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

The medicine is dispensed with a doctor's prescription only

Janess®
Intrauterine Delivery System

The active ingredient is levonorgestrel 13.5 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.

The medicine is not intended for use before the first menstrual bleeding (first menses).

1) WHAT IS THE MEDICINE INTENDED FOR?

What is Janess?

Janess is a T-shaped intrauterine delivery system which slowly releases a small amount of the hormone levonorgestrel after its installation inside the womb.

The system is intended for contraception for a period of up to 3 years.

Janess works by reducing the monthly growth of the lining of the womb and thickening of the cervical mucosal layer. These actions prevent the sperm and egg from coming into contact and so prevent fertilization of an egg by sperm.

Therapeutic group: Janess belongs to a group of medicines that contain the female hormone progestogen.

2) BEFORE USING THE MEDICINE

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredient levonorgestrel or any of the other ingredients contained in the medicine. For a list of the inactive ingredients, see section 6 "Further Information".
- you are pregnant (see "Pregnancy, breastfeeding and fertility" in section 2).
- you have, or have had several times in the past, pelvic inflammatory disease (PID) (infection of the female reproductive organs).
- you suffer from conditions associated with increased risk of contracting pelvic infections.

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- you have an infection of the lower genital tracts (infection of the vagina or cervix).
- you have or have had an infection of the womb after giving birth, after a miscarriage or after an abortion within the past 3 months.
- you have precancerous changes in the cervix.
- you have or are suspected of having cervical cancer or uterine cancer.
- you have tumors whose growth is sensitive to progestogen-type hormones, e.g., breast cancer.
- you are suffering from unexplained uterine bleeding.
- you suffer from structural changes in the uterus or cervix, including fibroids which cause distortion of the uterine cavity.
- you have an active liver disease or a liver tumor.

Special warnings regarding use of the medicine:

- Before using Janess, the doctor will ask you some questions about your medical history.
- In this leaflet, several situations in which Janess should be removed, or where the effectiveness of Janess may be decreased are described. In such situations, either abstain from intercourse, or use a condom or another barrier contraceptive method.
- Janess, like other hormonal contraceptives, does not protect against contraction of AIDS (HIV) or any other sexually transmitted disease.
- Janess is not suitable for use as an emergency contraceptive (postcoital contraceptive).
- **Before using the medicine, tell the doctor if:**
  - you have diabetes. There is generally no need to alter your diabetic medication while using Janess, but your doctor may have to consider it.
  - you have epilepsy. A seizure may occur during installation or removal.
  - you have had an extrauterine pregnancy in the past.
- Inform the doctor if you have any of the following conditions before using Janess, or if any of the conditions occur for the first time while using Janess:
  - migraine, with visual disturbances or other symptoms which may be signs of transient cerebral ischemia (temporary blockage of the blood supply to the brain).
  - exceptionally severe headache.
  - jaundice (yellowing of the skin, whites of the eyes and/or nails).
  - marked increase of blood pressure.
  - severe disease of the arteries such as stroke or heart attack.
- The following signs and symptoms may indicate an extrauterine pregnancy and therefore, you must refer to

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your doctor immediately (see "Pregnancy, breastfeeding and fertility" in section 2):
- o Your menstrual periods have stopped and then you start having persistent bleeding or pain.
- o You have pain in your lower abdomen that is severe or persistent.
- o You have normal signs of pregnancy, but you also have bleeding and dizziness.
- o You performed a pregnancy test and it was positive.

- Refer to your doctor immediately if you experience any of the following conditions (see section 4 "Side Effects"). Remind your doctor that you have a Janess device inserted, especially if he is not the doctor who inserted it:
  - o severe pain (like menstrual cramps) or heavy bleeding after installation of Janess or if you have pain/bleeding which persists for more than a few weeks. These signs may indicate, for example, an infection, perforation or that the system is not in the correct position.
  - o you no longer feel the threads of the system in your vagina. This may be a sign of expulsion of the system or perforation. You can check by gently putting a finger into your vagina and feeling for the threads at the end of your vagina near the opening of your womb (cervix). Do not pull the threads because you may accidentally pull Janess out. Use a barrier contraceptive method (such as condoms) until an examination by your doctor confirms that the system is still in the correct position.
  - o you or your partner can feel the lower end of Janess. Abstain from intercourse until an examination by your doctor confirms that the system is still in the correct position.
  - o your partner feels the system's threads during intercourse.
  - o you think you may be pregnant.
  - o you have persistent abdominal pain, fever, or unusual vaginal discharge, which may be a sign of infection. Infections must be treated immediately.
  - o you feel pain or discomfort during sexual intercourse, which may be, for example, a sign of infection, ovarian cyst or that the system is not in the correct position.
  - o there are sudden changes in your menstrual periods (for example, if you have little or no menstrual bleeding, and then you start having persistent bleeding or pain, or you start bleeding heavily), which may be a sign that the system is not in the correct position or has been expelled.

