



WE'RE FOR HER

We're for health. We're for access. We're for her.



INDICATION FOR KYLEENA (levonorgestrel-releasing intrauterine system) 19.5 mg

Kyleena® is indicated for the prevention of pregnancy for up to 5 years. Replace the system after 5 years if continued use is desired.

INDICATIONS FOR MIRENA (levonorgestrel-releasing intrauterine system) 52 mg

Mirena® is indicated for prevention of pregnancy for up to 6 years; replace after the end of the sixth year. Mirena is indicated for the treatment of heavy menstrual bleeding for up to 5 years in women who choose to use intrauterine contraception as their method of contraception; replace after the end of the fifth year if continued treatment of heavy menstrual bleeding is needed.

INDICATION FOR SKYLA (levonorgestrel-releasing intrauterine system) 13.5 mg

Skyla® is indicated for the prevention of pregnancy for up to 3 years. Replace the system after 3 years if continued use is desired.

IMPORTANT SAFETY INFORMATION ABOUT KYLEENA, MIRENA AND SKYLA

Who is not appropriate for Kyleena, Mirena and Skyla

Use of Kyleena, Mirena or Skyla is contraindicated in women with: known or suspected pregnancy and cannot be used for post-coital contraception; congenital or acquired uterine anomaly, including fibroids if they distort the uterine cavity; known or suspected breast cancer or other progestin-sensitive cancer, now or in the past; known or suspected uterine or cervical malignancy; liver disease, including tumors; untreated acute cervicitis or vaginitis, including lower genital tract infections (eg, bacterial vaginosis) until infection is controlled; postpartum endometritis or infected abortion in the past 3 months; unexplained uterine bleeding; current IUD; acute pelvic inflammatory disease (PID) or history of PID (except with later intrauterine pregnancy); conditions increasing susceptibility to pelvic infection; or hypersensitivity to any component of Kyleena, Mirena or Skyla.

Please see Important Safety Information continued on next page.

[Click here to read Full Prescribing Information for Kyleena.](#) **[Click here to read Full Prescribing Information for Mirena.](#)**

[Click here to read Full Prescribing Information for Skyla.](#)

OUR MISSION

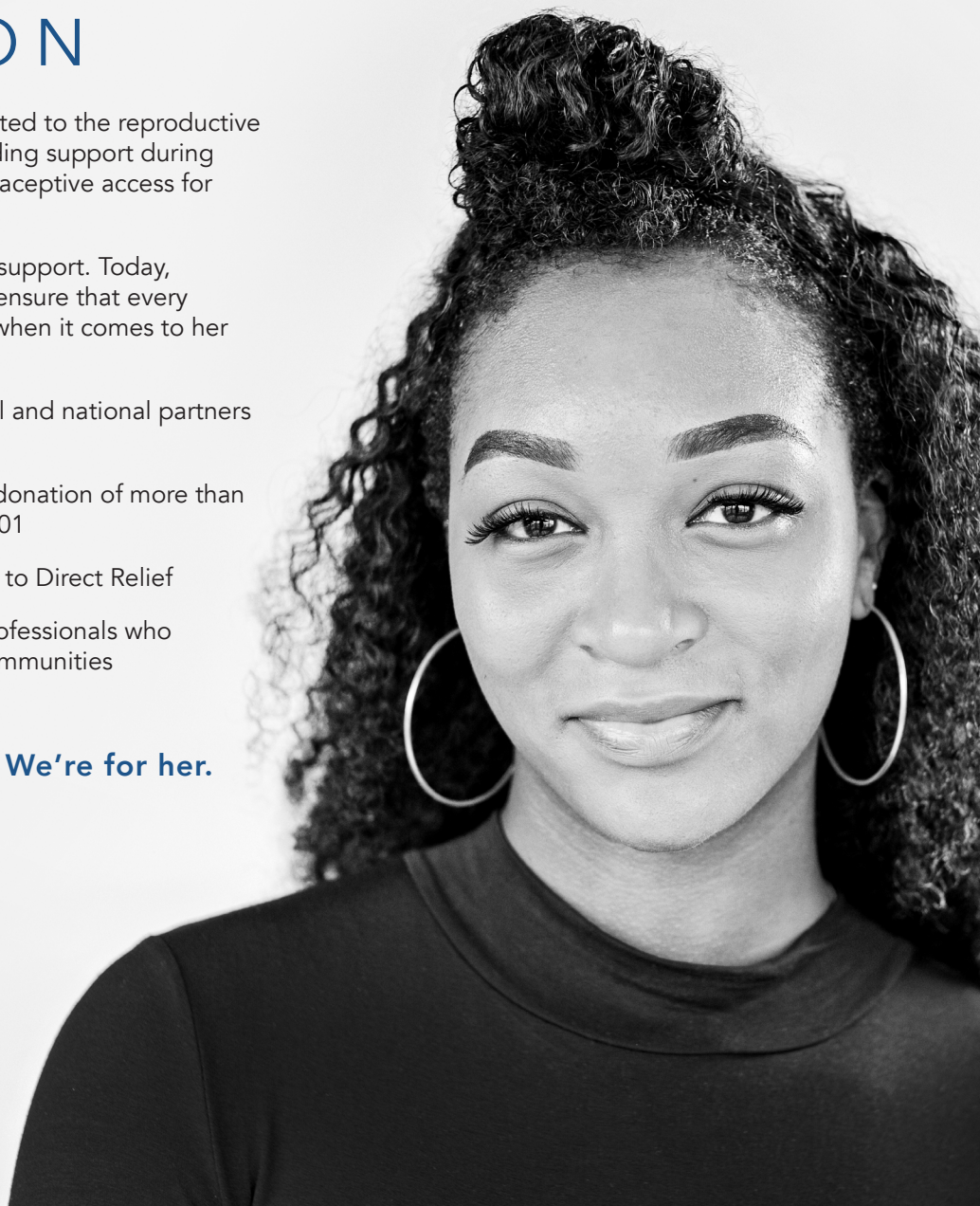
For over 50 years, BAYER® has been committed to the reproductive health of women—from education, to providing support during public health emergencies like Zika, to contraceptive access for those in need.

