substances and/or product groups. The first sign of this can be the appearance of breakthrough bleeding. These include:

- drugs used in treating epilepsy such as hydantoins (e.g. phenytoin), barbiturates (e.g. phenobarbital), primidone, carbamazepine, oxcarbazepine, topiramate and felbamate,
- drugs used in treating tuberculosis (e.g. rifampicin),
- ritonavir, rifabutin, efavirenz, nevirapine, nelfinavir,
- griseofulvin,
- herbal medicines that contain St. John's wort (*Hypericum perforatum*).

If you receive treatment with any of the above-mentioned drugs for a short period (up to one week) you should use barrier methods (e.g. condom) alongside FAMY-POP, both during treatment with such drugs and for another 28 days.

If you need to take such drugs for longer periods, please ask your doctor for advice. When considered necessary, you should use a different, non-hormonal contraceptive method.

Parallel treatment with antibiotics, such as ampicillin or tetracyclines, may reduce the efficacy of FAMY-POP.

Taking activated charcoal can diminish the absorption of the active substance of FAMY-POP, thus reducing contraceptive reliability. In this case, take note of the explanations in section 3.4 "If you forgot to take FAMY-POP".

Hormonal contraceptives may interfere with the metabolism of other drugs. Accordingly, blood and tissue concentrations may be affected (e.g. by cyclosporine).

Note: You should refer to the instructions for use of the respective concomitant medication to identify any possible interactions.

Inform any health care provider who prescribes medicines for you that you are taking FAMY-POP. They will be able to tell you whether and for how long you must use additional, non-hormonal contraceptive methods.

#### Influencing laboratory findings

Use of FAMY-POP may influence the results of certain laboratory tests, including the results of liver, thyroid, adrenal gland and kidney function testing, as well as certain blood protein levels, e.g. proteins which affect lipid metabolism, carbohydrate metabolism or coagulation and fibrinolysis. As a rule, however, these changes remain within the normal range.

#### **Pregnancy and breastfeeding**

If you are pregnant or are breastfeeding, or if you suspect that you are pregnant or are intending to become pregnant, ask your health care provider for advice before starting to take this medicine.

#### Pregnancy

You must not be pregnant before starting FAMY-POP. If you should get pregnant while using FAMY-POP, you have to stop taking it immediately.

Undesired hormonal effects on the development of urinary and sex organs cannot be completely ruled out, but most of the scientific studies carried out to date have revealed neither an increased risk of birth defects in children born to women who used contraceptives prior to pregnancy, nor a deformity-causing effect when progestogens have been taken inadvertently during pregnancy at doses like those contained in FAMY-POP.

#### Breastfeeding:

If you are breastfeeding, you should avoid taking FAMY-POP. During lactation, FAMY-POP is considered to comprise the next choice category after non-hormonal methods.

There appear to be no adverse effects on growth or development of the suckling infant, if FAMY-POP is started six weeks after childbirth. FAMY-POP does not appear to affect the quantity or quality of breast milk, however, small amounts of the active substance are excreted with the milk.

#### **Ability to drive and ability to operate machines**

No special precautions are necessary.

#### **FAMY-POP contains milk sugar (lactose).**

If you have been told by your health care provider that you have an intolerance to some sugars, contact your health care provider before taking this medicinal product.

### **3. HOW TO TAKE FAMY-POP**

Take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

### **The recommended dose**

Unless the health care provider prescribes otherwise, the usual dose is 1 tablet daily

FAMY-POP is taken continuously, i.e. without any break.

This means that after the first blister pack has been finished, the next pack should be started without interruption.

FAMY-POP must be taken at the same time each day, continuously, without any break, without regard to any bleeding (menstrual bleeding or even intermenstrual bleeding).

The attempt should always be made to maintain an interval of exactly 24 hours between tablets. This interval should by no means be exceeded by more than 3 hours, otherwise protection against conception may be at risk. The greatest possible reliability of FAMY-POP can be assured only by adhering as closely as possible to the 24-hour intervals.

### **When should you start taking the pill from the first blister pack?**

- If you did not take a contraceptive "pill" last month:  
Start taking FAMY-POP on day 1 of your natural cycle, i.e. the first day of your menstrual bleeding.

If you start taking FAMY-POP later than on the first day of menstruation, an additional barrier method of contraception is to be used during the first seven days. If you proceed as described earlier, however, contraception is guaranteed from the start of tablet taking.

- Switching from a "combined pill":  
Start taking FAMY-POP on the day after you take the last tablet of the "combined pill" that contained active substances.  
If the pack of the "previous pill" also contains tablets without active substances, you must not take them.

If you do not know which is the last tablet containing an active substance, ask your health care provider.

If you proceed as described earlier, however, continuous contraception is guaranteed.

- Switching from another minipill:  
You can stop taking the previous minipill on any day you wish and start taking FAMY-POP the very next day.

If you take the tablets correctly, it is not necessary to take any additional contraceptive measures.

- Switching from an injection or implant:  
Start taking FAMY-POP at the time you would normally get the next injection or on the day the implant is removed.

When switching from an implant or injectable product, an additional barrier method of contraception should be used during the first seven days.

- After childbirth:  
Women who are not breastfeeding can start taking the tablets 21 days after giving birth. An additional barrier method should be used during the first seven days. If sexual intercourse has already taken place in the meantime, pregnancy must be ruled out before starting to take FAMY-POP, or it is necessary to wait for the first menstrual bleeding.



