

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

FOMINIC® , Tablets

Each tablet contains Desogestrel 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 this 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?

Fominic is used to prevent pregnancy.

Therapeutic Group: Progestogens, hormonal contraceptives.

- There are two main kinds of hormone contraceptives.
 - The combined pill, "**The Pill**", which contains two types of female sex hormones, oestrogen and progestogen.
 - The progestogen-only pill, POP, which doesn't contain oestrogen.
- **Fominic** is a progestogen-only pill (POP or mini-pill).
- **Fominic** contains a small amount of one kind of female sex hormone, the progestogen **desogestrel**.
- Most progestogen-only pills (POPs) work primarily by preventing the sperm cells from entering the womb, but do not always prevent the egg cell from ripening, which is the primary way that combined pills work.
- **Fominic** is different from most progestogen-only pills (POPs) in having a dose that in most cases prevents the egg cell from ripening. As a result, **Fominic** is a highly effective contraceptive.
- In contrast to the combined pills, **Fominic** can be used by women who do not tolerate oestrogen and by women who are breastfeeding.
- A disadvantage is that vaginal bleeding may occur at irregular intervals during the use of **Fominic**. On the other hand, you may not have any bleeding at all.

2. Before using the medicine

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

Do not use the medicine if:

- you are hypersensitive (allergic) to desogestrel, or to any of the other ingredients this medicine contains (see section 6).
- you have a thrombosis. Thrombosis is the formation of a **blood clot** in a blood vessel [e.g. of the legs (deep venous thrombosis) or the lungs (pulmonary embolism)].
- you have or have had **jaundice** (yellowing of the skin) or severe liver disease and your liver function is still not normal.
- you have or are suspected to have a **cancer** that develops by the effect of sex-hormones, such as certain types of breast cancer.
- you have unexplained **vaginal bleeding**.

If any of these conditions apply to you, tell your doctor before you start to use **Fominic**. Your doctor may advise you to use a non-hormonal method for birth control.

If any of these conditions appear for the first time while using **Fominic**, consult your doctor immediately.

Special warnings regarding the use of the medicine

Before the treatment with Fominic, tell the doctor if:

- you have ever had **breast cancer**.
- you have **liver cancer**, since a possible effect of **Fominic** cannot be excluded.
- you have ever had a **thrombosis**.
- you have **diabetes**.
- you suffer from **epilepsy** (see section "Drug interactions").
- you suffer from **tuberculosis** (see section "Drug interactions").
- you have high **blood pressure**.
- you have or have had **chloasma** (yellowish-brown pigmentation patches on the skin, particularly on the face); if so, avoid too much exposure to sun or ultraviolet radiation.

When **Fominic** is used in presence of any of these conditions, you may need to be kept under close observation. Your doctor can explain what to do.

Breast cancer

- It is important to check your breasts regularly and refer to the doctor as soon as possible if you feel any lump in your breasts.
- Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. When women stop taking the Pill, the risk gradually decreases, so that 10 years after stopping the pill, the risk is the same as for women who have never taken the Pill.

Breast cancer is rare under 40 years of age, but the risk increases as the woman gets older. Therefore, the extra number of breast cancers diagnosed is higher if a woman continues to take the Pill when she is older. How long she takes the Pill is less important.

- In every 10,000 women who take the Pill for up to 5 years but stop taking it by the age of 20, there would be less than 1 extra case of breast cancer found up to 10 years after stopping, in addition to the 4 cases normally diagnosed in this age group.
- In every 10,000 women who take the Pill for up to 5 years but stop taking it by the age of 30, there would be 5 extra cases in addition to the 44 cases normally diagnosed.
- In every 10,000 women who take the Pill for up to 5 years but stop taking it by the age of 40, there would be 20 extra cases in addition to the 160 cases normally diagnosed.

The risk of breast cancer in users of progestogen-only pills like **Fominic** is assumed to be similar to that in women who use combined Pills, but the evidence is not conclusive.

Breast cancers found in women who take the Pill, seem less likely to have spread than breast cancers found in women who do not take the Pill.

It is not known with certainty whether the Pill causes an increase in the risk for breast cancer. It may be that the women were examined more often, so that breast cancer

was noticed earlier.

