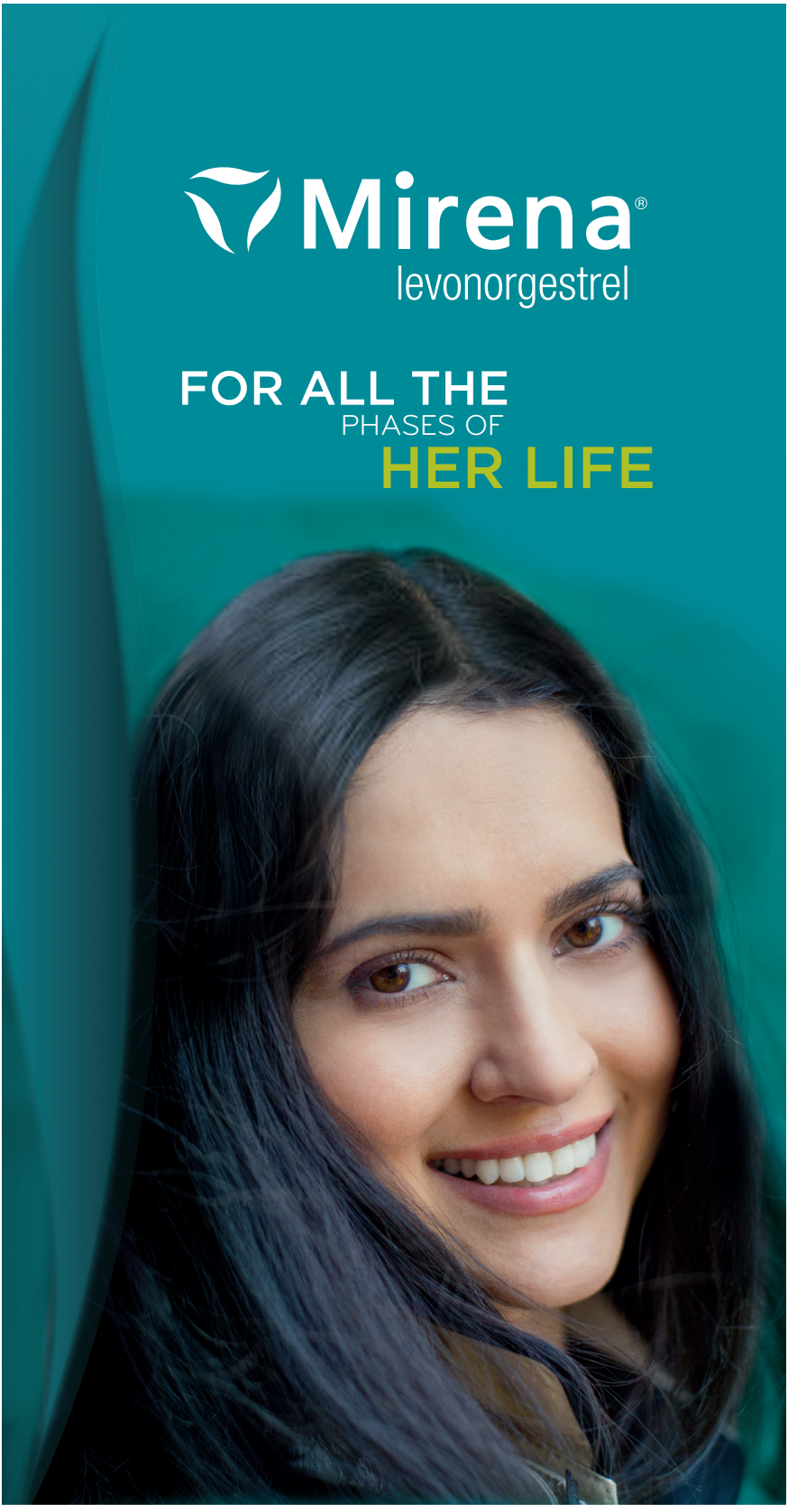

Mirena®
levonorgestrel
FOR ALL THE
PHASES OF
HER LIFE

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Mirena®

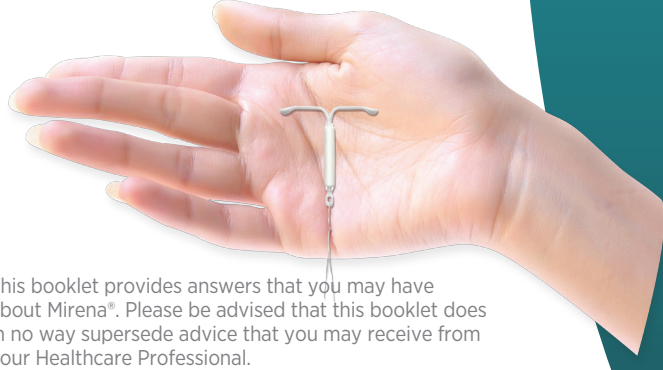
Confidence that lasts

YOUR HEALTHCARE PROFESSIONAL HAS PRESCRIBED MIRENA® FOR YOU

Mirena® is well researched and studied and available from a Gynaecologist or a General Practitioner trained in Mirena® insertion technique.

LEARN MORE ABOUT MIRENA®:

- As a Contraceptive
- As treatment of Idiopathic Heavy Menstrual Bleeding (HMB)
- As protection of the endometrium during Hormone Replacement Therapy (HRT)



This booklet provides answers that you may have about Mirena®. Please be advised that this booklet does in no way supersede advice that you may receive from your Healthcare Professional.
** Photo's used are from actors.*

Mirena®

For all the phases of her life

ABOUT MIRENA®



ABOUT MIRENA®



1 WHAT MIRENA® CONTAINS[1]

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

2 WHAT IS MIRENA® USED FOR?[1]

Mirena® is used for contraception (prevention of pregnancy), idiopathic menorrhagia (excessive menstrual bleeding) and for protection from endometrial hyperplasia (excessive growth of the lining of the womb) during estrogen replacement therapy.

3 HOW TO USE MIRENA®

How effective is Mirena®:

In contraception, Mirena® is 99.8 % effective, similar to female sterilization.[2] Mirena® has a failure rate of approximately 0.1 % per year. In the treatment of excessive menstrual bleeding Mirena® causes a strong reduction of menstrual bleeding already after three months. Some users have no periods at all.[1]

When should Mirena® be inserted:

You can have Mirena® inserted within 7 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.[1]

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 estrogen replacement therapy, it can be inserted at any time in an amenorrheic woman (a woman who has no monthly bleeding), or during the last days of menstruation or withdrawal bleeding.[1]

Mirena® should be inserted by a Healthcare Professional who is trained/experienced in Mirena® insertion.[1]

How is Mirena® inserted?[1]

- Your Healthcare Professional will give you 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 anesthesia 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 Healthcare Professional?[1]

You should have your Mirena® Intrauterine System (IUS) checked 4-12 weeks after insertion, and thereafter regularly, at least once a year. In addition, you should contact your Healthcare Professional 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 headaches that recur, sudden problems with vision, jaundice, or high blood pressure.

