PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986
This medicine is dispensed with a doctor's prescription only

Visabelle®

Tablets

Each tablet contains:
Dienogest 2 mg
Inactive ingredients and allergens: See section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the 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.

1) WHAT IS THE MEDICINE INTENDED FOR?

Visabelle is intended for the treatment of endometriosis (symptoms of pain due to displaced tissue of the lining of the womb).

Therapeutic group: Visabelle belongs to a group of hormonal medicines called progestogens.

2) BEFORE USING THE MEDICINE

Do not use the medicine if:
- You are pregnant or breastfeeding.
- You are **sensitive (allergic)** to dienogest or to any of the other ingredients contained in the medicine. For the list of inactive ingredients, see section 6 "Further Information".
- You suffer from a **blood clot** (venous thrombosis) in the veins, for example, in the blood vessels of the legs (deep vein thrombosis) or in the lungs (pulmonary embolism). See "Visabelle and blood clots in the vein" in section 2.
- You suffer, or have suffered in the past, from a **severe arterial disease**, including a cardiovascular disease such as **heart attack, stroke** or a **heart disease** which causes a reduced blood supply (angina pectoris). See "Visabelle and blood clots in the artery" in section 2.
- You suffer from **diabetes** with vascular damage.
- You suffer, or have suffered in the past, from a **severe liver disease** (and liver function values are still not normal). Symptoms of liver disease may be yellowing of the skin and/or itching all over the body.
- You have, or have ever had, a **benign or malignant liver tumor**.
- You have, or have ever had, or suspect you may have a hormone-dependent **malignant** tumor, such as breast cancer or cancer of the genital organs.
- You have unexplained **vaginal bleeding**.

If one of the aforementioned conditions occurs for the first time while using Visabelle, immediately stop taking the medicine and consult the attending doctor.

Special warnings regarding use of the medicine
- Do not use hormonal contraceptives of any form (pills, patch, vaginal ring or intrauterine system containing hormones) during the course of treatment with Visabelle.
- Visabelle is not intended as a contraceptive. If you want to prevent pregnancy, use condoms or other nonhormonal contraceptive measures.
- In some situations, special caution is necessary while using Visabelle, and you will therefore have to be regularly checked by your doctor. Tell the doctor if one of the following conditions applies to you:
  - You have ever had a **blood clot** (venous thrombosis) or anyone in your immediate family has had a blood clot at a relatively young age.
  - A close relative has or has had **breast cancer**.
  - You have ever suffered from **depression**.
  - You have **high blood pressure** or develop high blood pressure while using Visabelle.
  - You develop a **liver disease** while using Visabelle. Symptoms can include yellowing of the skin or eyes or itching all over the body. Also inform your doctor if such symptoms occurred during a previous pregnancy.
  - You have **diabetes** or had temporary diabetes during previous pregnancy.
  - You have ever had **chloasma** (golden-brown patches on the skin, particularly on the face). In such a case, avoid excessive exposure to the sun or ultraviolet radiation.
  - You suffer from **pain in the lower abdomen** while using Visabelle.
- While using Visabelle, your chance of becoming pregnant is reduced because Visabelle may affect ovulation.

If you become pregnant while using Visabelle, the **risk** of ectopic pregnancy (the embryo develops outside of the womb) **increases slightly**. If you had an ectopic pregnancy in the past or if you suffer from impaired function of the Fallopian tubes, tell your doctor before you start using the medicine.

Visabelle and serious uterine bleeding
There may be cases in which use of the medicine worsens uterine bleeding, for example, in women suffering from a condition where the mucous membrane of the uterus (endometrium) grows into the muscle layer of the uterus (called adenomyosis uteri or **benign tumors of the womb**, sometimes called fibroids [uterine leiomyomata]). If bleeding is heavy and continuous over time, there may be a drop in red blood cell levels (anemia), which may be severe in some cases. In the event of anemia, consult with your doctor whether you should stop using the medicine.

Visabelle and changes in bleeding pattern
Most women using Visabelle experience changes in their menstrual bleeding pattern (see section 4 "Side Effects").

Visabelle and blood clots in the vein
Several studies indicate that there may be a slight, but not statistically significant, increase in risk of a **blood clot in the legs (venous thrombosis)** associated with the use of progestogen-containing preparations such as Visabelle. Very rarely, blood clots may cause serious permanent disabilities or may be life-threatening.
The risk of **blood clot in a vein** increases:
- With age.
- If you are overweight.
- If you or someone in your immediate family had a blood clot in the leg (thrombosis), lungs (pulmonary embolism), or other organs at a young age.
- If you must undergo surgery, if you have had a serious accident or if you are immobilized for a long time. Tell your doctor in advance that you are taking Visabelle, as the treatment may have to be stopped. Your doctor will tell you when you can resume taking Visabelle. Resumption of treatment will usually be about 2 weeks after return to activities and mobility.