Use of sanitary pads is recommended. If you use tampons or menstrual cups, change them with care so as not to accidentally pull the threads of the system. If you think you may have pulled the system out of place (please see list above for possible signs), avoid intercourse or use a barrier contraceptive (such as condoms), and contact your doctor.

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Psychiatric disorders
Some women using hormonal contraceptives, including Janess, 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, contact your doctor for further medical advice as soon as possible.

Girls and adolescent girls
Janess is not intended for use in girls and adolescent girls before the start of the first menstrual cycle.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Also inform the doctor or pharmacist if you may start taking any medicines.

Pregnancy, breastfeeding and fertility
Pregnancy
Do not use Janess during pregnancy.

Some women may not have their periods while using Janess. Not having a period is not necessarily a sign of pregnancy. If you do not have your period and have other symptoms indicative of pregnancy, refer to the doctor for an examination and to perform a pregnancy test.

If you have not had a period for six weeks and you are concerned, consider having a pregnancy test. If you get a negative test result, there is no need to carry out another test unless you have other signs of pregnancy.

If you become pregnant with Janess installed in your womb, refer to your doctor immediately to have the system removed. The removal of the system may cause a miscarriage. However, if the system is left in place during pregnancy, not only is the risk of having a miscarriage higher, but also the risk of having preterm labour. If the system cannot be removed, talk with your doctor about the benefits and risks of continuing the pregnancy, and possible effects of the hormone on the developing baby.

Due to local exposure to the active ingredient, a possible effect on female fetuses cannot be ruled out.

If you want to become pregnant, refer to your doctor to have Janess removed.

Extrauterine pregnancy
It is uncommon for women to become pregnant while using Janess. However, if you become pregnant while using Janess, the risk that the pregnancy could develop outside the womb (an extrauterine pregnancy) increases. Women who have already had an extrauterine pregnancy, surgery of the Fallopian tubes or a pelvic infection carry a higher risk of having an extrauterine pregnancy. An extrauterine

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pregnancy is a serious condition which calls for immediate medical attention (see "The following signs and symptoms may indicate an extrauterine pregnancy" in section 2) and may impact future fertility.

Breastfeeding
Janess can be used during breastfeeding. Levonorgestrel (the active ingredient in Janess) has been identified in small quantities in the breast milk of breastfeeding women. However, no negative effects have been seen on infant growth and development or on the amount or the quality of the breast milk.

Fertility
Your usual level of fertility will return after Janess is removed.

Driving and operating machinery
Janess does not affect ability to drive or use machinery.

3) HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.

- Janess is installed by a doctor trained to do so, after a gynecological examination.
- Installation of Janess
  Janess can be installed:
  - within 7 days from the start of your menstrual bleed (your monthly period).
  - immediately after a first trimester abortion, provided that there are no genital infections.
  - at least six weeks after giving birth and only after the womb has returned to its normal size (see "Perforation" in section 4).

  Before installation of Janess, the doctor will perform various tests, which can include:
  - a cervical smear test (Pap smear).
  - examination of the breasts.
  - other tests, e.g., for infections, including sexually transmitted diseases, as necessary. Your doctor will also do a gynecological examination to determine the position and size of the womb.

  After a gynecological examination:
  - An instrument called a speculum is placed into the vagina. The doctor may use a disinfectant solution to clean the cervix. The system is then placed into the womb using a thin and flexible plastic tube (the placement tube). Local anesthesia may be applied to the cervix prior to placement.
  - Some women feel dizzy or faint during or after placement or after the system is removed.
  - You may experience some pain and bleeding during or after installation.

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After placement of Janess, you should receive a patient reminder card from your doctor for follow-up examinations. Bring this card with you to every appointment scheduled for you.

Tests and Follow-up

Medical follow-up and when to seek advice from the doctor: Have the doctor check the system 4-6 weeks after placement, and thereafter regularly, at least once a year. Your doctor may determine how often and what kinds of check-ups are required in your case. If you received a patient reminder card from your doctor, bring it with you to every appointment scheduled for you. In addition, refer to your doctor if one or more of the symptoms described in section 2 "Special warnings regarding use of the medicine" occur.

- Removal of Janess
  The system should be removed no later than the end of the third year of use.

  Your doctor can easily remove the system at any time, and afterwards, you can become pregnant. Some women feel dizzy or faint during or after the removal. You may experience some pain and bleeding during removal of Janess.

  If you do not want to become pregnant, do not remove Janess after the 7th day of the menstrual cycle (monthly period) unless you are using other methods of contraception (e.g., condoms) for at least 7 days before the removal of the system.

  If you have irregular periods (menses) or no periods, use a barrier method of contraception for 7 days before removal of the system.

  A new Janess can be placed immediately after removal, and in such a case no additional protection is needed.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4) SIDE EFFECTS

As with any medicine, use of Janess 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.

Contact your doctor immediately if you notice any of the following symptoms:

- allergic reactions including rash, hives (urticaria), and angioedema (characterized by sudden swelling, of the eyes, mouth or throat, for example).

Please see section 2 for when to contact your doctor promptly.