And now, more than ever, women need our support. Today, we continue to break down barriers to help ensure that every woman can feel empowered and confident when it comes to her reproductive decisions and health.

We work to create positive change with local and national partners by offering:

- + **CONTRACEPTIVE ACCESS** through the donation of more than 277,000 IUDs for women in need since 2001
- + **COLLABORATION** in the form of funding to Direct Relief
- + **EDUCATIONAL TOOLS** for healthcare professionals who provide care to women in underserved communities

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IMPORTANT SAFETY INFORMATION (CONTINUED)

Clinical considerations for use and removal of Kyleena, Mirena and Skyla

Use Kyleena, Mirena or Skyla with caution after careful assessment in patients with coagulopathy or taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removing the intrauterine system if these or the following arise during use: uterine or cervical malignancy or jaundice. If the threads are not visible or are significantly shortened they may have broken or retracted into the cervical canal or uterus. If Kyleena, Mirena or Skyla is displaced (e.g., expelled or perforated the uterus), remove it. Kyleena and Skyla can be safely scanned with MRI only under specific conditions.

Pregnancy related risks with Kyleena, Mirena and Skyla

If pregnancy should occur with Kyleena, Mirena or Skyla in place, remove the intrauterine system because leaving it in place may increase the risk of spontaneous abortion and preterm labor. Removal or manipulation may result in pregnancy loss. Evaluate women for ectopic pregnancy because the likelihood of a pregnancy being ectopic is increased with Kyleena, Mirena or Skyla. Also consider the possibility of ectopic pregnancy in the case of lower abdominal pain, especially in association with missed menses or if an amenorrheic woman starts bleeding. Tell women about the signs of ectopic pregnancy and associated risks, including loss of fertility. Women with a history of ectopic pregnancy, tubal surgery, or pelvic infection carry a higher risk of ectopic pregnancy.

Please see Important Safety Information continued on next page.

[Click here to read Full Prescribing Information for Kyleena \(levonorgestrel-releasing intrauterine system\) 19.5 mg. Click here to read Full Prescribing Information for Mirena \(levonorgestrel-releasing intrauterine system\) 52 mg. Click here to read Full Prescribing Information for Skyla \(levonorgestrel-releasing intrauterine system\) 13.5 mg.](#)

WE'RE FOR HER IN ACTION

+ CONTRACEPTIVE ACCESS

WE'RE FOR HER is in line with Bayer's goal to provide **100 million** women across the world with access to contraception by 2030 through two key programs in the US:



Bayer US Patient Assistance Foundation

A charitable organization that helps eligible patients get their Bayer prescription medicine at no cost.

Please have your patient contact the program at 1-866-2BUSPAF (228-7723) Monday–Friday, 9 AM–6 PM EST, or visit the foundation website at www.patientassistance.bayer.us to see if they might qualify for assistance.



Partnership with Direct Relief

In 2020, we committed to a partnership with the humanitarian medical organization, Direct Relief, to provide IUDs to health facilities caring for women in need across the country.*

*Interested health facilities can learn more by visiting www.directrelief.org or by contacting Direct Relief at 1-805-964-4767.

+ COLLABORATION

We commit annual funds that are distributed by Direct Relief to clinics of their choosing within the Direct Relief US Safety Net Network.

These funds allow clinics to establish and expand modern approaches to patient education, service, and care thus removing barriers to reproductive healthcare and contraception for underserved women and communities.

+ EDUCATIONAL TOOLS

Through Bayer training and content we strive to help ensure the safe and effective use of our IUDs:

- Healthcare professional training materials
- Patient education materials

Ask your Bayer Sales Representative about getting access to educational materials.

