



## News You Need to Know About YAZ and Yasmin

Information has been circulating about the risk of blood clots that may be causing you concern if you're one of the many women who use our birth control pills. In agreement with the FDA, the product information for YAZ and Yasmin has been revised to indicate that these products have a comparable risk of blood clots compared to other combination birth control pills (also known as "the Pill").

Bayer believes in and stands behind the safety and efficacy of its products. YAZ and Yasmin are safe and effective at preventing pregnancy, when used as directed by healthcare providers in accordance with product information. When it comes to your health, especially your birth control, Bayer believes it's important for you to have the facts. Learn more and talk to your healthcare provider.

1. **Do YAZ or Yasmin carry any greater risk for blood clots (VTE), than other birth control pills?**

According to the product information, the scientific data indicates that the risk of developing blood clots while taking YAZ and Yasmin is comparable to other birth control pills.

Talk to your healthcare provider before taking any birth control pills to be sure that it is right for you.

Refer to Question #2 for additional information regarding the risk of blood clots with the use of all birth control pills including YAZ and Yasmin.

[Click here to see additional Important Safety information about YAZ and Yasmin including boxed warnings or see below.](#)

2. **Does the Pill carry the risk of blood clots (venous thrombosis or VTE), stroke and heart attack?**

Yes, birth control pills, including YAZ and Yasmin, carry the risk of blood clots, stroke and heart attack. These serious side effects of the Pill occur very infrequently, especially if you are young and in good health. However, it is important that you are familiar with these serious risks because any of these conditions can be life-threatening.

The Pill may increase the tendency to develop strokes (stoppage or rupture of blood vessels in the brain) and heart attacks (blockage of blood vessels in the heart). Blood clots (venous thrombosis) and blockage of blood vessels are the most serious side effects of taking birth control pills. In particular, a clot in the legs (deep vein thrombosis), can cause pain and swelling, and a clot that travels to the lungs (pulmonary embolism) can cause sudden blocking of the vessel carrying blood to the lungs.

**Women using the Pill, especially those over the age of 35, should not to smoke because it increases these risks.**

**Some women should not use the Pill including women who have blood clots, certain cancers, a history of heart attack or stroke, as well as those who are or may be pregnant.**

Talk to your healthcare provider before taking any birth control pills to be sure that it is right for you.

[Click here to see additional Important Safety information about YAZ and Yasmin including boxed warnings or see below.](#)

3. **What makes YAZ different from other birth control pills on the market?**

If you choose the Pill for birth control, YAZ is the only Pill proven to treat both the symptoms of PMDD (Premenstrual Dysphoric Disorder) and moderate acne.

- PMDD is a mood disorder related to the menstrual cycle, with symptoms that occur regularly before a woman's menstrual period. Symptoms include markedly depressed mood, anxiety or tension, mood swings, and persistent anger or irritability. Other symptoms associated with PMDD may include breast tenderness, headache, joint or muscle pain, bloating and weight gain. Other features include decreased interest in usual activities, difficulty concentrating, lack of energy, change in appetite or sleep, and feeling out of control. Unlike PMS (premenstrual syndrome), symptoms of PMDD are severe enough to interfere with your life and may significantly affect work or school, or usual social activities and relationships with others. Only your healthcare provider can determine if you have PMDD. YAZ is not approved to treat PMS, a less serious cluster of symptoms occurring before menstruation. If you or your healthcare provider believes you have PMS, you can still use YAZ if you want to prevent pregnancy but not for the treatment of PMS.
- For the treatment of moderate acne, YAZ can be used if you are at least 14 years old, started having menstrual periods, and want to use the Pill for birth control.

For the treatment of PMDD and moderate acne, YAZ may not work for everyone.

