

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

DIAMILLA

Film-coated Tablets

Active ingredient

Each tablet contains: Desogestrel 0.075 mg
For information on inactive and allergenic ingredients, see section 2 "Important information about some of the ingredients of DIAMILLA" and section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about DIAMILLA. If you have further questions, ask your doctor or pharmacist.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

DIAMILLA is used to prevent pregnancy.

Therapeutic group: Progestogens, hormonal contraceptives.

- There are two main kinds of hormonal contraceptive.
 - The combined pill, "The Pill", which contains two types of female sex hormones: estrogen and progestogen.
 - The progestogen-only-pill, **POP**, which does not contain estrogen.
- DIAMILLA is a progestogen-only-pill (POP or a mini-pill).
- DIAMILLA contains a small amount of one type of female sex hormone, the progestogen **desogestrel**.
- Most POPs work primarily by preventing the sperm cells from entering the womb, but they do not always prevent the egg cell from ripening, which is the main way that combined pills work.
- DIAMILLA is different from most POPs in that its dosage, in most cases, prevents the egg cell from ripening. As a result, DIAMILLA is a highly effective contraceptive.
- In contrast to the combined pills, DIAMILLA can be used by women who cannot take estrogen and by breastfeeding women.
- Its disadvantage is that irregular vaginal bleeding may occur during use of DIAMILLA. On the other hand, you may not experience any bleeding at all.

2. BEFORE USING DIAMILLA

DIAMILLA, like other hormonal contraceptives, does not protect against contraction of HIV (AIDS) or any other sexually transmitted disease.

2.1 Do not take DIAMILLA if:

- You are **sensitive (allergic)** to desogestrel or to any of the other ingredients of DIAMILLA (for the list of inactive ingredients, see section 6.1).
- 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 is still not working properly.
- You have or you are suspected of having a **cancer** that develops under the influence of sex hormones, such as certain types of breast cancer.
- You have any unexplained **vaginal bleeding**.

If any of these conditions apply to you, tell your doctor before starting to use DIAMILLA. The doctor may advise you to use a non-hormonal method of birth control. If any of these conditions occur for the first time while using DIAMILLA, consult your doctor immediately.

2.2 Special warnings regarding the use of DIAMILLA

Before treatment with DIAMILLA, tell your doctor if:

- You have ever had **breast cancer**.
- You have **liver cancer**, since a possible effect of DIAMILLA cannot be excluded.
- You have ever had a **thrombosis**.
- You have **diabetes**.
- You suffer from **epilepsy** (see section 2.4 "Taking other medicines").
- You suffer from **tuberculosis** (see section 2.4 "Taking other medicines").
- You have **high blood pressure**.
- You have or have had **chloasma** (brown-yellowish pigmentation patches on the skin, particularly on the face); if so, avoid too much exposure to the sun or ultraviolet radiation.

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

2.2.1 Breast cancer

- It is important to regularly check your breasts and you should refer to a 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 pills than in women of the same age who do not take pills. When women stop using the pill, this reduces the risk, so that 10 years after stopping the pills, the risk is the same as for women who have never taken pills.

Breast cancer is rare under the age of 40, but the risk increases as the woman gets older. Therefore, the extra number of breast cancer cases diagnosed is higher if a woman continues to take the pill when she is older. The duration of use of the pill is less important.

- In every 10,000 women who take the pill for a period of up to 5 years, but stop taking it by the age of 20, there will 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 10,000 women who take the pill for a period of up to 5 years, but stop taking it by the age of 30, there will be 5 extra cases in addition to the 44 cases normally diagnosed.
- In 10,000 women who take the pill for a period of up to 5 years, but stop taking it by the age of 40, there will be 20 extra cases in addition to the 160 cases normally diagnosed.

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

Breast cancers found in women who take pills seem less likely to spread than breast cancers found in women who do not take pills.

It is not certain whether the pill causes the increased risk of breast cancer. It may be that the women were examined more often, so that the breast cancer was discovered earlier.

2.2.2 Thrombosis

See a doctor immediately if you notice possible signs of a thrombosis (see also "Regular check-ups"). Thrombosis is the formation of a **blood clot**, which may block blood vessels. A thrombosis sometimes forms in the deep veins of the legs (deep venous thrombosis). If this clot breaks away from the veins where it was formed, it may reach and block the arteries of the lungs, causing a "pulmonary embolism". A pulmonary embolism can cause chest pain, breathlessness, collapse or 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. It is assumed that the risk with use of progestogen-only-pills, like DIAMILLA, is lower than in users of pills that also contain estrogens (combined pills).

2.2.3 Psychiatric disorders

Some women using hormonal contraceptives, including DIAMILLA, have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms, refer to your doctor for further medical advice as soon as possible.

2.3 Children and adolescents

The medicine is not intended for children and adolescents under the age of 18 because no clinical data on efficacy and safety are available in this population.

2.4 Taking other medicines

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the attending doctor or pharmacist. In addition, tell any other doctor or dentist who prescribes another medicine for you (or your pharmacist) that you are taking DIAMILLA. They will be able to tell you if you need to use additional contraceptive measures (for example, condoms) and if so, for how long or whether it is necessary to change the use of another medicine you need.

