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SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

MIRENA
Intrauterine Delivery System (IUS)
Levonorgestrel Intrauterine delivery system 20µg/ 24 hours.

Read this leaflet carefully before MIRENA is inserted.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MIRENA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT MIRENA CONTAINS

- The active substance is levonorgestrel. Each sterile intrauterine system contains levonorgestrel 52 mg.
- The other ingredients are barium sulphate, iron oxide, polydimethylsiloxane elastomer, polydimethylsiloxane tubing and polyethylene.

2. WHAT MIRENA IS USED FOR

MIRENA is used for

- contraception (prevention of pregnancy),
- idiopathic menorrhagia (excessive menstrual bleeding)
- protection from endometrial hyperplasia (excessive growth of the lining of the womb) during oestrogen replacement therapy.

3. BEFORE YOU USE MIRENA

Your doctor will examine you and ask you about your medical history in order to decide whether you can use MIRENA.

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Do not use MIRENA:

If you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of MIRENA.

Do not use MIRENA under any of the following conditions:

- if you are pregnant or think you might be pregnant
- if you currently or recurrently have an infection of the female reproduction organs
- if you have a lower genital tract infection.
- if you have an infection of the womb after delivery.
- if you have had an infection of the womb after abortion during the past 3 months
- if you have infection of the cervix (neck of womb).
- if you have cell abnormalities in the cervix.
- if you have cancer of suspected cancer of the cervix or womb.
- if you have tumours which depend on progestogen hormone to grow.
- if you have unexplained abnormal vaginal bleeding.
- if you have abnormality of the cervix or womb including fibroids if they distort the cavity of the womb.
- if you have conditions associated with increased susceptibility to infections.
- if you have active liver disease or liver tumour.

Take special care with MIRENA:
If any of the conditions mentioned below exists or appears for the first time while using MIRENA, consult a specialist who may decide to continue using MIRENA or remove the system. The conditions are:

- migraine, asymmetrical visual loss or other symptoms which may be signs of a transient cerebral ischaemic (temporary blockage of the blood supply to the brain).
- exceptionally severe headache
- jaundice (a yellowing of the skin, white of the eyes and/or nails)
- marked increase of blood pressure
- severe disease of arteries such as stroke or heart attack.

MIRENA may be used with caution in women who have congenital heart disease or valvular heart disease at risk of infective inflammation of the heart muscle. Antibiotic preventive medication should be administered to these patients when inserting or removing MIRENA.

If you have diabetes and you are using MIRENA your blood glucose concentration should be monitored.

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Irregular bleedings may mask some symptoms and signs of endometrial polyps or cancer, and in these cases diagnostic measures have to be considered.

MIRENA is not the method of first choice for young women who have never been pregnant, nor for postmenopausal women with shrinking of the womb.

Medical examination/consultation

Examination before insertion may include a cervical smear test(Pap smear), examination of the breasts and other tests, e.g. for infections, including sexually transmitted diseases, as necessary.
A gynaecological examination should be performed to determine the position and size of the womb.

MIRENA is not suitable for use as post-coital contraceptive (used after intercourse).

What you should be aware of with the use of MIRENA:

Infections: The insertion tube helps to prevent MIRENA from contamination with micro-organisms during the insertion, and the MIRENA inserter has been designed to minimize the risk of infections. Despite this, there is an increased risk of pelvic infection immediately and during the first month after insertion. Pelvic infections in IUS (Intra Uterine System) users are often related to sexually transmitted diseases. The risk of infection is increased if the woman or her partner has several sexual partners. Pelvic infections must be treated promptly. Pelvic infection may impair fertility and increase the risk of a future extra-uterine pregnancy (pregnancy outside the womb).

Cases of severe infection or sepsis (very severe infection, which may be fatal) can occur shortly after MIRENA insertion.

MIRENA must be removed if there are recurrent pelvic infections or infections of the lining of the womb, or if an acute infection is severe or does not respond to treatment within a few days.

Consult a doctor without delay if you have persistent lower abdominal pain, fever, pain in conjunction with sexual intercourse or abnormal bleeding. Severe pain or fever developing shortly after insertion may mean that you have a severe infection which must be treated immediately.