IMPORTANT SAFETY INFORMATION (CONTINUED)

Educate her about PID

Kyleena, Mirena and Skyla are contraindicated in the presence of known or suspected PID or in women with a history of PID unless there has been a subsequent intrauterine pregnancy. IUDs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. Promptly examine users with complaints of lower abdominal pain or pelvic pain, odorous discharge, unexplained bleeding, fever, genital lesions or sores. Inform women about the possibility of PID and that PID can cause tubal damage leading to ectopic pregnancy or infertility, or infrequently can necessitate hysterectomy, or cause death. PID is often associated with sexually transmitted infections (STIs); Kyleena, Mirena and Skyla do not protect against STIs, including HIV. PID may be asymptomatic but still result in tubal damage and its sequelae.

In clinical trials with:

- Kyleena – PID occurred more frequently within the first year and most often within the first month after insertion.
- Mirena – upper genital infections, including PID, occurred more frequently within the first year. In a clinical trial with other IUDs and a clinical trial with an IUD similar to Mirena, the highest rate occurred within the first month after insertion.
- Skyla – PID occurred more frequently within the first year and most often within the first month after insertion.

Please see Important Safety Information continued on next page.

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IMPORTANT SAFETY INFORMATION (CONTINUED)

Expect changes in bleeding patterns with Kyleena, Mirena and Skyla

Spotting and irregular or heavy bleeding may occur during the first 3 to 6 months. Periods may become shorter and/or lighter thereafter. Cycles may remain irregular, become infrequent, or even cease. Consider pregnancy if menstruation does not occur within 6 weeks of the onset of previous menstruation.

Because irregular bleeding/spotting is common during the first months of Kyleena, Mirena or Skyla use, exclude endometrial pathology (polyps or cancer) prior to the insertion of the IUD in women with persistent or uncharacteristic bleeding. If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology.

Be aware of other serious complications and most common adverse reactions

Some serious complications with IUDs like Kyleena, Mirena and Skyla are sepsis, perforation and expulsion. Severe infection, or sepsis, including Group A streptococcal sepsis (GAS) have been reported following insertion of a LNG-releasing IUS. Aseptic technique during insertion of the IUD is essential in order to minimize serious infections, such as GAS.

Perforation (total or partial, including penetration/embedment of Kyleena, Mirena or Skyla in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may reduce contraceptive efficacy. If perforation occurs, locate and remove the intrauterine system. Surgery may be required. Delayed detection or removal of the intrauterine system in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera. The risk of perforation may be increased if inserted when the uterus is not completely involuted or fixed retroverted. A postmarketing safety study over a 1-year observational period reported that lactation at the time of insertion of an IUS/IUD was associated with an increased risk of perforation. In this study, for Mirena users, the incidence of uterine perforation was reported as 6.3 per 1,000 insertions for lactating women, compared to 1.0 per 1,000 insertions for non-lactating women.

Partial or complete expulsion of Kyleena, Mirena or Skyla may occur resulting in the loss of contraceptive protection. Delay insertion a minimum of six weeks or until uterine involution is complete following a delivery or a second trimester abortion. Remove a partially expelled IUD. If expulsion has occurred, a new Kyleena, Mirena or Skyla can be inserted any time the provider can be reasonably certain the woman is not pregnant.

Ovarian cysts may occur and are generally asymptomatic, but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent enlarged ovarian cysts. In clinical trials with:

- Kyleena – the most common adverse reactions ($\geq 5\%$) were vulvovaginitis (24%), ovarian cyst (22%), abdominal/pelvic pain (21%), headache/migraine (15%), acne/seborrhea (15%), dysmenorrhea/uterine spasm (10%), breast pain/breast discomfort (10%), and increased bleeding (8%).
- Mirena
 - Adverse reactions reported in $\geq 5\%$ users are alterations of menstrual bleeding patterns [including unscheduled uterine bleeding (31.9%), decreased uterine bleeding (23.4%), increased scheduled uterine bleeding (11.9%), and female genital tract bleeding (3.5%)], abdominal/pelvic pain (22.6%), amenorrhea (18.4%), headache/migraine (16.3%), genital discharge (14.9%), vulvovaginitis (10.5%), breast pain (8.5%), back pain (7.9%), benign ovarian cyst and associated complications (7.5%), acne (6.8%), depression/depressive mood (6.4%) and dysmenorrhea (6.4%).
 - In the 6 year extension study, a consistent adverse reaction profile was observed. By the end of Year 6 of use, amenorrhea and infrequent bleeding are experienced by 24% and 31% of users, respectively; irregular bleeding occurs in 15%, and prolonged bleeding in 2% of users.
- Skyla – the most common adverse reactions ($\geq 5\%$ users) were vulvovaginitis (20.2%), abdominal/pelvic pain (18.9%), acne/seborrhea (15.0%), ovarian cyst (13.2%), headache (12.4%), dysmenorrhea (8.6%), breast pain/discomfort (8.6%), increased bleeding (7.8%), and nausea (5.5%).

Teach patients to recognize and immediately report signs or symptoms of the aforementioned conditions. Evaluate patients 4 to 6 weeks after insertion of Kyleena, Mirena or Skyla and then yearly or more often if clinically indicated.

[Click here to read Full Prescribing Information for Kyleena.](#) **[Click here to read Full Prescribing Information for Mirena.](#)** **[Click here to read Full Prescribing Information for Skyla.](#)**

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