For how long can Mirena® be used?[1]

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?[1]

The Intrauterine System (IUS) can be easily removed at any time by your Healthcare Professional, after which pregnancy is possible.

Once Mirena® is removed, fertility returns to your fertility level at your current age.

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®?[1]

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?[1]

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 3-6 months after they have Mirena® inserted. Some women may have heavy or prolonged bleeding during this time. Please inform your Healthcare Professional, 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 hemoglobin value. When the system is removed, periods return to normal.

Is it abnormal to have no periods?[1,3]

Menstrual bleeding can become less or stop completely in 20 % of women. If no menstrual bleeding occurs for 6 weeks after a previous bleed, a pregnancy test is recommended. If you find that you are not having 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 occur, 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.

How will I know if I'm pregnant?[1]

Pregnancy is unlikely in women using Mirena®, even if they do not have periods.

If you have not had a period for 6 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?[1]

Some women feel pain (like menstrual cramps) in the first few weeks after insertion. You should return to your Healthcare Professional 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?[1]

Neither you nor your partner should feel Mirena® Intrauterine System (IUS) during intercourse. If you do, intercourse should be avoided until your Healthcare Professional has checked that the Mirena® Intrauterine System (IUS) is still in the correct position.

How long should I wait to have sexual intercourse after the insertion?[1]

It is best to wait about 24 hours after having Mirena® inserted before having sexual intercourse. However, as soon as it is inserted, Mirena® prevents pregnancy if inserted within the first 7 days of menses.

Can tampons be used?[1]

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®.

What happens if Mirena® comes out by itself?[1]

It is possible that Mirena® may dislodge or fall out. Should the system come out either completely or partially, there may be some signs to alert you i.e. an unusual increase in bleeding, the return of your normal periods and/or you or your partner can feel the lower end of the system itself.

If Mirena® comes out completely or partially, you will not be protected against pregnancy. Contact your Healthcare Professional as soon as possible and use another reliable contraceptive method until you see your Healthcare Professional.

How can I tell whether Mirena® is in place?[1]

At the end of the Mirena® are tiny, thin threads – so small that you will not feel them unless you specifically insert a finger into your vagina to feel for them. They will be at the end of the vagina near the opening of your womb. Do not pull the threads because you may accidentally pull the Mirena® out.



NOTES:

Mirena®

For all the phases of her life

BENEFITS OF THE MIRENA®



BENEFITS OF THE MIRENA®

AGED* 19



LUCIANA

Mirena® allows me to be free and not have to worry about remembering to take my contraceptive tablets every day. With reliable contraception for the next 5 years, I can enjoy my life and activities to the fullest.

OLIVIA

AGED 30

Mirena® provides me with confidence and comfort. The fact that the Mirena® is easily fitted and easily removed means that when I choose to start a family, my fertility will return to normal straight away. Mirena®'s flexibility means I can use it again post-birth and when I am breastfeeding.



AGED 42



HELENA

I used to have heavy menstrual periods which left me drained and exhausted. I thought I may have to have a hysterectomy! I'm grateful to my Mirena® as I now hardly have periods at all, and no surgery is needed. Mirena® results in less bleeding and I don't have to worry about contraception.

DEBORAH

AGED 55

Mirena® is perfect for my lifestyle. I want a simple, easy, solution to overcome my menopausal symptoms, without the added risk of endometrial hyperplasia. Although I need hormone therapy to ease my symptoms, Mirena® works where it is needed to provide endometrial protection.



*While Mirena® can be prescribed for nulligravid women - it may not be the first choice of contraceptive for women who have not been pregnant before. *All patients used in this booklet are fictitious.*

Mirena®

For all the phases of her life

CONTRACEPTION



CONTRACEPTION



1 HOW DOES MIRENA® PREVENT PREGNANCY?[4]

Mirena® contains a hormone called levonorgestrel, which is a progestogen. This hormone prevents pregnancy by:

- Reducing the monthly growth of the lining of the uterus.[4]
- Thickening of the cervical mucus, so that it is difficult for the sperm to get through to the egg.[4]
- Inhibition of binding of the sperm to the egg.[4]

2 HOW EFFECTIVE IS MIRENA®?

In contraception, Mirena® is 99.8 % effective, similar to female sterilization.[2] Once Mirena® is removed, fertility rapidly returns to your fertility level at your current age.[1]

In the treatment of excessive menstrual bleeding, a strong reduction of menstrual bleeding will occur within the first 3 months of fitting Mirena®. Bleeding patterns vary based on the patient. Some users have no periods at all.[1]

3 DOES MIRENA® REMAIN EFFECTIVE THROUGHOUT THE 5-YEAR PERIOD?

Yes. The efficacy of Mirena® in contraception is similar throughout the 5-year lifespan of the system.[1,3,5]

4 WHY IS MIRENA® A PARTICULARLY GOOD CONTRACEPTIVE CHOICE?

Because of Mirena®'s long wearing time, there is no need for daily attention.[1] The long-term nature and reversibility of Mirena®'s contraceptive action meets the needs of most women – even young women who may want to be protected from unplanned pregnancies during the years they complete their professional education until they are ready for motherhood.[6]

5 HOW SOON AFTER I REMOVE MIRENA® WILL I BE ABLE TO FALL PREGNANT?

Once Mirena® is removed, fertility rapidly returns to your fertility level at your current age.[1]

In fact, unless a pregnancy is desired, Mirena® should not be removed after the seventh day of the menstrual cycle in a sexually active woman.[1] If Mirena® is removed in mid-cycle and you have had intercourse within the previous week, you may become pregnant unless a new system is inserted immediately.[1]



NOTES:

Mirena®

For all the phases of her life

HEAVY MENSTRUAL BLEEDING (HMB)



HEAVY MENSTRUAL BLEEDING (HMB)

1 AND HOW DOES MIRENA® COMPARE TO HYSTERECTOMY?

Mirena® is effective in the treatment of idiopathic Heavy Menstrual Bleeding (HMB) and is a good alternative to hysterectomy.[7] Studies specifically comparing Mirena® to hysterectomy showed that surgery and the associated risks were avoided in 58 % of the women who participated in the study.[7]

Medical treatment e.g. with Mirena® is recommended as first-line treatment for idiopathic Heavy Menstrual Bleeding (HMB). Hysterectomy is not a first choice treatment in this context.[8]

Although Mirena® is a proven alternative to hysterectomy, many surgical procedures are still performed without first evaluating Mirena® or other medical treatments.[7]

Mirena® is indicated for the treatment of idiopathic Heavy Menstrual Bleeding (HMB)[1] and has been found to reduce menstrual blood loss with comparatively few side effects.[9]

As a contraceptive, Mirena is 99.8 % effective, similar to female sterilization.[2]

Recent treatment guidelines from the National Institute of Health and Clinical Excellence (NICE) recommend that Mirena® be considered as first-line treatment – particularly where long-term use (at least 12 months) is anticipated.[10]

2 WHY WOULD IT MAKE SENSE TO PRESCRIBE MIRENA® FOR WOMEN WHO ARE TAKING ESTROGEN AS THEIR HORMONE REPLACEMENT THERAPY (HRT)?