**You should also know that YAZ and Yasmin have a different type of hormone (drospirenone) that for some may increase potassium too much. So don't take either if you have kidney, liver or adrenal disease because this could cause serious heart and health problems. Tell your healthcare provider if you're on daily long-term treatment (see medications below) for chronic conditions like cardiovascular or inflammatory diseases. Women who take certain medications should have their potassium levels checked in the first month of taking YAZ or Yasmin.**

Medications that may increase potassium include NSAIDs-ibuprofen (Motrin<sup>®</sup>, Advil<sup>®</sup>), naproxen (Naprosyn<sup>®</sup>, Aleve<sup>®</sup>, and others) when taken long-term and daily for arthritis or other diseases or conditions, Potassium-sparing diuretics (spironolactone and others), Potassium supplementation, ACE inhibitors (Capoten<sup>®</sup>, Vasotec<sup>®</sup>, Zestril<sup>®</sup>, and others), angiotensin-II receptor antagonists (Cozaar<sup>®</sup>, Diovan<sup>®</sup>, Avapro<sup>®</sup>, and others), aldosterone antagonists, and heparin.

[Click here to see additional Important Safety information about YAZ and Yasmin including boxed warnings or see below.](#)

4. **How do I know if I'm experiencing a blood clot, heart attack or stroke?**

These serious side effects of the Pill occur very infrequently, especially if you are young and in good health. However, the following are possible warning signals:

Pain and swelling in the calf could indicate a possible clot in the leg. Sharp chest pain, coughing of blood or sudden shortness of breath could be an indication of a possible clot in the lung. If you experience crushing chest pain or heaviness in the chest, this could indicate a possible heart attack. In addition, sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness, or numbness in an arm or leg could be symptoms of a possible stroke.

If any of these serious side effects occur while taking birth control pills, call your healthcare provider immediately.

[Click here to see additional Important Safety information about YAZ and Yasmin including boxed warnings or see below.](#)

5. **Are there additional benefits to YAZ beyond birth control?**

Yes. For women who choose YAZ for birth control, YAZ is also approved for the treatment of the symptoms of Premenstrual Dysphoric Disorder (PMDD) and the treatment of moderate acne. YAZ is not approved for the treatment of premenstrual syndrome (PMS). If you or your healthcare provider believes you have PMS, you can still use YAZ if you want to prevent pregnancy; and not for the treatment of PMS.

In addition to preventing pregnancy, there are also non-contraceptive health benefits that are associated with the use of all birth control pills. These can include shorter lighter periods, regulation of your cycle, reduction in cramps, as well as fewer pelvic infections, and fewer cancers of the ovary and the lining of the uterus.

[Click here to see additional Important Safety information about YAZ and Yasmin including boxed warnings or see below.](#)

For additional information about YAZ, as well as Tools and Tips, visit [www.YAZ-us.com](http://www.YAZ-us.com)

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**What are YAZ and Yasmin prescribed for?**

**YASMIN**<sup>®</sup> (3 mg drospirenone & 0.03 mg ethinyl estradiol) is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive

**YAZ**<sup>®</sup> (3 mg drospirenone & 0.02 mg ethinyl estradiol) is indicated for:

- The prevention of pregnancy in women who elect to use an oral contraceptive.
- Treatment of the emotional and physical symptoms of premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive as their method of contraception.
  - The effectiveness of YAZ for PMDD when used for more than 3 menstrual cycles has not been evaluated. YAZ has not been evaluated for the treatment of premenstrual syndrome (PMS).

- Treatment of moderate acne vulgaris
  - In women at least 14 years of age, who have no known contraindications to oral contraceptive therapy and have achieved menarche. YAZ should be used for the treatment of moderate acne only if the patient desires an oral contraceptive for birth control.

### **Important Safety Information About YAZ<sup>®</sup> and YASMIN<sup>®</sup>**

**Who Shouldn't Take Any Oral Contraceptives (OCs)?** Some women should not use OCs, including women who have blood clots, certain cancers, a history of heart attack or stroke, as well as those who are or may be pregnant.