Thrombosis

Refer to the doctor immediately, if you notice possible signs of thrombosis (see also "Regular checkups").

Thrombosis is the formation of a **blood clot**, which may block blood vessels. Thrombosis sometimes occurs in deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it is formed, it may reach and block pulmonary arteries, causing a pulmonary embolism. Pulmonary embolism may cause chest pain, dyspnea, breakdown and even death.

- Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. It can also happen if you become pregnant.

The risk is higher in Pill-users than in non-users. The risk with progestogen-only pills like **Fominic** is assumed to be lower than in users of Pills that contain oestrogens as well (combined Pills).

Psychiatric disorders

A number of women who use hormonal contraceptives including **Fominic** have reported depression or a depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience changes in mood and depressive symptoms, refer to your doctor for additional medical advice as soon as possible.

Children and adolescents

The medicine is not intended for children and adolescents below 18 years, because no clinical data on efficacy and safety is available in this population.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Also, tell any other doctor or dentist who prescribes you another medicine (or your pharmacist) that you are taking **Fominic**. They can tell you if you need to use additional contraceptives (e.g. condoms) and if so, for how long or if there is a need to change the use of the other medicine you need.

Some of the medicines:

- may affect blood levels of **Fominic**.
- may cause it to be **less effective in preventing pregnancy**.
- may cause unexpected bleeding.

These include medicines, which are used for the treatment of:

- epilepsy (e.g. primidone, phenytoin, carbamazepine, oxcarbazepine, felbamate, topiramate and phenobarbital);
- tuberculosis (e.g. rifampicin, rifabutin);
- HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz);
- hepatitis C virus infection (e.g. boceprevir, telaprevir);
- or other infectious diseases (e.g. griseofulvin);
- high blood pressure in pulmonary blood vessels (bosentan);
- depressive moods (the herbal remedy St. John's Wort);
- certain bacterial infections (e.g. clarithromycin, erythromycin);
- fungal infections (e.g. ketoconazole, itraconazole, fluconazole);
- high blood pressure (hypertension), chest pain (angina pectoris) or certain heart rate disorders (e.g. diltiazem).

If you are taking drugs or herbal products that may cause **Fominic** to be less effective, an additional contraceptive method (barrier method) should be used as well. Since the effect of another medicine on **Fominic** can last up to 28 days after stopping the use of the medicine, the barrier method of contraception should be used during all that time. Your doctor can tell you if you need to take additional contraceptive precautions and if so, for how long.

Fominic may also interfere with how certain medicines work, causing either an increase in effect (e.g. medicines containing cyclosporine) or a decrease in effect (e.g. lamotrigine).

Ask your doctor's or pharmacist's advice before taking any medicine.

Use of this medicine and food:

Fominic can be taken regardless to food.

Pregnancy and breastfeeding:

Pregnancy

Do not use **Fominic** if you are pregnant, or think you may be pregnant.

Breastfeeding

Fominic may be used while you are breastfeeding. **Fominic** does not appear to influence the production or the quality of breast milk. However, there have been infrequent reports of a decrease in breast milk while using **Fominic**. A small amount of the active substance of **Fominic** passes over into the milk.

The health of children breastfed for 7 months, whose mothers were using **Fominic**, has been studied until they reached the age of 2.5 years. No effects on growth and development of the children were observed.

If you are breastfeeding and want to use **Fominic**, you should consult your doctor.

If you are pregnant or breastfeeding, consult the doctor or pharmacist before using medicines.

Driving and using machines:

Fominic has no known effect on the ability to drive and operate machines.

Important information about some of the ingredients of the medicine:

Fominic contains lactose. If you have previously been told by the doctor that you have an intolerance to certain sugars, consult the doctor before starting treatment with this medicine.

Regular check-ups:

During the use of **Fominic**, the doctor will refer you for regular check-ups. In general, the frequency and nature of these check-ups will be determined by your personal condition.