Estrogen can alleviate the symptoms associated with menopause. But, when estrogen is administered without a progesterone as " counter-balance", the lining of the womb may be stimulated to grow "unchecked".[9] The rationale for adding in a progesterone (as you would do with the use of Mirena®) is to prevent estrogen induced endometrial growth that can lead to cancer.[9]

As Mirena® contains only progesterone – and this progesterone is delivered directly into the womb.[1]

The use of Mirena® vs. Oral Hormone Replacement Therapy (HRT) allows the adverse effects caused by the systemic administration of progesterone (such as when Hormone Replacement Therapy (HRT) is taken by mouth) to be minimised[3] – and also allows the free choice of estrogen with regard to type, dose and administration i.e. whether by mouth or by skin patch.[3]

3 CAN I SIMPLY CONTINUE WITH MY MIRENA® IF I ALREADY HAVE IT IN?

Yes! That is the beauty of Mirena®.

The system has to be replaced every 5 years.[1] So if you wish to continue with Mirena® as part of your Hormone Replacement Therapy (HRT) you can insert a new one when the old one is removed.[1]

4 WHAT IF I HAVE NEVER USED MIRENA® BEFORE?

You can start using it as part of your Hormone Replacement Therapy (HRT) at the time estrogen is first prescribed for you.[1]

5 WHEN CAN MIRENA® BE INSERTED IF I CHOOSE TO USE IT AS PART OF MY HORMONE REPLACEMENT THERAPY (HRT)?

If you are already not having periods then Mirena® can be inserted at any time.[1] If you are still menstruating then Mirena® can be inserted during the last days of menstruation.[1]

6 CAN MIRENA® STOP ME FROM HAVING MY PERIODS?

Yes! One of the advantages of Mirena® is that when used in combination with estrogen replacement therapy a non-bleeding pattern gradually develops in most women during the first year.[1]

Some bleeding and spotting may occur in the first few months of use before bleeding patterns settle down. It is comforting to know that the average number of spotting days decrease gradually and after the first 3 months there are usually only a few days of bleeding.[1]

Mirena®

For all the phases of her life

POST-PARTUM



POST-PARTUM

1 CAN MIRENA® BE USED DURING BREASTFEEDING?

Mirena® may be used in breastfeeding women if indicated by your Healthcare Professional. Levonorgestrel, the active ingredient of Mirena®, has been identified in small quantities in the breast milk of nursing women. However, there appears to be no negative effects on infant growth or development when using any progestogen-only method starting six weeks after delivery.[1] A study conducted to assess the possible effects of Mirena® on breastfeeding performance, infant growth and infant development during the first year after birth compared to a copper Intrauterine Device (IUD) showed that 89 % of women using Mirena® were still breastfeeding at 1 year, and that there were no significant differences in breastfeeding performance, or any of the infant growth or development parameters between Mirena® and a copper containing intrauterine device.[11]

2 HOW SOON AFTER DELIVERY CAN MIRENA® BE INSERTED?

Mirena® should be inserted only after the womb has returned to its normal size after delivery, if it has still not returned to its normal size after 6 weeks, consider waiting 12 weeks post-partum.[1]

3 WHAT IF I WANT TO BECOME PREGNANT AGAIN?

Mirena® can be removed at any time by your Healthcare Professional, after which pregnancy is possible based on your fertility level at that time of your life.

Removal usually is a painless procedure. 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.[1]

Mirena®

For all the phases of her life

POST-ABORTION





POST-ABORTION

1 WHY DO I NEED CONTRACEPTION AS SOON AS POSSIBLE AFTER AN ABORTION?

The World Health Organization reported 43.8 million induced abortions globally in 2008.[12] A large proportion of abortions are repeat abortions.[13]

Ovulation may return as early as 8 - 10 days after an induced abortion with no difference between medical and surgical abortion and 83 % of women have ovulation during the first cycle after abortion. More than 50 % of women have been found to reinitiate sexual activity within two weeks after the induced abortion.[13]

Women who have their intrauterine contraceptive inserted during the first trimester post-abortion have a highly effective contraceptive method already at the first post-abortion ovulation.[13] Furthermore, it is possible that early insertion of an intrauterine contraceptive after medical abortion could be technically less complicated and less painful, due to the dilated cervix found immediately after a medical termination of pregnancy.[13]

2 WHY IS MIRENA® SUITABLE AS POST-ABORTION CONTRACEPTIVE?

Mirena® is 99.8 % effective as a contraceptive,[2] and is generally recommended as a category 1 contraceptive in the World Health Organization medical eligibility criteria for contraception.[14] Mirena® can be inserted immediately after a first trimester abortion provided that there are no genital infections, and it remains effective for 5 years, after which it needs to be replaced.[1] The contraceptive effect of Mirena® is fully reversible, and fertility rapidly returns to your fertility level at your current age once Mirena® is removed.[1]

Mirena®

For all the phases of her life

MENOPAUSE AND OSTEOPOROSIS



MENOPAUSE AND OSTEOPOROSIS



1 WILL MIRENA® HAVE AN EFFECT ON MY MENSTRUATION AND CAUSE OSTEOPOROSIS?[3]

No, because Mirena®'s effect is mainly localized in the uterus, most women will ovulate regularly even though they are not menstruating. The studies show the same estrogen concentrations for women menstruating and those who are not.

2 HOW WILL I KNOW IF I'VE REACHED MENOPAUSE?[15]

Menopause is the term for the last period you will ever have.

Apart from changes in bleeding pattern, the majority of women have noticeable signs when they reach this period of their lives, e.g. hot flushes, mood changes, unusual sweating and other symptoms. If you feel that this applies to you, your Healthcare Professional can do tests to check.

3 I HAVE REACHED PERIMENOPAUSE. MUST I HAVE MIRENA® REMOVED?[15]

No, unless you are going to use another form of contraception. You could still fall pregnant in this time.

If you decide to use estrogen replacement therapy to alleviate the symptoms you are experiencing, Mirena® is indicated for the protection of your womb from the effect of the estrogen component of the hormone replacement.[1] Your Healthcare Professional will advise you on which form of estrogen to take.

4 I DO NOT NEED CONTRACEPTION ANYMORE BUT HAVE HEAVY PERIODS. CAN I USE MIRENA®?[1]

Yes. Your Healthcare Professional will first exclude other causes of Heavy Menstrual Bleeding (HMB) before Mirena® is considered.

Mirena® has been prescribed to you for one of the following uses:[1]

1) Contraception.

2) Treatment of idiopathic Heavy Menstrual Bleeding (HMB) (Heavy Menstrual Bleeding of unknown cause).

3) Protection of the uterus against the effect of estrogen during Hormone Replacement Therapy (HRT).

