



Women's Health

Women have the unique ability to bear children, which requires a highly sophisticated reproductive system complete with unique sexual hormones and organs. Hormones have a major role to play in a woman's body, directing puberty, the development of eggs and menstruation, and later, to menopause. At each step of a woman's life, hormones change and, in some sense, define the stage of life in which the woman finds herself. Due to the complex interplay between the reproductive system and the rest of the body, many women must undergo some form of hormone monitoring and adjustment to ensure proper body function. Treatments aid in the achievement of total balance in a woman's body.

Contraception

Women today have many options available to them when it comes to birth control. Many of these options involve hormones, and can be oral (the “pill”), implanted (either in the uterus or under the skin), injected, or absorbed (from vaginal devices or patches worn on the skin). Most hormone contraceptives are combinations of estrogen and progesterone, and work in two ways: they prevent the monthly release of an egg from the ovaries, and they thicken the mucous in the cervix and vagina, making it difficult for sperm to get through in case an egg is accidentally released. All of these options are reversible - if a woman decides she wants to become pregnant, she can simply stop using whatever method of contraception she has chosen.

| Indication | Company | Product | Phase |
|---------------|-------------------------|--|-------|
| Contraception | Bayer HealthCare | Levlite Tablets (levonorgestrel, ethinyl estradiol) | M |
| | Bayer HealthCare | Mirena (levonorgestrol) Intrauterine System | M |
| | Bayer HealthCare | Tri-Levlen/Triquilar (levonorgestrel, ethinyl estradiol) | M |
| | Bayer HealthCare | Yasmin (drospirenone / ethinyl estradiol) | M |
| | Bayer HealthCare | Yaz (drospirenone, ethinyl estradiol) | M |

Infertility

Infertility primarily refers to the biological inability of a man or a woman to contribute to conception. Infertility may also refer to the state of a woman who is unable to carry a pregnancy to full term. According to the American Society for Reproductive Medicine, infertility affects about 6.1 million people in the U.S., equivalent to ten percent of the reproductive age population. Female infertility accounts for one third of infertility cases, male infertility for another third, combined male and female infertility for another 15 percent, and the remainder of cases are “unexplained.”

| Indication | Company | Product | Phase |
|-------------|--------------------------|----------------|-------|
| Infertility | Cytoc Corporation | E-Tegrity Test | M |

Hormone Replacement Therapy

Hormone replacement therapy is used on perimenopausal and postmenopausal women to prevent discomfort and health problems caused by the diminished estrogen hormones in the body. Treatment involves a series of drugs designed to artificially boost hormone levels. Estrogen, progesterone, progestin, and testosterone are the main hormones involved.

| Indication | Company | Product | Phase |
|-----------------------------|-------------------------|--|-------|
| Hormone Replacement Therapy | Bayer HealthCare | Androgen / Progestin Replacement Therapy | II |

Libido

Libido is commonly defined as sexual desire and is affected by many things. Obesity, being underweight, oral contraceptives, SSRIs and beta blockers can all affect a woman's desire for sexual activity. Usually, if the cause of reduced libido (in women this is called female androgen deficiency) is determined, it can be removed and libido will return to normal. There are instances, however, in which libido slows down to the point where desire for sexual contact is strongly reduced. In these cases, treatments, both psychological and medicinal, can be sought to help return libido to its normal level.

| Company | Product | Phase | Indication |
|-----------|----------------------------------|-------|------------|
| VIVUS Inc | Testosterone MDTs (testosterone) | II | Libido |

Menopause

Many of the changes women experience during menopause are due to declining levels of the hormones estrogen and progesterone. Menopause happens to all women and usually begins around age 40, as they shift out of the reproductive stage of their lives. It can also happen to women of any age who have undergone removal of their ovaries, which produce estrogen and progesterone, or their uterus, which helps regulate the body's hormone levels. Every woman is affected differently by menopause and symptoms may include hot flashes, changes in the menstrual cycle, insomnia, mood changes, sexual and urinary problems, and bone loss, which can lead to osteoporosis. Some women may experience many symptoms, others almost none at all.

| Company | Product | Phase | Indication |
|------------------|--|-------|-----------------------------|
| Depomed Inc | Gabapentin ER / Gabapentin GR | II | Menopausal Symptoms |
| Bionovo Inc | MF101 | III | |
| VIVUS Inc | Evamist (estradiol MDTs) | A | |
| Bayer HealthCare | Angeliq (drospirenone and estradiol) | M | |
| Bayer HealthCare | Climara Pro (estradiol/levonorgestrel) Transdermal system | M | |
| Bayer HealthCare | Climara (estradiol) Transdermal system | M | Postmenopausal Osteoporosis |
| Bayer HealthCare | Climara Pro (17-beta ethinyl estradiol and levonorgestrel) | M | |
| Bayer HealthCare | Menostar (estradiol) Transdermal System | M | |

Premenstrual Dysmorphic Disorder

Premenstrual Dysmorphic Disorder, or PMDD, is a chronic condition that can severely impact a woman's life and requires medical evaluation and treatment. It is estimated that only 3 to 8 percent of women have PMDD during their reproductive years. During her monthly menstrual cycle, a woman's hormones generally rise and fall, and often lead to premenstrual symptoms (PMS). Symptoms of PMDD are like those of PMS but much worse. These include breast tenderness, acne, headaches, gastrointestinal discomfort, hot flashes, mood swings, increased appetite, difficulty concentrating and oversensitivity.

| Indication | Company | Product | Phase |
|---------------------------------|-----------------------------------|---------------------------------------|-------|
| Premenstrual Dysphoric Disorder | Pherin Pharmaceuticals Inc | PH80 | II |
| | Bayer HealthCare | Yaz (drospirenone, ethinyl estradiol) | M |

Vaginal Dryness

Vaginal dryness occurs when the vagina does not produce enough naturally occurring lubricant. It is normal for the amount and consistency of the lubricant to vary during a woman's menstrual cycle, but certain medications, diets, and illnesses can decrease the amount produced. This can lead to discomfort during sexual intercourse. Treatments seek to restore natural moisture levels to a woman's vagina.

| Indication | Company | Product | Phase |
|-----------------|------------------------------------|-----------|-------|
| Vaginal Dryness | Parnell Pharmaceuticals Inc | Feminease | M |

Vaginal Infections

Vaginitis is an inflammation of the vagina and falls into one of three categories: hormonal, irritant, or infectious. Most infections are due to external irritants such as allergies to condoms, spermicides, soaps, perfumes, tampons, or topical medications and infectious irritants such as yeast, Chlamydia, herpes, and gonorrhea. Vaginitis is usually harmless; however, if it is caused by an infectious organism such as Chlamydia, the infection can spread to the fallopian tubes or ovaries and lead to infertility. Symptoms include irritation and/or itching of the genital area, inflammation of the genitals, vaginal discharge, foul odor, and discomfort upon urinating. Treatments usually include topical ointments and antibiotics.

| Indication | Company | Product | Phase |
|--------------------|-----------------|----------|-------|
| Vaginal Infections | Osel Inc | Lactin-V | II |