Expulsion: The muscular contractions of the womb during menstruation may sometimes push MIRENA out of place or expel it. Possible symptoms are pain and abnormal bleeding. If MIRENA is displaced, the effectiveness may be reduced. If MIRENA is expelled, you are not protected against pregnancy anymore. It is recommended that you check for the threads with your finger, for example while having a shower. If you have signs indicative of an expulsion or you cannot feel the threads, you should avoid intercourse or

use another contraceptive, and consult your doctor. As MIRENA decreases menstrual flow, increase of menstrual flow may be indicative of an expulsion.

Perforations: During insertion of MIRENA, part of MIRENA or the entire system may penetrate the inside wall of the womb or pierces the womb and becomes lodged outside the womb. MIRENA is then ineffective and must be removed as soon as possible. The risk of perforation is increased in breastfeeding women and in women who had a delivery up to 36 weeks before insertion and may be increased in women with uterus fixed and leaning backward (towards the bowel).

Extrauterine pregnancy: Although it is rare to become pregnant while using MIRENA, if you become pregnant while using MIRENA, the risk that you could carry the foetus outside of your womb (have an extrauterine pregnancy) is increased. About 1 in a 1000 women using MIRENA have an extrauterine pregnancy per year. Woman who already had an extrauterine pregnancy, surgery of the tubes from the ovaries to the womb or a pelvic infection carry a higher risk. An extrauterine pregnancy is a serious condition which calls for immediate medical attention. The following symptoms could mean that you may have an extrauterine pregnancy and you should see your doctor immediately:

- Your menstrual periods have ceased and then you start having persistent bleeding or pain
- You have vague or very bad pain in your lower abdomen
- You have normal signs of pregnancy, but you also have bleeding and feel dizzy.

Faintness: Some women feel dizzy after MIRENA is inserted. This is a normal physical response. Your doctor will tell you to rest for a while after you have had MIRENA inserted.

Enlarged ovarian follicle (cells that surround a maturing egg in the ovary): Since the contraceptive effect of MIRENA is mainly due to its local effect, ovulatory cycles with follicular rupture usually occur in women of fertile age. Sometimes degeneration of the follicle is delayed and the development of the follicle may continue. Most of these follicles give no symptoms, although some may be accompanied by pelvic pain or pain during intercourse. These enlarged follicles may require medical attention, but they usually disappear on their own.

Pregnancy and Breastfeeding

If MIRENA comes out, you are no longer protected and must use another form of contraception until you see your doctor.

Some women may not have their periods while using MIRENA. Not having a period is not necessarily a sign of pregnancy. If you do not have your period and have other symptoms of pregnancy (for example

nausea, tiredness, and breast tenderness) you should see your doctor for an examination and have a pregnancy test.

If you become pregnant with MIRENA in place, you should have MIRENA removed as soon as possible. If you leave MIRENA in place during pregnancy, the risk of having a miscarriage, infection or preterm labour will be increased. The hormone in MIRENA is released into the womb. This means that the foetus is exposed to a relatively high concentration of hormone locally, although the amount of the hormone received through the blood and placenta is little. The effect of such an amount of hormone on the foetus should be taken into consideration, but to date, there is no evidence of birth defects caused by MIRENA use in cases where pregnancy has continued to term with MIRENA in place.

MIRENA can be used during breastfeeding. Levonorgestrel has been identified in small quantities in the breast milk of nursing women. There appears to be no negative effects on infant growth or development when using MIRENA six weeks after delivery. Progestogen-only methods do not appear to affect the amount or the quality of breast milk.

Ask your doctor or pharmacist for advice before taking any medicine when you are pregnant or breastfeeding.

Driving and using machinery
There are no known effects that affect driving and using of machinery.

Important information about some of the ingredients of MIRENA:
The T-frame of MIRENA contains barium sulphate, which makes it visible in X-ray examination.

Using other medicines with MIRENA:
Please tell your doctor if you are taking other medicines on a regular basis, including complementary or traditional medicines, and medicines obtained without a prescription. The metabolism of levonorgestrel may be increased by concomitant use of other medicines, such as epilepsy medication (e.g. phenobarbital, phenytoin, carbamazepine) and antibiotics (e.g. rifampicin, rifabutin, nevirapine, efavirenz). Since the mechanism of action of MIRENA is mainly local, this is not believed to have major importance for the contraceptive efficacy of MIRENA.

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4. HOW TO USE MIRENA

When should MIRENA be inserted:

You can have MIRENA inserted within seven days from the onset of the menstrual bleeding. MIRENA can also be inserted immediately after a first trimester abortion provided that there are no genital infections. MIRENA should be inserted only after the womb has returned to its normal size after delivery and not earlier than 6 weeks after delivery (see section "Before you use MIRENA – Perforations"). MIRENA can be replaced by a new system at any time of the cycle. When MIRENA is used to protect the lining of the womb during oestrogen replacement therapy, it can be inserted at any time in an amenorrhoeic woman (woman who has no monthly bleeding), or during the last days of menstruation or withdrawal bleeding.