Very common side effects – effects that occur in more than 1 in 10 users

- headache
- abdominal/pelvic pain
- acne/oily skin

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- changes in bleeding pattern, including increased or decreased menstrual bleeding, spotting, infrequent periods and absence of bleeding (see “infrequent or irregular bleeding” in section 4)
- ovarian cyst (see “ovarian cyst” in section 4)
- inflammation of the external genitals and vagina (vulvovaginitis)

Common side effects – effects that occur in up to 1 in 10 users
- depressed mood/depression
- decreased libido
- migraine
- nausea
- hair loss
- upper genital tract infection
- painful menstruation
- breast pain/discomfort
- system expulsion (complete and partial) - (see “Expulsion of the system” in section 4)
- vaginal discharge
- weight gain

Uncommon side effects – effects that occur in up to 1 in 100 users
- dizziness
- excessive body hair
- perforation of the womb (see “Perforation” in section 4).

Infrequent or irregular bleeding
Janess is likely to affect your menstrual cycle. Janess can change your menstrual periods so that you have spotting (a small amount of bleeding), shorter or longer periods, lighter or heavier bleeding, or no bleeding at all.

You may have bleeding or spotting between menstrual periods, especially during the first 3-6 months. Sometimes the bleeding will be heavier than usual at first.

Overall, you are likely to have a gradual reduction in the amount and number of days of bleeding each month. In some women, periods eventually stop altogether.

The monthly thickening of the lining of the womb may not happen due to the effect of the hormone and therefore, there is nothing to be discharged as a menstrual period. This does not necessarily mean that you have reached menopause or are pregnant. Your hormone levels usually remain normal.

When the system is removed, your period should return to normal within a short time.

Pelvic infection
The Janess system and its inserter are sterile. Despite this, there is an increased risk of pelvic infections (infections in the lining of the womb or of the Fallopian tubes) at the time of installation and during the first 3 weeks afterwards.

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Pelvic infections in women using intrauterine delivery systems are often related to sexually transmitted diseases. The risk of infection is increased if you or your partner have multiple sexual partners or if you have had pelvic inflammatory disease (PID) before.

Pelvic infections must be treated promptly.

Pelvic infections such as PID may have serious consequences and they may impair fertility and increase the risk of a future extrauterine pregnancy. In extremely rare cases, severe infection or sepsis (severe infection, which may be fatal) may occur shortly after installation.

Janess must be removed if you experience recurring PID or if the infection is severe or does not respond to treatment.

Expulsion of the system
The muscular contractions of the womb during menstruation may sometimes push the system out of place or expel it. This is more likely to occur if you are overweight at the time of IUS insertion or have a history of heavy periods. If the IUS is out of place, it may not be as effective as expected and therefore, the risk of pregnancy is increased. If the IUS is expelled, you are not protected against pregnancy anymore. Possible symptoms of expulsion of the system are pain and abnormal bleeding but Janess may also come out without you noticing. As Janess typically decreases menstrual flow over time, increase of menstrual flow may be a sign that Janess has been expelled. See section 2 “Special warnings regarding use of the medicine” for how to check if Janess is in place and what to do if you suspect that Janess is no longer in place.

Perforation
Penetration or perforation of the wall of the womb may occur during placement of Janess, although it may not be detected until sometime later. If Janess becomes lodged outside the cavity of the womb, it is not effective at preventing pregnancy and it must be removed as soon as possible. You may need surgery to have the device removed. The risk of perforation is increased in women who are breast-feeding at the time of insertion and in women who have Janess inserted up to 36 weeks after birth, and may be increased in women whose uterus is fixed and leaning backwards (fixed retroverted uterus). If you suspect you may have experienced a perforation, see your doctor immediately and remind them that you have Janess inserted, especially if they were not the person who inserted it.

Ovarian cyst
Since the contraceptive effect of Janess is mainly due to its local effect in the womb, ovulation (release of the egg) usually continues while using Janess. Sometimes, an ovarian cyst

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may develop. In most cases, there are no symptoms.

Occurrence of ovarian cyst may require medical attention, or more rarely, surgery, but it usually disappears on its own.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this 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 closed 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 the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- There are no special storage conditions. Storage at room temperature is recommended.
- Do not open the blister. Only your doctor should do so.

6) FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Polydimethylsiloxane elastomer, silica colloidal anhydrous, polyethylene, barium sulfate, iron oxide black, silver
- What does the medicine look like and what are the contents of the package?
  Janess is a T-shaped intrauterine delivery system. The vertical arm of the T-body contains a drug reservoir containing the active ingredient levonorgestrel. Two removal threads are tied to the loop at the lower end of the vertical arm. In addition, the vertical arm contains a silver ring located close to the horizontal arms, which is visible under ultrasound examination.

  The intrauterine delivery system is packaged in a blister and is provided in a box with a single system.
- **Registration Holder and address:** Bayer Israel Ltd., 36 Hacharash St., Hod Hasharon 4527702.
- **Manufacturer and address:** Bayer OY, Turku, Finland.
- Revised in February 2022 according to MOH guidelines.
- Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:
  153-52-34106-00,
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