Refer to the doctor as soon as possible if:

- you notice possible signs of a **blood clot**, e.g. severe pain or swelling in either of your legs, unexplained chest pain, breathlessness, an unusual cough, especially when you cough up blood (possibly indicating a **thrombosis**);
- you have a sudden, severe stomach ache or **jaundice** (you may notice yellowing of the skin, the white of the eye, or dark urine, possibly a sign of **liver problems**);

- you feel a lump in your breast (possibly indicating **breast cancer**);
- you have a sudden or severe pain in the lower abdomen or stomach area (possibly indicating an **ectopic pregnancy**, a pregnancy outside the womb);
- you are about to be immobilized or are about to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you suspect that you are **pregnant**.

3. How to use this medicine

Always use this medicine according to the doctor's instructions. You should check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage, method and duration of treatment will be determined by the doctor only.

Do not exceed the recommended dose.

When and how to take the tablets?

Each **Fominic** blister contains 28 tablets – a supply for 4 weeks.

- **Take the tablet each day at about the same hour. Swallow the whole tablet, with water.**
- Arrows are printed on the front side of the blister, between the tablets. Days of the week are printed above the tablets. Each day corresponds to one tablet.
- Every time you start a new pack of **Fominic**, take a tablet from the top row. Don't start with just any tablet. For example, if you start on Wednesday, you must take a tablet from the top row marked with 'ד ו'.
- Continue to take one tablet every day until the blister is empty, always following the direction indicated by the arrows. By looking at your blister you can easily check if you have already taken the tablet on a particular day.
- You may have vaginal bleeding while using **Fominic**, (see section 4 "Side effects"), but you should continue to take the pills as usual.
- When the blister is empty, you must start a new blister of **Fominic** the following day - without interruption and without waiting for a bleed.

No information is available regarding crushing/splitting/chewing of the tablets.

Starting your first packet of Fominic

- **If you are not using hormonal contraception at present (or in the past month):** Wait for your period to begin. On the first day of your period take the first **Fominic** tablet. Additional contraceptive precautions are not necessary. If you take the first tablet on days 2-5 of your cycle, use an additional barrier method of contraception for the first 7 days of taking the tablets.

- **When you switch from a combined pill (COC), vaginal ring, or transdermal patch: If you don't have** a tablet, ring or patch-free break

- Start taking **Fominic** on the day after you take the last tablet from the present Pill pack, or on the day of removal of your vaginal ring or patch (this means without a break between the pills, vaginal ring or patch and starting **Fominic**).
- If your present Pill pack also contains inactive tablets (placebo) you can start using **Fominic** on the day after taking the last active tablet (if you are not sure which tablet this is, refer to the doctor or pharmacist).

- **If you follow these instructions, additional contraceptive precautions are not necessary.**
- **If you have** a tablet, ring or patch-free break
- You can also start taking **Fominic** on the day following the end of the tablet, vaginal ring or patch-free break, or when you have taken all the inactive tablets (placebo) of your present contraceptive.

- **If you follow these instructions, make sure you use an additional barrier method of contraception for the first 7 days of taking the tablets.**
- **When switching from another progestogen-only pill:** Switch on any day from another mini-pill. Additional contraceptive precautions are not necessary.
- **When switching from an injection or implant or hormonal intrauterine device (IUS):** Start taking **Fominic** when your next injection is due or on the day that your implant or your IUS is removed. Additional contraceptive precautions are not necessary.

- **After giving birth:** You can start using Fominic between 21 to 28 days after giving birth. If you start later, make sure you use an additional barrier method of contraception until you have completed the first 7 days of taking the tablets. However, if you have already had intercourse, pregnancy should be ruled out before starting to use **Fominic**. Additional information for breastfeeding women can be found in section "Pregnancy and breastfeeding". You can also consult your doctor.

- **After a miscarriage or an abortion:** Consult your doctor.
- **If you forget to take the medicine**
- If you are **less than 12 hours** late:
 - Take the missed tablet as soon as you remember and take the next tablet at the usual time. **Fominic** will still protect you from pregnancy.