MIRENA should be inserted by a medical practitioner who is experienced in MIRENA insertion.

How is MIRENA inserted?

- Your doctor will do a normal pelvic (gynaecological) examination and find the particular position of your womb,
- An instrument called a speculum is inserted into the vagina,
- The cervix is cleansed with an antiseptic solution.
- MIRENA is then inserted into the womb via a thin, flexible plastic tube (the inserter). Local anaesthesia may be applied to the cervix prior to insertion, if appropriate.
- The flexible plastic tube will be withdrawn from your body leaving MIRENA in your womb.

Some women may experience pain and dizziness after insertion. If these do not pass within half an hour in the resting position, MIRENA may not be correctly positioned. An examination should be carried out and MIRENA removed if necessary.

When should I see my doctor?

You should have your MIRENA checked 4 to 12 weeks after insertion, and thereafter regularly, at least once a year.

You should contact your doctor if any of the following occurs:

- You no longer feel the threads in your vagina
- You can feel the lower end of the system
- You think you may be pregnant
- You have persistent abdominal pain, fever, or unusual discharge from the vagina
- You or your partner feels pain or discomfort during sexual intercourse
- 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

- You have other medical problems, such as migraine headaches or intense headache that recur, sudden problems with vision, jaundice, or high blood pressure
- You experience any of the conditions mentioned in the section "Before you use MIRENA".

For how long can MIRENA be used?
MIRENA is effective for five years, after which it has to be removed. If you like, you may have a new MIRENA inserted when the old one is removed.

What if I want to become pregnant or have MIRENA removed for another reason?
The MIRENA can be easily removed at any time by your doctor, after which pregnancy is possible. Removal usually is a painless procedure. Fertility returns to normal after removal of MIRENA.

If pregnancy is not desired, MIRENA should not be removed after the seventh day of the menstrual cycle unless contraception is covered with other methods (e.g. condoms) for at least seven days before the removal. When the woman has no menses, she should use barrier methods of contraception for seven days before removal until her menstruation reappears. A new MIRENA can also be inserted immediately after removal, in which case no additional protection is needed.

Can I become pregnant after stopping use of MIRENA?
Yes. After MIRENA is removed, it does not interfere with your normal fertility. You may become pregnant during the first menstrual cycle after MIRENA is removed.

Can MIRENA affect my menstrual periods?
MIRENA does affect your menstrual cycle. It can change your menstrual periods so that you have spotting (a small amount of blood loss), shorter or longer periods, lighter or heavier bleeding, or no bleeding at all.

Many women have frequent spotting or light bleeding in addition to their periods for the first 3 to 6 months after they have MIRENA inserted. Some women may have heavy or prolonged bleeding during this time. Please inform your doctor, especially if this persists.

Overall, you are likely to have a gradual reduction in the number of bleeding days and in the amount of blood lost each month. Some women eventually find that periods stop altogether. As the amount of menstrual bleeding is usually reduced with the use of MIRENA, most women experience an increase in their blood haemoglobin value.

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When the system is removed, periods return to normal.

Is it abnormal to have no periods?
Not when you are using MIRENA. If you find that you do not have periods with MIRENA it is because of the effect of the hormone on the lining of the womb. The monthly thickening of the lining does not happen. Therefore there is nothing to come away as a period. It does not necessarily mean that you have reached menopause or are pregnant. Your own hormone levels remain normal.

In fact not having periods can be a great advantage for a woman's health.

How will I know if I am pregnant?
Pregnancy is unlikely in women using MIRENA, even if they do not have periods.

If you have not had a period for six weeks and are concerned, then consider having a pregnancy test. If this is negative, there is no need to carry out another test unless you have other signs of pregnancy, e.g. sickness, tiredness or breast tenderness.

Can MIRENA cause pain or discomfort?
Some women feel pain (like menstrual cramps) in the first few weeks after insertion. You should return to your doctor or clinic if you have severe pain or if the pain continues for more than three weeks after you have had MIRENA inserted.

Will MIRENA interfere with sexual intercourse?
Neither you nor your partner should feel MIRENA IUS during intercourse. If you do, intercourse should be avoided until your doctor has checked that the MIRENA IUS is still in the correct position.