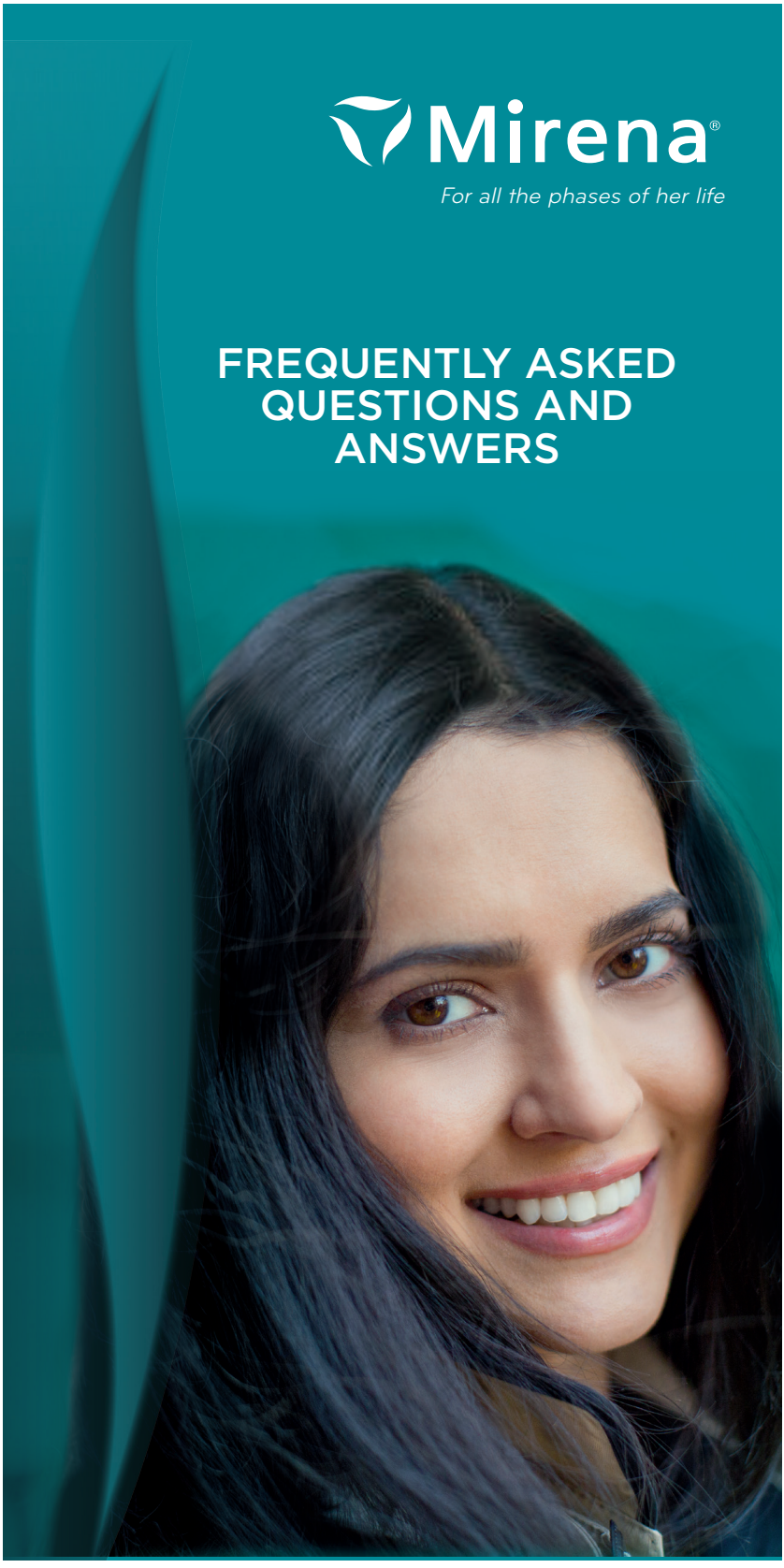


NOTES:

Mirena®

For all the phases of her life

FREQUENTLY ASKED QUESTIONS AND ANSWERS



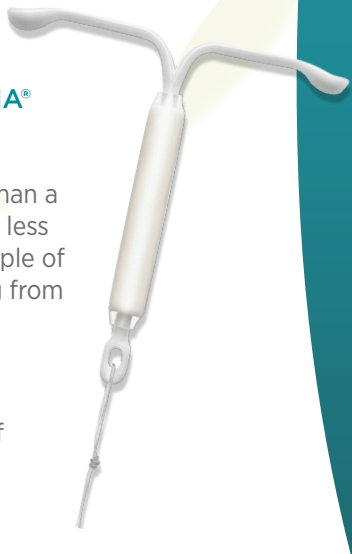
FREQUENTLY ASKED QUESTIONS AND ANSWERS

1 WHAT DOES IT MEAN THAT MIRENA® IS AN INTRAUTERINE SYSTEM (IUS) AND NOT AN INTRAUTERINE DEVICE (IUD)?

An Intrauterine Device (IUD) is a contraceptive device, e.g. like a 'coil', that exerts its contraceptive effect mechanically and not via a hormone.[16] Often a major problem with this is that it tends to make your periods heavier, longer and sometimes more painful.[16]

Mirena® is an IUS (Intrauterine System). In addition to having a mechanical effect it secretes levonorgestrel which reduces the monthly growth of the lining of the uterus, thickens the cervical mucus so that it is difficult for the sperm to get through to the egg, and inhibits binding of the sperm to the egg.[4]

2 WHAT DOES MIRENA® LOOK LIKE?



It's not much longer than a match, and is more or less T-shaped. It has a couple of short threads hanging from the foot of the 'T'.[3]

Most importantly, the stem of the 'T' contains a reservoir of female hormone, of the type known as a 'progestogen'.[3]

This hormone is steadily released into your womb,[3,5] day after day, for up to five years, making it 99.8 % effective as a contraceptive, similar to female sterilization.[2]

3 SO WHAT ARE THE ADVANTAGES OF THE INTRAUTERINE SYSTEM (IUS)?

- It doesn't interfere with sex.[1]
- It's effective.[2]
- You can keep it in for 5 years.[1]
- You can decide to remove it before 5 years.[1]
- Once removed you can fall pregnant – it does not compromise your fertility.[1]
- Once removed, fertility rapidly returns to your fertility level at your current age. You may fall pregnant during the first menstrual cycle after removal.[1]



Effective![2]

More effective than most other contraceptive methods.[2]



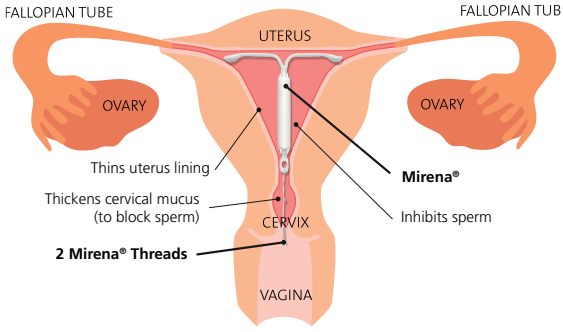
Flexible!

Use it for up to 5 years... remove it before that, if you want to fall pregnant.[1]

Anyway you look at it – you're in control!