Visabelle and blood clots in the artery
There is little evidence of an association between preparations containing progestogens, such as Visabelle, and an increased risk of a blood clot in, for example, the blood vessels of the heart (heart attack) or the brain (stroke). In women with hypertension, use of such preparations may slightly increase the risk of stroke.
The risk of an arterial blood clot increases:
- **If you smoke. You are strongly advised to stop smoking while using the medicine, especially if you are older than 35 years of age.**
- If you are overweight.
- If someone in your immediate family had a heart attack or stroke at a young age.
- If you have high blood pressure.

Consult your doctor before taking Visabelle.
Stop using the medicine and refer to the doctor immediately if you notice possible signs of a blood clot, symptoms of possible formation of a blood clot are detailed in section 4 "Side Effects".

Visabelle and cancer
It is not clear from the currently available data, whether or not Visabelle increases the risk of breast cancer.
Breast cancer has been diagnosed slightly more often in women taking hormones, compared to women not taking hormones, but it is not known whether this difference is caused by the treatment. For example, it may be that the increased number of diagnosed tumors and early diagnoses in women taking hormones is as a result of women taking hormones being checked more often by the doctor.
The occurrence of breast tumors gradually declines after stopping the hormone treatment. **It is important to regularly check your breasts** and refer to your doctor if you feel any lump.
In rare cases, benign liver tumors have been reported, and in even rarer cases, malignant liver tumors have been reported in women taking hormones. Contact your doctor if you have unusually severe abdominal pain.

Visabelle and osteoporosis
Changes in bone density
Use of Visabelle may affect bone strength in adolescent girls (from the age of 12 years to under 18 years of age). If you are under 18 years of age, your doctor will weigh the expected benefits and risks to you in using Visabelle, while taking possible risk factors of bone depletion (osteoporosis) into account.
If you take Visabelle, it will help your bones if you have an adequate intake of calcium and vitamin D via food or nutritional supplements.
If you have an increased risk for osteoporosis (weakening of bones due to loss of bone minerals), the doctor will consider the risks and benefits of treatment with Visabelle, since this medicine moderately suppresses the production of estrogen (another type of female hormone) in your body.

Children and adolescents girls
Visabelle is not for use in girls before menarche (first menstrual bleeding). Use of Visabelle may affect bone strength in adolescent girls (from the age of 12 years to under 18 years of age). If you are under 18 years of age, your doctor will weigh the expected benefits and risks to you in using Visabelle, while taking possible risk factors of bone depletion (osteoporosis) into account.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Certain medicines may affect Visabelle blood levels, thereby reducing its efficacy, or cause occurrence of side effects. In particular, inform the doctor or pharmacist if you are taking:
- medicines to treat epilepsy (e.g., phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate)
- medicines to treat tuberculosis (e.g., rifampicin)
- medicines to treat infections of the AIDS virus (HIV) and hepatitis type C, called protease inhibitors and non-nucleoside reverse transcriptase inhibitors (e.g., ritonavir, nevirapine, efavirenz)
- medicines to treat fungal infections (such as griseofulvin, ketoconazole)
- the herbal preparation St. John's wort (*Hypericum*)

Similarly, inform any other doctor, including the dentist, as well as the pharmacist, that you are taking Visabelle.

Use of the medicine and food
During the course of treatment with Visabelle, avoid drinking grapefruit juice, due to concern of increased Visabelle levels in your blood. This condition may increase the risk of occurrence of side effects.

Laboratory tests
If you have to undergo a blood test, tell your doctor or the laboratory staff, that you are taking Visabelle, since the medicine may affect the results of certain tests.

Pregnancy and breastfeeding
Do not use the medicine if you are pregnant or breastfeeding.

Driving and use of machines
No effects on the ability to drive and operate machinery have been observed among Visabelle users.

Important information regarding some of the ingredients of the medicine
This medicine contains lactose.
Consult the doctor before using this medicine if you are suffering from intolerance to certain sugars.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use in accordance with the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
- The dosage and treatment regimen will be determined by the doctor only. In adult women, the usual dosage is generally one tablet per day.

Do not exceed the recommended dose
- The following instructions for use apply to Visabelle, unless you have received other instructions from your doctor. To achieve the maximum benefit from the medicine, follow the instructions.