- After a miscarriage or an abortion:  
Please talk to your health care provider about when to start taking the tablets.
- Use in breastfeeding women:  
(see "Pregnancy, Breastfeeding and fertility")

### **Method of administration**

This medicinal product is to be taken orally. You should take the tablets whole (do not chew) with sufficient liquid (preferably with a glass of water).

### **If you take more FAMY-POP than you should**

There have been no reports of serious health effects from taking several FAMY-POP on one occasion. If multiple tablets are taken at once, nausea, vomiting and also slight vaginal bleeding may occur.

If you discover that a child has inadvertently swallowed several tablets, please see a health care provider.

### **If you forget to take FAMY-POP**

Even if only one tablet was taken late (i.e. if more than 27 hours have elapsed since the last tablet was taken) or if one tablet was forgotten, contraceptive protection may be impaired.

The missed tablet should be taken as soon as possible, even if this means having to take two tablets at the same time. Then resume taking the tablets at your usual time. In addition, barrier methods have to be used for the next seven days.

If you have had sexual intercourse in the last seven days, you could be pregnant. If this happens, please see your health care provider. The risk of becoming pregnant increases with the number of tablets you have forgotten.

### **If you suffer from vomiting and/or diarrhea**

If you have to vomit within the first three to four hours of taking the tablet and/or have diarrhea, your body may not have completely absorbed the active substance. This situation is comparable to missing a tablet. If this happens, please follow the advice given in the previous section. An additional barrier method of contraception has to be used for the following seven days. Take any replacement tablet(s) from the end of the blister pack, so that you can still monitor your daily use according to the days of the week marked on the blister pack.

### **If you stop taking FAMY-POP**

You can stop taking FAMY-POP at any time. If you do not want to become pregnant, ask your health care provider about other reliable contraception methods.

If you have any further questions on the use of this medicine, ask your health care provider.

## **4. POSSIBLE SIDE EFFECTS**

Like any drug, this medicinal product may cause side effects, although not everybody gets them.

The following side effects have been reported following the use of FAMY-POP:

Very common (more than 1 in 10 users can be affected):

Bleeding disturbances, such as spotting, intermenstrual bleeding or absence of menstrual bleeding

Common (up to 1 in 10 users can be affected):

Depressed mood, change in libido, headache, dizziness, nervousness, nausea, vomiting, acne, breast pain, breast tension, painful menstruation, vaginal inflammation, prolonged menstrual bleeding\*, prolonged intermenstrual bleeding\*

Uncommon (up to 1 in 100 users can be affected):

Yellowish-brown pigmentation spots (chloasma), fluid retention in tissue

Rare (up to 1 in 1,000 users can be affected):

Hypersensitivity reactions, contact lens intolerance, excess male pattern hair growth (hirsutism), skin conditions\*, changes in vaginal discharge, weight changes.

(\* generally applies to progestogen-only products)

As regards other severe side effects, such as the formation of blood clots, liver tumors, breast or cervical cancer, see "Warnings and precautions".

Ectopic pregnancies are more likely to occur among users of FAMY-POP than among users of combined oral contraceptives (see also "FAMY-POP and tubal (ectopic) pregnancy"). Persistent ovarian follicles (functional ovarian cysts) may occur during the use of FAMY-POP (see also "FAMY-POP and persistent ovarian cysts").

## 5. HOW TO STORE FAMY-POP

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label. The expiry date refers to the last day of that month.

Do not store above 30°C. Protect from light. Store tablets in blisters in the provided carton.

Do not throw any medicines into wastewater or in household waste. Ask your health care provider 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 FAMY-POP contains

Each tablet contains levonorgestrel 30µg.

The other ingredients are: colloidal silicon dioxide, hypromellose, lactose monohydrate, magnesium stearate, polyethylene glycol, povidone, talc and titanium dioxide.

### What FAMY-POP looks like and contents of the pack

FAMY-POP are round, white to off-white, biconvex, film coated tablets, debossed with 'E' on one side and plain on other side.

FAMY-POP are available in:

PVC/PVdC-Al blister containing 28 tablets. Each carton contains 3 blisters of 28 tablets and;

PVC/PVdC-Al blister containing 35 tablets. Each carton contains 3 blisters of 35 tablets.

### Supplier and Manufacturer

#### Supplier

Mylan Laboratories Limited  
Plot No.564/A/22  
Road No.92, Jubilee Hills  
Hyderabad, Telangana - 500033  
India

#### Manufacturer

Mylan Laboratories Limited  
Plot No. 20/21, Pharmez  
The Pharmaceutical Special Economic Zone  
Sarkhej - Bavla National Highway No-8A, Nr.  
Village Matoda  
Taluka-Sanand  
Dist-Ahmedabad 382 213  
Gujarat  
India

**For any information about this medicinal product, please contact the local representative of the supplier:**

{COUNTRY}

{Name}

<{Address}

{Town} {Postal code} – Country>

Tel: + {Telephone number}

<{e-mail}>

{COUNTRY}

{Name}

{Address}

{Town} {Postal code} – Country>

Tel: + {Telephone number}

{e-mail}>

**This leaflet was last approved in February 2017**

Detailed information on this medicine is available on the World Health Organization (WHO) web site:  
<https://extranet.who.int/prequal> .