4 HOW DOES MIRENA® WORK?

The vertical part of the "T" contains a progestogen, called levonorgestrel, which is similar to one of the hormones that is made in your body.[4] The system releases levonorgestrel into your uterus at a constant rate. The amount of hormone released is 20 micrograms/24 hours – which is a very low dose – but because this release occurs constantly,[4] the Mirena® is one of the most effective contraceptives available.[5]



5 HOW DOES MIRENA® PREVENT A PREGNANCY?[4]

Mirena® contains a hormone called levonorgestrel, which is a progestogen. This hormone prevents pregnancy by:

- Reducing the monthly growth of the lining of the uterus.[4]
- Thickening of the cervical mucus, so that it is difficult for the sperm to get through to the egg.[4]
- Inhibition of binding of the sperm to the egg.[4]

6 HOW EFFECTIVE IS MIRENA®?

In contraception, Mirena® is 99.8 % effective, similar to female sterilization.[2] Once Mirena® is removed, fertility returns to your fertility level at your current age.[1]

In the treatment of excessive menstrual bleeding, a strong reduction of menstrual bleeding will occur within the first three months of fitting Mirena®. Bleeding patterns vary between individuals. Some users will have no periods at all.[1]

7 DO I NEED TO USE ADDITIONAL CONTRACEPTION AFTER INSERTING MIRENA®?[1,4]

If Mirena® is fitted during the first 7 days of your menstruation, or if you are using another reliable contraceptive method at the time of insertion, there is no need for extra precaution.

8 FOR WHAT CAN MIRENA® BE USED?

Mirena® can be used for contraception and to treat idiopathic Heavy Menstrual Bleeding (HMB) (of unknown origin).[1,3] It prevents excessive growth of the lining of the womb during estrogen replacement therapy.[1]

9 CAN I BREASTFEED WHILE USING MIRENA®?

Non-hormonal contraceptive methods/ devices are methods of choice during breastfeeding.[4] Levonorgestrel has been identified in small quantities in the breast milk of nursing women, but the quality and quantity of the milk is not affected.[4]

10 FOR HOW LONG CAN MIRENA® BE USED?

Mirena® provides protection against pregnancy for up to 5 years, after which it has to be removed. If you like, you may have a new Mirena® inserted when the old one is removed.[1]

11 HOW IS MIRENA® FITTED?[1]

Only a Healthcare Professional trained on Mirena® insertion techniques can fit Mirena®. After a gynaecological examination, an instrument called a speculum is inserted into the vagina, and the cervix (opening of the womb) is cleaned with an antiseptic solution. Your Healthcare Professional will use a thin

instrument called a “sound” to measure the depth of your womb for correct positioning of Mirena®. Mirena® is fitted into the womb via a thin, flexible plastic tube. The threads pass from the system through the cervix and into the vagina. The threads are then cut to about 2-3 cm in length, outside the cervix.

12 WHEN SHOULD MIRENA® BE FITTED?[1]

You can have Mirena® inserted within 7 days from the onset of the menstrual bleeding. Mirena® can also be inserted immediately after a first trimester miscarriage or termination of pregnancy, provided there are no genital infections. Mirena® should not be inserted earlier than 6 weeks after delivery. If the womb has still not returned to its normal size after 6 weeks, consider waiting 12 weeks post-partum. Mirena® can be replaced by a new system at any time of the cycle.

13 IS IT PAINFUL TO FIT?[1]

You can feel the insertion but it should not cause much pain. Some women may experience pain and dizziness after insertion, and pain intensity may differ among individuals. This is a normal physiological response and should pass within half an hour in the resting position.

14 DO I NEED TO HAVE MIRENA® CHECKED REGULARLY?[1,4]

You should have your Mirena® checked twice during the first year, firstly 4-12 weeks after insertion, and again after 12 months. Thereafter, you should have your Mirena® checked once a year unless your Healthcare Professional advises otherwise.

15 CAN I FALL PREGNANT WITH MIRENA® IN PLACE?

No method is 100 % effective. Clinical studies have demonstrated that Mirena® is 99.8 % effective in preventing pregnancy.[2]

It is therefore rare for women to fall pregnant with Mirena® in place.[1]

But if Mirena® comes out, you are no longer protected and must use another form of contraception until you see your Healthcare Professional. 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, breast tenderness) you should see your Healthcare Professional for an examination and have a pregnancy test.[1]

16 WHAT IF I WANT TO BECOME PREGNANT OR WANT TO REMOVE MIRENA® FOR OTHER REASONS?

The Mirena® can be removed at any time by your Healthcare Professional, after which pregnancy is possible.

Removal usually is a painless procedure. Fertility rapidly returns to your fertility level at your current age 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. If you have no menses, you should use barrier methods of contraception for 7 days before removal until your menstruation reappears. A new Mirena® can also be inserted immediately after removal, in which case no additional protection is needed.

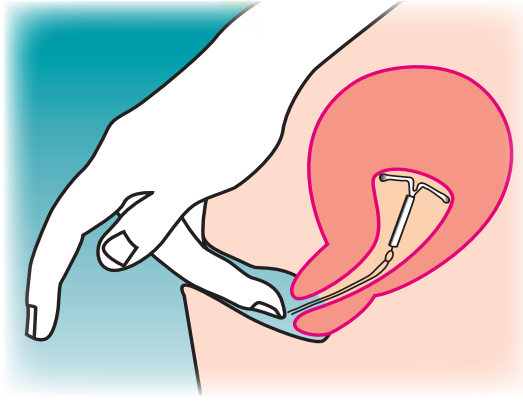
17 CAN MIRENA® BECOME DISLODGED OR FALL OUT?[1,4]

It is possible that Mirena® may dislodge or fall out. Should the system come out either completely or partially, there will be some signs to alert you i.e. an unusual increase in bleeding, the return of your normal periods and/or you or your partner can feel the lower end of the system itself.

If Mirena® comes out completely or partially, you will not be protected against pregnancy. Contact your Healthcare Professional as soon as possible and use another reliable contraceptive method until you see your Healthcare Professional.

18 DO I HAVE TO CHECK WHETHER MY MIRENA® IS IN PLACE?[1]

It is recommended that you check – it is a very simple procedure. At the end of the Mirena® are tiny, thin threads – so small that you will not feel them unless you specifically insert a finger into your vagina to feel for them. They will be at the end of the vagina near the opening of your womb. Do not pull the threads because you may accidentally pull the Mirena® out.



19 WILL MIRENA® INTERFERE WITH SEXUAL INTERCOURSE?[1]

Neither you nor your partner should feel Mirena® during intercourse. If you do, intercourse should be avoided until your Healthcare Professional has checked that Mirena® is still in the correct position.

20 HOW LONG SHOULD I WAIT TO HAVE SEXUAL INTERCOURSE AFTER THE INSERTION?[1]

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 if inserted within the first 7 days of menses.

21 IS THERE A SETTLING-IN PERIOD WITH REGARDS TO MY PERIODS?[1]

Mirena® does affect your menstrual cycle. Many women have frequent spotting or light bleeding in addition to their periods for the first 3-6 months after they have Mirena® inserted. This is a normal part of the settling–in phase and will regulate with time.