- Some medicines:
- Can affect the blood levels of DIAMILLA.
 - Can make it **less effective in preventing pregnancy**.
 - Can cause unexpected bleeding.

These include medicines 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 the blood vessels of the lungs (bosentan)
- Depressive moods (St. John's Wort, a herbal medicine)
- Certain bacterial infections (e.g., clarithromycin, erythromycin)
- Fungal infections (e.g., ketoconazole, itraconazole, fluconazole)
- High blood pressure (hypertension), angina or certain heart rhythm disorders (e.g., diltiazem)

If you are taking medicines or herbal products that might make DIAMILLA less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on DIAMILLA may last up to 28 days after stopping the medicine, use the barrier contraceptive method for that long.

Your doctor can tell you if you need to take additional contraceptive measures and if so, for how long.

DIAMILLA may also interfere with the activity of other medicines, causing either an increase in effect (e.g., medicines containing ciclosporin) or a decrease in effect (e.g., lamotrigine).

Ask your doctor or pharmacist for advice before taking any medicine.

2.5 Taking DIAMILLA with food

DIAMILLA can be taken without regard to food.

2.6 Pregnancy and breastfeeding

Pregnancy
Do not take DIAMILLA if you are pregnant or think you may be pregnant.

Breastfeeding

DIAMILLA can be used during breastfeeding. DIAMILLA does not appear to influence the production or the quality of breast milk. However, there have been rare reports of a decrease in breast milk production while using DIAMILLA. A small amount of the active ingredient of DIAMILLA passes into the milk.

The health of children who were breastfed for 7 months while their mothers were using DIAMILLA has been studied up until they were 2.5 years of age. No effects on the growth and development of the children were observed.

If you are breastfeeding and want to use DIAMILLA, consult the doctor.

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

2.7 Driving and operating machinery

DIAMILLA has no known effect on the ability to drive or operate machinery.

2.8 Important information about some of the ingredients of DIAMILLA

DIAMILLA contains lactose (milk sugar) and soy oil. If you have been told by the doctor that you are sensitive to certain sugars, refer to a doctor before taking DIAMILLA. If you are allergic to peanuts or soya, do not use this preparation.

2.9 Regular check-ups

During use of DIAMILLA, the doctor will refer you for regular check-ups. In general, the frequency and type of check-ups will be determined according to your personal situation.

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 one of the legs; unexplained pains in the chest, breathlessness, an unusual cough, especially coughing up blood (this may be a sign of a **thrombosis**)
- You have a sudden, severe stomachache or **jaundice** (you may notice yellowing of the skin, the whites of the eyes, or dark urine; this may be a sign of **liver problems**)
- You feel a lump in the **breast** (this may be a sign of **breast cancer**)
- You have a sudden or severe pain in the lower abdomen or stomach area (this may be a sign of an **ectopic pregnancy** – a pregnancy outside the womb)
- You are due to be immobilized or to undergo surgery (consult the doctor at least four weeks in advance)
- You have unusual, heavy **vaginal bleeding**
- You suspect that you are **pregnant**

3. HOW SHOULD YOU USE DIAMILLA?

Always use DIAMILLA according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the medicine dosage and treatment regimen. The dosage, regimen and duration of treatment will be determined by the doctor only.

Do not exceed the recommended dose.

3.1 When and how to take the pills?

Each tray of DIAMILLA contains 28 pills – 4-week supply.

- **Take the pill each day, at about the same time. Swallow the pill whole, with water.**
- Arrows are printed on the front of the tray, between the pills. The days of the week are printed on the back of the tray. Each day corresponds with one pill.
- Every time you start a new tray of DIAMILLA, take a pill from the top row. Do not start with just any pill. For example, if you start on a Wednesday, you must take the pill from the top row marked WED (Wednesday).
- Continue to take one pill every day until the package is empty, always following the direction indicated by the arrows. By looking at the back of your package, you can easily check if you have already taken the pill on a particular day.
- You may have some vaginal bleeding during use of DIAMILLA (see section 4 "Side Effects") but you must continue taking the pills as normal.
- When the tray is empty, you should start a new tray of DIAMILLA on the following day – without interruption and without waiting for bleeding.

There is no information regarding crushing/halving/chewing of the pills.

3.2 Starting the first pack of DIAMILLA

If you are not currently using a hormonal contraceptive (or in the last month):

Wait for your period to begin. On the first day of your period, take the first DIAMILLA pill. Additional contraceptive measures are not necessary. If you take the first pill on days 2-5 of your period, use a barrier method of contraception for the first 7 days of taking the pills.

When you switch from a combined pill (COC), vaginal ring, or transdermal patch:

- **If you do not have a pill-, ring- or patch-free break**
 - Start taking DIAMILLA on the day after you take the last pill from the present pill package, or on the day of removal of the vaginal ring or patch (this means no pill-, ring- or patch-free break before commencement of DIAMILLA).
- If your present pill package also contains inactive (placebo) pills, you can start DIAMILLA on the day after taking the last active pill (if you are not sure which pill this is, refer to the doctor or pharmacist).