- If you are **more than 12 hours** late:
 - If you are more than 12 hours late in taking any tablet, you **may not be completely protected against pregnancy**. The more consecutive tablets you have missed, the higher the risk that you might become pregnant.
 - Take a tablet as soon as you remember and the next tablet at the usual time.
 - Meaning, you may be taking two tablets on the same day. This is not harmful. (If you have forgotten more than one tablet, you don't need to take the tablets missed earlier). Continue to take the tablets as usual, but you must also use an additional contraception method, such as a condom, for the **next 7 days**.
- If you are more than 12 hours late taking your tablet and have had intercourse, it is safe to use an **emergency contraception**; consult your pharmacist or doctor.
- If you missed one or more tablets during the **first week** of starting the tablets and have had intercourse in the week prior to missing the tablet/tablets, you might become pregnant. Consult your doctor.

If you suffer from gastrointestinal disorders (e.g. vomiting, severe diarrhoea)

If you vomit within 3-4 hours after taking a **Fominic** tablet or if you have severe diarrhoea, the active ingredient may not have been completely absorbed. Follow the instructions regarding forgotten tablets in the section above.

If you have accidentally taken a higher dosage (overdose)

There have been no reports on serious harmful effects as a result of taking too many desogestrel tablets simultaneously. Symptoms that may appear are nausea, vomiting and, in young girls, slight vaginal bleeding. For further information, consult your doctor.

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you stop taking the medicine

You can stop taking **Fominic** whenever you want. From the day you stop you are no longer protected against pregnancy.

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

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

4. Side effects

Like any medicine, the use of **Fominic** 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.

Tell your doctor if you notice any undesirable effect, especially if it's severe or persistent.

Serious side effects associated with the use of **Fominic** are described under section 2 "Special warnings concerning use of the medicine". Please read this section for further information on "Breast cancer" and "Thrombosis" and consult your doctor immediately if necessary.

See also "**Refer to the doctor as soon as possible if**" above.

You must refer to the doctor immediately if you experience an allergic (hypersensitivity) reaction, including swelling of the face, lips, tongue and/or throat that causes breathing or swallowing difficulties (angioedema and/or anaphylaxis).

Irregular vaginal bleeding may appear during the use of **Fominic**. This may be only a slight staining which may not even require a pad, or heavier bleeding, which looks rather like a mild period. You may need to use tampons or sanitary pads. You may not have any bleeding at all. Irregular bleeding is not a sign that **Fominic** is not working. In general, you do not need to take any action; just continue to take **Fominic**. **If bleeding is heavy or prolonged, you should consult your doctor.**

Additional side effects

Common side effects (effects that appear in 1-10 out of 100 users): mood changes, depressed mood, decreased sexual drive (libido), headaches, nausea, acne, breast pain, irregular or no periods, weight increase.

Uncommon side effects (effects that appear in 1-10 out of 1,000 users): vaginal infection, difficulties in wearing contact lenses, vomiting, hair loss, painful periods, ovarian cysts, tiredness.

Rare side effects (effects that appear in 1-10 out of 10,000 users): skin conditions such as: rash, hives, painful blue-red skin lumps (erythema nodosum).

Side effects with unknown frequency (effects for which a frequency has not yet been determined): an allergic reaction

Apart from these side effects, breast secretion or leakage may occur.

If a side effect appears, if any 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 via the link

"דיווח על תופעות לוואי - עקב טיפול תרופתי" that can be found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine

- Avoid Poisoning! This medicine and any other medicine must 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.
- Do not use this medicine after the expiry date (Exp.) which is stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** store below 25°C.
- The active degradation substance etonogestrel presents an environmental hazard to fish.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Lactose monohydrate, maize starch, povidone K-30, hypromellose 2910, titanium dioxide, silica colloidal anhydrous, stearic acid, polyethylene glycol, RRR- α -Tocopherol, silica colloidal hydrated.

What the medicine looks like and what the package contains:

Round white tablet.

Approved package sizes:

A carton box with 1 or 3 blisters. One blister of **Fominic** contains 28 tablets.

Not all package sizes may be marketed.

Manufacturer and address:

Laboratorios León Farma S.A., Navatejera, León, Spain.

Revised in January 2021

Registration number of the medicine at the national drug registry of the Ministry of Health: 155-65-34262-00

Fominic PIL PB1020-06

Registration holder: **Dexcel® Ltd.**

1 Dexcel St., Or Akiva 3060000, Israel