22 ISN'T IT ABNORMAL NOT TO HAVE A PERIOD?[1,3]

Menstrual bleeding can become less or stop completely in 20 % of women. If no menstrual bleeding occurs for 6 weeks after a previous bleed, a pregnancy test is recommended. If you find that you are not having 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 occur, therefore there is nothing to come away as a period. It does not necessarily mean that you have reached menopause or are pregnant.

23 IS THERE ANY MEDICATION MY HEALTHCARE PROFESSIONAL CAN PRESCRIBE TO SHORTEN THE SPOTTING PERIOD?

There is no proof that medication will have an effect on the bleeding pattern.

24 CAN I USE TAMPONS?[1]

Use of sanitary pads is recommended. If you use tampons, remove them with care, to ensure that you do not pull the threads of Mirena®.

25 IS IT GUARANTEED THAT MY PERIODS WILL DISAPPEAR COMPLETELY?[3]

No. This happens for about 20 % of users after a year of Mirena® use. Others may still have a short, light bleed every month or merely a scanty discharge. If you suddenly have a heavy bleed after a long period not having any bleeding, it is best to contact your Healthcare Professional.

26 I HAVE A SKIN PROBLEM AND AM USING A HORMONAL CONTRACEPTIVE TO CONTROL IT. IS MIRENA® A GOOD CHOICE FOR ME?

The hormone in Mirena® does not contain any properties to treat acne. There are contraceptives that are specifically indicated for acne and most oral contraceptives will have some effect on your skin due to the estrogen (Mirena® does not contain any estrogen).[4] Unless there is a specific medical reason, Mirena® is not ideal if you need hormonal acne treatment as well as a contraceptive.

Some women will develop acne in their adulthood with no prior history of acne. This is called “late onset acne”.[17]

27 WILL MIRENA® CAUSE ME TO GAIN WEIGHT?[6]

It should not.

5 year follow-up studies with Mirena® compared to copper Intrauterine Devices (IUDs) (loop) showed the same gradual increase in weight as women become older.

28 DOES MIRENA® CAUSE ACNE?

During the first few months after insertion of Mirena®, you may experience transient hormonal side effects including water retention, headache, breast tenderness and acne or other skin problems. However, the incidence decreases over time. Only 3-4 % of women reported acne as a side effect 3 months after the Mirena® was inserted, and this decreased to just over 1 % at 5 years.[3]

29 WILL MIRENA® CAUSE AN ECTOPIC PREGNANCY (A PREGNANCY IN THE FALLOPIAN TUBE)?[6]

The rate of ectopic pregnancies in users of Mirena® is significantly low at 5 per 10,000 women-years. Furthermore, the risk of an ectopic pregnancy with Mirena® is lower than in someone who is not using any contraception at all.[6]

However, should a woman fall pregnant with Mirena® in place, her risk of ectopic pregnancy is about 1 in 20, and she should seek medical advice to exclude an ectopic pregnancy.[6]

Women with a previous history of ectopic pregnancy, tubal surgery or pelvic infection carry a higher risk of ectopic pregnancy.[1] The highest number of ectopic pregnancies occur in sexually active women not using any contraception.[6]

30 WILL MIRENA® CAUSE INFECTIONS?[1,6]

The insertion tube helps to prevent Mirena® from contamination with microorganisms during the insertion. The risk of developing infection is very low in women at low risk of Sexually Transmitted Infections (STIs). Any infection, including Sexually Transmitted Infections (STIs), should be excluded before insertion of Mirena®.

31 DOES MIRENA® CAUSE CYSTS ON MY OVARIES?[1,4]

Since the contraceptive effect of Mirena® is mainly due to its local effect inside the womb, women of fertile age will keep ovulating even though they are using Mirena® as a contraceptive. Sometimes the release of the egg is delayed and the follicle keeps on growing. These enlarged follicles cannot be distinguished from ovarian cysts on sonar. Enlarged follicles have been diagnosed in about 12 % of women using Mirena®. These are mostly symptom free but some may be accompanied by pelvic pain, or painful intercourse. In most cases, these follicles disappear spontaneously after two to three months' observation.

32 WILL ANY OF THE HORMONES IN MIRENA® BE ABSORBED INTO MY BODY?[3]

Although the effect of the hormone in Mirena® is mainly local (inside the womb), a small amount of the hormone will be absorbed into your blood circulation and enter your body. Most women will still ovulate because the amount absorbed into the bloodstream is not enough to suppress ovulation.

33 WHAT SIDE EFFECTS CAN I EXPECT?[3,4]

As with any product some people can experience side effects. The following adverse events have been reported (in order of frequency of occurrence): irregular bleeding, headache, lower abdominal pain, back pain, skin disorders, vaginal discharge, breast tenderness, mood changes, nausea and fluid retention.

Bleeding irregularities are the most frequently reported adverse events. Side effects are more common during the first months after the insertion, and subside during prolonged use.