If you follow these instructions, additional contraceptive measures are not necessary.

If you have a pill-, ring- or patch-free break

- You can also start on the day following the pill-, ring- or patch-free break, or when you have taken all the inactive (placebo) pills 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 pills.**

When switching from another progestogen-only-pill:

Switch on any day from another mini-pill. Additional contraceptive measures are not necessary.

When switching from an injection or implant or hormonal intrauterine system (IUS):

Start taking DIAMILLA when your next injection is due or on the day that your implant or your IUS is removed. Additional contraceptive measures are not necessary.

After childbirth:

You can start using DIAMILLA between 21 to 28 days after the delivery. If you start later, make sure that you use an additional barrier method of contraception until you have completed the first 7 days of taking the pills. However, if you have already had sex, rule out pregnancy before starting DIAMILLA. Further information for breastfeeding women can be found in the "Pregnancy and breastfeeding" section. You can also consult with your doctor.

After a miscarriage/abortion:

Consult your doctor.

3.3 If you forget to take DIAMILLA

- If you are **less than 12 hours** late:
 - Take the forgotten pill as soon as you remember and take the next pill at the usual time. DIAMILLA 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 pill, **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 pill as soon as you remember and take the next pill at the usual time. This may mean taking two pills in one day. This is not harmful. (If you have forgotten more than one pill, you don't need to take the earlier missed ones). Continue to take the pills as usual but you must also use an extra contraceptive method, such as a condom, for the **next 7 days**.

If you are more than 12 hours late taking your pill and have had sex, it is safe to use **emergency contraception**; consult your pharmacist or doctor.

If you missed one or more pills **during the first week** of starting the pills and had intercourse in the week before forgetting the pills, you can become pregnant.

Consult your doctor.

3.4 If you suffer from gastro-intestinal disturbances (e.g., vomiting, severe diarrhea)

If you vomit within 3-4 hours after taking the DIAMILLA pill, or if you have severe diarrhea, the active ingredient may not have been fully absorbed. Follow the instructions regarding forgotten pills in the section above.

3.5 If you accidentally take a higher dosage (overdose)

There have been no reports of serious harmful effects as a result of taking too many DIAMILLA pills at one time. Symptoms that may occur are nausea, vomiting and, in young girls, slight vaginal bleeding. For further information, consult your doctor.

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

3.6 If you stop taking DIAMILLA

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

Adhere to the treatment as recommended by the doctor.

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 regarding use of the medicine, ask your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of DIAMILLA 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 is severe or persistent.

Serious side effects associated with the use of DIAMILLA are described under section 2 "Before Using Diamilla".

Please read this section for additional information on 'Breast cancer' and 'Thrombosis' and consult your doctor immediately if necessary.

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

Refer to the doctor immediately if you experience an allergic reaction (hypersensitivity), including swelling of the face, lips, tongue and/or throat causing difficulty in breathing or swallowing (angioedema and/or anaphylaxis).

Irregular vaginal bleeding may occur while using DIAMILLA. This may be just slight staining which may not even require a pad, or heavier bleeding, which looks like a light period.

You may need to use tampons or sanitary pads. You may also not have any bleeding at all. Irregular bleeding is not a sign that DIAMILLA is not working. In general, no action has to be taken; just continue taking DIAMILLA. **If bleeding is heavy or prolonged, consult your doctor.**

Additional side effects

Common side effects (affecting less than 1 in 10 women):

- Mood changes, depressed mood, decreased sexual drive (libido)
- Headaches
- Nausea
- Acne
- Breast pain, irregular or no periods
- Weight gain

Uncommon side effects (affecting less than 1 in 100 women):

- Vaginal infection
- Difficulty in wearing contact lenses
- Vomiting
- Hair loss
- Painful periods, ovarian cysts
- Tiredness

Rare side effects (affecting less than 1 in 1,000 women):

- Skin conditions such as rash, hives, painful blue-red skin lumps (erythema nodosum)

Side effects of unknown frequency (cannot be estimated from the available data):

- Allergic reaction.

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

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

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

• Do not use DIAMILLA after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

• **Store below 25°C.**

• The active ingredient shows an environmental risk to fish. Do not dispose of medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION

6.1 What does DIAMILLA contain?

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

Lactose Monohydrate, Maize Starch, Hydroxypropylmethylcellulose, Silica Colloidal Anhydrous, RRR-Alpha-Tocopherol, Silica Colloidal Hydrated, Hypromellose 2910, Titanium Dioxide, Polyethylene Glycol.

Each tablet contains approximately 55 mg lactose monohydrate.

Also see under section 2.8 "Important information about some of the ingredients of DIAMILLA".

6.2 What the medicine looks like and the contents of the package:

The tablet is film-coated, white and round.

Package size:

The carton box contains one or three tray(s) (blister). Each DIAMILLA tray contains 28 tablets and may be packaged in a separate pouch.

Not all package sizes may be marketed.

License holder and its Address:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020 Israel.

Name of Manufacturer and its Address:

Laboratorios Leon Farma SA, Spain, 24008 Navatejera, Leon, Spain.

This leaflet was revised in May 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 155.98.34400