You can start taking the medicine on any day of the month.
Adult women: Take one tablet every day, with a bit of fluid, preferably at a set time. Once you have finished taking all the tablets in a pack, immediately start taking the tablets of the next pack, without taking a break. Also continue taking the tablets on the days of menstrual bleeding.

Mode of administration
There is no information regarding crushing/halving/chewing.

If you accidentally took too high a dosage
There are no reports of severe, harmful side effects after taking too many Visabelle tablets at once. In any case, if you are concerned, contact your doctor.
If you have taken an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine or if you are suffering from vomiting or diarrhea, the effectiveness of the treatment declines. If you forgot to take one or more tablets, take only one tablet as soon as you remember, and then continue taking a tablet the next day at your set time.
If you vomit within 3-4 hours of taking the tablet, or you have severe diarrhea, there is a risk that the active ingredient in the tablet will not be absorbed by your body. The situation is similar to forgetting to take a tablet. In the event of vomiting or diarrhea within 3-4 hours of taking Visabelle, take another tablet as soon as possible.
Do not take a double dose to make up for a forgotten tablet.
Adhere to the treatment regimen recommended by the doctor. Even if there is improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking the medicine, the original endometriosis symptoms may return.
- **Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

4) SIDE EFFECTS

As with any medicine, use of Visabelle 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. The side effects are more common during the first months of use of the medicine and usually disappear with continued use. You may also experience changes in your bleeding pattern, such as spotting, irregular bleeding or your periods may stop completely.

Discontinue use of the medicine and refer to a doctor immediately if you notice possible signs of a blood clot, such as:
- severe pain and/or swelling in one of your legs
- sudden severe pain in the chest that can radiate to the left arm
- sudden shortness of breath
- sudden coughing for no apparent reason
- any unusual, severe or prolonged headache or worsening of migraine
- partial or total loss of vision or double vision
- speech difficulty or inability to speak
- dizziness or fainting
- weakness, strange sensation or numbness in any part of the body

Additional side effects
Common side effects – effects that occur in 1-10 users in 100:
- weight gain
- depressed mood, sleeping problems, nervousness, loss of interest in sex, or changed mood
- headache or migraine
- nausea, abdominal pain, wind, swollen abdomen or vomiting
- acne or hair loss
- back pain
- breast discomfort, ovarian cysts or hot flushes
- uterine/vaginal bleeding including spotting
- weakness or irritability

Uncommon side effects – effects that occur in 1-10 users in 1,000:
- anemia
- weight loss or increase in appetite
- anxiety, depression or mood swings
- imbalance in the autonomic nervous system (controls involuntary functions, e.g., perspiration) or disturbed attention
- dry eyes
- tinnitus
- unspecific circulatory problems or abnormal palpitations
- low blood pressure
- shortness of breath
- diarrhea, constipation, abdominal discomfort, gastrointestinal inflammation, gingivitis
- dry skin, excessive sweating, severe itching over the whole body, hirsutism (male-pattern hair growth), brittle nails, dandruff, inflammation of the skin (dermatitis), abnormal hair growth, hypersensitivity to light or problems with skin pigmentation
- pains in the bones, muscle spasms, pains and/or a sensation of heaviness in the arms and hands or legs and feet
- urinary tract infections
- vaginal thrush, dryness of the genitals, vaginal discharge, pelvic pain, atrophic inflammation of the genitals with discharge (atrophic vulvovaginitis), or a lump or lumps in the breasts
- swelling due to fluid retention

Additional side effects in adolescent girls (from the age of 12 to under 18 years of age) – reduced bone density

If a side effect occurs, if one of the side effect worsens or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor or pharmacist.

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, should be kept in a safe place out of the reach 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 the medicine 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 in the original package to protect from light.
- Do not discard medicines in the waste bin or waste water. Ask the pharmacist what to do with medicines you no longer need. This will help protect the environment.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Lactose monohydrate, potato starch, cellulose microcrystalline, povidone K25, talc, crospovidone, magnesium stearate.
  Each tablet contains 62.8 mg lactose monohydrate.
- What the medicine looks like and the contents of the package:
  Round, flat, bevel-edged white to cream-white tablets, marked with a "B" on one side and are 7 mm in diameter.
  The tablets are provided in trays (blisters) in packs of 14 tablets. Each package contains 2 or 6 packs.
  Not all package sizes may be marketed.
- Registration Holder and address: Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 4527702.
- Manufacturer and address: Bayer Weimar GmbH und Co. KG, Weimar, Germany.
- Revised in April 2021 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 146 40 33320 00

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