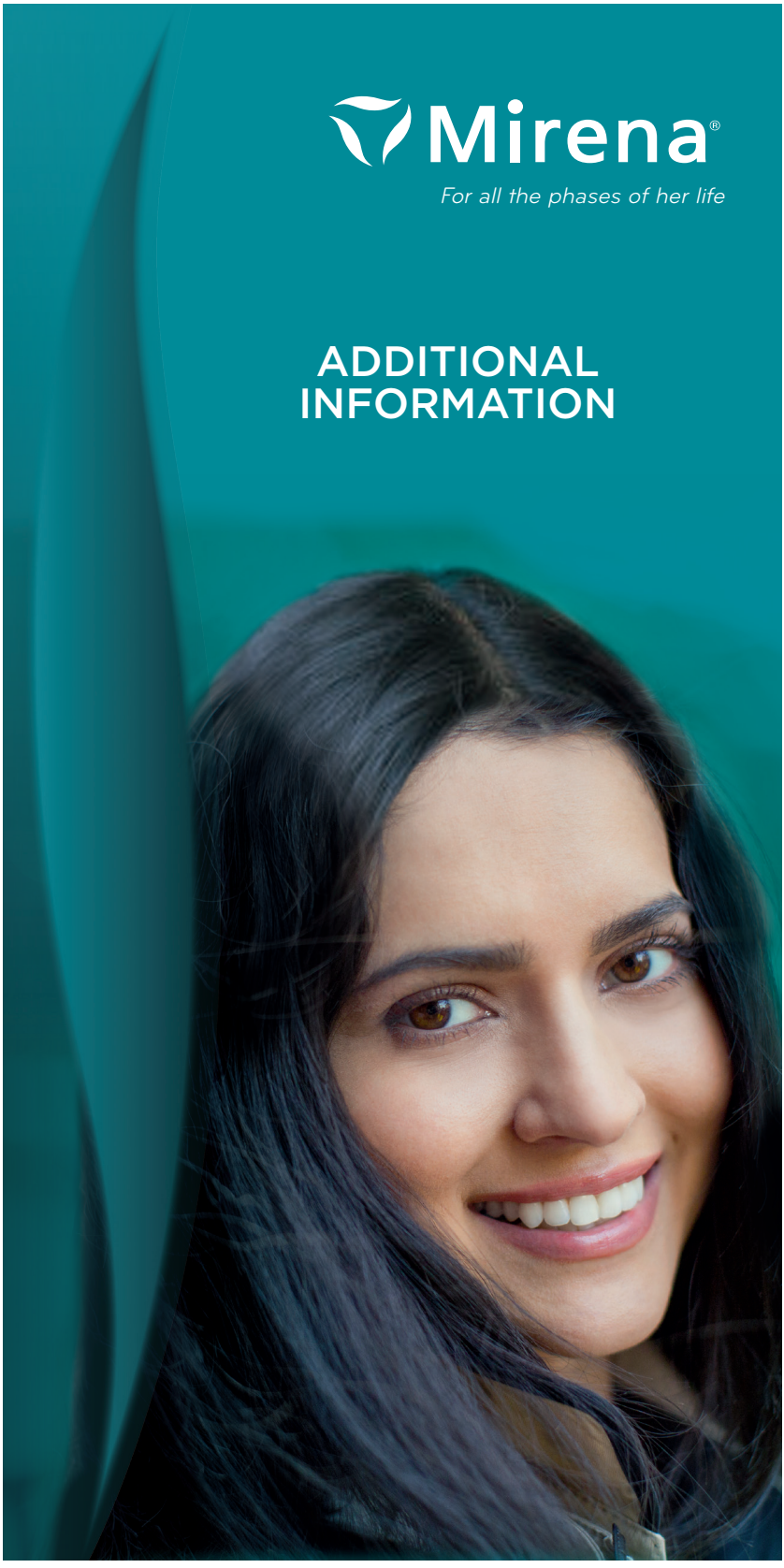


NOTES:

Mirena®

For all the phases of her life

ADDITIONAL INFORMATION



ADDITIONAL INFORMATION

Your Healthcare Professional will examine you and ask you about your medical history in order to decide whether you can use Mirena®.

Do not use Mirena®:[1]

- If you are hypersensitive (allergic) to Mirena® or any of the other ingredients of Mirena®.
- If you are pregnant or suspect that you may be pregnant.
- If you have any of the following conditions:
  - Known or suspected pregnancy.
  - Current or recurrent infection of the female reproduction organs.
  - Lower genital tract infection.
  - Infection of the womb after delivery.
  - Infection of the womb after abortion during the past 3 months.
  - Infection of the cervix (neck of womb).
  - Cell abnormalities in the cervix.
  - Cancer or suspected cancer of the cervix or womb.
  - Tumors which depend on progestogen hormone to grow.
  - Unexplained abnormal vaginal bleeding.
  - Abnormality of the cervix or womb including fibroids if they distort the cavity of the womb.
  - Conditions associated with increased susceptibility to infections.
  - Active liver disease or liver tumor.

Take special care with Mirena®:[1]

If any of the conditions mentioned below exists or appears for the first time while using Mirena®, consult your Healthcare Professional immediately.

The conditions are:

- Migraine, asymmetrical visual loss or other symptoms which may be signs of a transient cerebral ischemia (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 whom are at risk of infective inflammation of the heart muscle. Antibiotic preventive medication should be administered to these patients when inserting or removing Mirena®.

In diabetic users of Mirena®, the blood glucose concentration should be monitored. Irregular bleeding 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[1]

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. A gynaecological examination should be performed to determine the position and size of the womb.

Mirena® may not be suitable for use as a 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 microorganisms during the insertion, and the Mirena® inserter has been designed to minimise 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 Intrauterine System (IUS) 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 extrauterine pregnancy (pregnancy outside the womb). 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.[1]

Consult a Healthcare Professional without delay if you have persistent lower abdominal pain, fever, pain in conjunction with sexual intercourse or abnormal bleeding.[1]

Expulsion:

The muscular contractions of the womb during menstruation may sometimes push the Intrauterine System (IUS) out of place or expel it. Possible symptoms are pain and abnormal bleeding. If the Intrauterine System (IUS) is displaced, the effectiveness may be reduced. Mirena® decreases menstrual flow, therefore an increase of menstrual flow may be an indicator of an expulsion of the device.[1]

Perforations:

In very rare cases, during insertion of Mirena®, part of Mirena® or the entire system penetrates the inside wall of the womb or pierces the womb and becomes lodged outside the womb. Mirena® becomes ineffective and must be removed as soon as possible. The risk of perforation may be increased if Mirena® is inserted shortly after delivery, in lactating women, or in women with uterus fixed and leaning backward (towards the bowel).[1]

Extrauterine pregnancy:

It is very rare to become pregnant while using Mirena®. The overall risk of an ectopic pregnancy when using Mirena® is very low, at about 1 in 1000 in 5 years.[6] It is very rare to become pregnant with Mirena®. However, if you become pregnant with Mirena® in place, the risk of ectopic pregnancy is about 1 in 20.[6] 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 Healthcare Professional 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.[1]

Faintness:

Some women feel dizzy or faint due to a drop in blood pressure after Mirena® is inserted. This is a normal physical response. Your Healthcare Professional will tell you to rest for a while after you have had Mirena® inserted.[1]

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 inside the womb, women of fertile age will keep ovulating even though they are using Mirena® as a contraceptive. Sometimes the release of the egg is delayed and the follicle keeps on growing. These enlarged follicles cannot be distinguished from ovarian cysts on sonar. Enlarged follicles have been diagnosed in about 12 % of women using Mirena®. These are mostly symptom free but some may be accompanied by pelvic pain, or painful intercourse. In most cases, these follicles disappear spontaneously after 2 to 3 months' observation.

Pregnancy and Breastfeeding:

It is very rare for a woman to become pregnant with Mirena® in place. But if Mirena® comes out, you are no longer protected and must use another form of contraception until you see your Healthcare Professional.[1]

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 Healthcare Professional for an examination and have a pregnancy test.[1]

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 fetus 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 fetus cannot be completely

ruled out, but to date, there is no evidence of birth defects caused by Mirena®.

Mirena® can be used during breastfeeding. Levonorgestrel, the active ingredient of Mirena®, has been identified in small quantities (about 0.1 %) in the breast milk of nursing women. However, there appears to be no negative effects on infant growth or development when using any progestogen-only method starting six weeks after delivery.[1] A study conducted to assess the possible effects of Mirena® on breastfeeding performance, infant growth and infant development during the first year after birth compared to a copper intrauterine device showed that 89.3 % of women using Mirena® were still breastfeeding at 1 year, and that there were no significant differences in breastfeeding performance, or any of the infant growth or development parameters between Mirena® and a copper containing intrauterine device.[11]

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.[1]

Using other medicines with Mirena®:

Please tell your Healthcare Professional 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®.[1]

How long has Mirena® been available?

For more than 20 years.

Research commenced in 1970. Mirena® became available to the general public for the first time in Finland in 1990 and it has been available in South Africa since June 1999.

Where can I buy Mirena®?

Mirena® is available from certain Healthcare Professional's practices.

You can also purchase Mirena® from your pharmacy, on presentation of a Healthcare Professional's script.

Leading pharmacies should have stock, but it's best to phone and check beforehand.

Does medical aid pay for Mirena®?

Reimbursement for Mirena® is dependent on the indication for which it's being used and varies from scheme to scheme. Medical aids do not generally reimburse contraception.