How long should I wait to have sexual intercourse after the insertion?
To give your body a rest, it is best to wait about 24 hours after having MIRENA inserted before having sexual intercourse. However, as soon as it is inserted, MIRENA will prevent pregnancy.

Can tampons be used?
Use of sanitary pads is recommended. If tampons are used, you should change them with care so as not to pull the threads of MIRENA.

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What happens if MIRENA comes out by itself?

It is rare but possible for MIRENA to come out during your menstrual period without you noticing. An unusual increase in the amount of bleeding during your period could mean that your MIRENA has come out through your vagina. It is also possible for part of MIRENA to come out of your womb (you and your partner may notice this during sexual intercourse). If MIRENA comes out completely or partially, you will not be protected from pregnancy.

How can I tell whether MIRENA is in place?

You can check yourself if the threads are in place after your period. Gently put a finger into your vagina after your period and feel 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 out MIRENA. If you cannot feel the threads, this may indicate that an expulsion or perforation has occurred. In this case you should avoid intercourse or use barrier contraceptives (such as condoms) and contact your doctor.

5. POSSIBLE SIDE EFFECTS

MIRENA can have side effects.

Below we list side effects when MIRENA is used for contraception (prevention of pregnancy) and idiopathic menorrhagia (excessive menstrual bleeding).

Possible side effects when MIRENA is used for protection of endometrial hyperplasia (excessive growth of the lining of the womb) during oestrogen replacement therapy were observed at a similar frequency unless specified (see footnote):

Frequent side effects:

- Headache
- Abdominal/pelvic pain
- Bleeding changes including increased and decreased menstrual bleeding spotting oligomenorrhoea (infrequent periods) and amenorrhoea (absence of bleeding)
- Vulvovaginitis (inflammation of the external genital organs or vagina)
- Genital discharge
- Depressed mood/ depression
- Migraine
- Nausea (feeling sick)
- Acne
- Hirsutism (excessive body hair)

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- Back pain
- Upper genital tract infection
- Ovarian cysts
- Dysmenorrhoea (painful menstruation)
- Breast pain
- Intrauterine contraceptive device expelled (complete or partial)

Less frequent:

- Alopecia (loss of hair)
- Uterine perforation*(piercing of the womb)

* The perforation risk is higher (between 1 and 10 in every 1000 patients) in women who are breastfeeding at the time of MIRENA insertion and when MIRENA is inserted up to 36 weeks after delivery.

Unknown frequency:

- Hypersensitivity (allergic reaction) including rash, urticaria (hives) and angioedema (characterised by sudden swelling of e.g. the eyes, mouth, throat.)
- Blood pressure increase

The removal threads may be felt by the partner during intercourse.

If you become pregnant while using MIRENA, there is a possibility that pregnancy is outside the womb.

Cases of sepsis (very severe systemic infection, which may be fatal) have been reported following intrauterine device insertions.

The risk of breast cancer is unknown when MIRENA is used in the indication protection from endometrial hyperplasia (excessive growth of the lining of the womb) during oestrogen replacement therapy. Cases of breast cancer have been reported (frequency unknown).

The following side effects have been reported in connection with MIRENA insertion or removal procedure:
Procedural pain, procedural bleeding, insertion-related vasovagal reactions with dizziness or syncope (fainting). The procedure may result in seizure (fit) in an epileptic patient.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist or other health care professional for advice.

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6. STORING AND DISPOSING OF MIRENA

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

Store at or below 30 °C. Protect from moisture and direct sunlight.
Do not use MIRENA after the expiry date which is stated on the package.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

7. PRESENTATION OF MIRENA

The system with accessories is packed into a heat sealed sterilised pouch.

8. IDENTIFICATION OF MIRENA

MIRENA is a T shaped intrauterine delivery system (IUS) which after insertion releases the hormone levonorgestrel into the womb. The purpose of the T-body is to adjust the system to the shape of the womb. The vertical arm of the T-body carries a cylinder containing levonorgestrel. Two removal threads are tied to the loop at the lower end of the vertical arm.

9. REGISTRATION NUMBER

A 32/34/0332

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Bayer (Pty) Ltd
Registration number: 1968/011192/07
27 Wrench Road
ISANDO
1609

11. DATE OF PUBLICATION

Date of registration certificate of the medicine:
26 February 1999

Date of the most recently revised package insert as approved by council:
05 June 2019