For the indication for idiopathic Heavy Menstrual Bleeding (HMB) certain schemes may pay a portion of the consultation, insertion procedure and device. It's advisable to contact your medical aid prior to insertion and discuss whether pre-authorization is required and from which benefit it will be covered.

Possible side effects[1]

Mirena® has side effects, although not everybody gets them. Some of the more common side effects (10 or more in every 100 patients are likely to get these) are listed below:

- Uterine or vaginal bleeding including spotting, infrequent periods (oligomenorrhea), and absence of bleeding (amenorrhea).
- Benign ovarian cysts

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your Healthcare Professional immediately.

How does the IUS Patient / Mirena® reminder service work?

This program offers a service which reminds you that your Intra Uterine System (IUS) i.e, your Mirena® needs to be replaced. Once you have registered, we will send you an SMS or email 3 months before the 5 years mark from the date of your insertion of your Mirena®, reminding you that your Mirena®, is due to be replaced. Should your contact details, that used during registration, have changed during this 5 year period, you can update it by sending an email to *za_psp@bayer.com*.

3 Months prior to your replacement date, an SMS or email will be sent to you in order to enable you to schedule an appointment with your healthcare practitioner for a replacement.

Your participation in the program is voluntary and your personal information is protected by the Privacy Statements contained in the consent you provide.

All information will be treated as strictly confidential. You may withdraw from the program at any time during the 5 year period. Should you choose to be part of the IUS Patient Reminder Program, kindly complete the consent form by clicking and registering on ***www.bayer.co.za/molr***. Please note you may also register using a hard copy version of the registration form, which is available from your attending healthcare professional.

Please remember to keep your insertion date as you will need this information to register on the system. Also remember to read page 55 for how to register for the IUS Patient reminder service.

NOTES:

Mirena®

For all the phases of her life

INSERTION PROCEDURE



INSERTION PROCEDURE

Your Healthcare Professional will insert Mirena® in 5 steps[4,18]

1. Measure uterus with the sound
2. PUSH to load and position Mirena®
3. Advance inserter until flange is 1,5-2 cm from cervix
4. PULL slider to the mark, insert until flange touches cervix
5. Pull slider all the way back, remove inserter and cut the threads 2-3 cm

Mirena®

For all the phases of her life

REMINDER SERVICE



IUS REMINDER SERVICE

1. Log on to website *www.bayer.co.za/molr*
2. Fill in your details and your insertion date
3. Ensure that you read and understand **ALL** the terms and conditions
4. Provide your Healthcare Professional's information
5. Click on the accept terms and conditions
6. Click Send

Your profile will be generated on the system and you will receive either a welcome SMS or Email depending on your preference for communication.

REMINDER CARD

(to be removed)

REMINDER CARD
PLACED HERE

Please remember to complete your reminder card and keep it in your wallet.

Mirena®

For all the phases of her life

BLEEDING CALENDAR



BLEEDING CALENDAR

This calendar is to help you and your Healthcare Professional to monitor your bleeding pattern. Please mark as indicated

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
JANUARY																															
FEBRUARY																															
MARCH																															
APRIL																															
MAY																															
JUNE																															
JULY																															
AUGUST																															
SEPTEMBER																															
OCTOBER																															
NOVEMBER																															
DECEMBER																															

Completed with the advice from the Family Planning Association and The Margaret Pyke Family Planning Centre.

Day of spotting

Day of bleeding

X Day of fitting



Mirena®
Confidence that lasts

BAYER

References: 1. Mirena® patient information leaflet. February 2009. **2.** Centers for Disease Control and Prevention. U.S. Selected Practice Recommendations for Contraceptive Use, 2013. Adapted from the World Health Organization Selected Practice Recommendations for Contraceptive Use, 2nd Edition. Morbidity and Mortality Weekly Report Early Release 2013;62:1-60. **3** Mirena® product monograph. April 2005. **4.** Mirena® approved package insert. February 2009. **5.** Luukainen T. Levonorgestrel-Releasing Intrauterine Device. Ann New York Acad Sci 1991:43-49. **6.** National Institute for Health and Clinical Excellence Guideline CG30. Long-acting reversible contraception: the effective and appropriate use of long-acting reversible contraception. [online] October 2005 [cited] 30 June 2016. Available from URL: https://www.nice.org.uk/Guidance/CG30. **7.** The ESHRE Capri Workshop Group. Intrauterine devices and intrauterine systems. Human Reproduction Update 2008;14(3):197-208. **8.** Marret H, Fauconnier A, Chabbert-Buffet N, *et al,* on behalf of the CNGOF. Clinical practice guidelines on menorrhagia: Management of abnormal uterine bleeding before menopause. Eur J Obstet Gynecol Reprod Biol 2010;152:133–7. **9.** Sitruk-Ware R, Inki P. The levonorgestrel intrauterine system: long-term contraception and therapeutic effects. Women's Health 2005;1(2):171-182. **10.** National Collaborating Centre for Women's and Children's Health. Heavy Menstrual Bleeding Clinical Guideline. London: RCOG Press for NICE; 2007. **11.** Shaamash AH, Sayed GH, Hussien MM, *et al.* A comparative study of the levonorgestrel-releasing intrauterine system Mirena® versus the Copper T380A intrauterine device during lactation: breast-feeding performance, infant growth and infant development. Contraception 2005;72:346-351. **12**. Guttmacher Institute. Facts on Induced Abortion Worldwide. [online] January 2012. Available from URL: http://www.guttmacher.org. **13.** Sääv I, Stephansson O, Gemzell-Danielsson K. Early versus Delayed Insertion of Intrauterine Contraception after Medical Abortion — A Randomized Controlled Trial. PLoS ONE 2012;7(11):e48948. **14.** WHO Medical eligibility criteria for contraceptive use. Part II. Using the recommendations. Available from URL: www.who.int/reproductivehealth/publications/family_planning/MEC-5. **15.** Wildemeersch D, Schacht E, Wildemeersch P. Contraception and treatment in the perimenopause with a novel "frameless" intrauterine levonorgestrel-releasing drug delivery system: an extended pilot study. Contraception 2002;66:93-99. **16.** Delvin D. The IUS (Mirena, Levosert and Jaydess) [online] February 2016 [cited] 14 July 2016. Available from URL: http://www.netdoctor.co.uk/conditions/sexual-health/a2214/the-ius-mirena-and-jaydess. **17.** Post-adolescent acne: a review of clinical features. British Journal of Dermatology. 1997;136(1): 66-70. **18.** Mirena® insertion instructions.

S4 Mirena® Levonorgestrel intrauterine system. Each sterile intrauterine system contains levonorgestrel 52 mg, 20 µg/24 hrs. Indication: Contraception. Idiopathic Menorrhagia. Protection from endometrial hyperplasia during estrogen replacement therapy. Reg No: 32/34/0332. For full prescribing information, refer to the package insert approved by the medicines regulatory authority.

Bayer (Pty) Ltd, Reg. No.: 1968/011192/07. 27 Wrench Road, Isando, 1609. Tel: 011 921 5000.

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