**In Addition, Who Shouldn't Take YAZ or YASMIN?** YAZ and YASMIN each contain drospirenone a different kind of hormone that for some may increase potassium too much. Therefore, you should not take YAZ or YASMIN if you have kidney, liver, or adrenal disease because this could cause serious heart and health problems. Tell your doctor if you are on daily long-term treatment for a chronic condition such as cardiovascular disease or chronic inflammatory disease. Women who take certain drugs (see below) should have their potassium levels checked in the first month of taking YAZ or YASMIN.

**What Drugs May Increase Potassium?** NSAIDs-ibuprofen (Motrin<sup>®</sup>, Advil<sup>®</sup>), naproxen (Naprosyn<sup>®</sup>, Aleve<sup>®</sup>, and others) when taken long-term and daily for arthritis or other diseases or conditions, Potassium-sparing diuretics (spironolactone and others), Potassium supplementation, ACE inhibitors (Capoten<sup>®</sup>, Vasotec<sup>®</sup>, Zestril<sup>®</sup>, and others), angiotensin-II receptor antagonists (Cozaar<sup>®</sup>, Diovan<sup>®</sup>, Avapro<sup>®</sup>, and others), aldosterone antagonists, and heparin.

**What Are The Risks Involved With Taking Any Oral Contraceptive (OC)?** OCs can be associated with an increased risk of several serious cardiovascular side effects, including blood clots, stroke, and heart attack. **Women, especially those 35 and over, are strongly advised not to smoke because it increases these risks. OCs do not protect against HIV infection or other STDs.**

### **What Side Effects Were Reported In The YAZ Clinical Trials?**

**Frequent (greater than 1%) side effects, which may or may not be related to YAZ, reported in all three types of YAZ clinical trials included:** upper respiratory infection, headache, breast pain, vaginal yeast infection, nausea, stomach pain, painful menstrual period, urinary tract infection, accidental injury, sinus infection, mood swings, suspicious Pap smear, weight gain, depression, menstrual disorder, and weakness.

**Other frequent (greater than 1%) side effects, which may or may not be related to YAZ, reported in either one or two types of YAZ clinical trials included:**

- **Contraception trial:** white or yellow vaginal discharge, diarrhea, vomiting, vaginal infection, flu syndrome, yeast infection, allergic reaction, bladder infection, tooth disorder, sore throat, infection, fever, surgery, back pain, migraine, indigestion, inflamed nasal passage, acne, inflammation of the intestines and stomach (e.g., stomach flu), bronchitis, skin disorder, bleeding between menstrual periods, decreased libido, pain, increased cough, dizziness, pain in extremity, and pelvic pain.
- **PMDD trials:** bleeding between menstrual periods, decreased libido, nervousness, heavy menstrual bleeding, pain in extremity, migraine, vaginal infection, elevated cholesterol or triglycerides, back pain, diarrhea, increased appetite, enlarged belly, and acne.
- **Acne trials:** irregular uterine bleeding, flu syndrome, heavy menstrual bleeding, inflammation of the intestines and stomach (e.g., stomach flu), tooth disorder, infection, vomiting, sore throat, joint pain, bronchitis, inflamed nasal passage, absence of menstrual periods, and urine abnormality.

**The most frequent (greater than 1%) side effects, which may or may not be related to Yasmin, that were present during the YASMIN clinical trials included:** headache, menstrual disorder, breast pain, abdominal pain, nausea, leukorrhea, flu syndrome, acne, vaginal moniliasis, depression, diarrhea, asthenia, dysmenorrhea, back pain, infection, pharyngitis, intermenstrual bleeding, migraine, vomiting, dizziness, nervousness, vaginitis, sinusitis, cystitis, bronchitis, gastroenteritis, allergic reaction, urinary tract infection, pruritus, emotional lability, surgery, rash, upper respiratory infection.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

For important risk and use information for YAZ, please see the full prescribing information.

For important risk and use information for YASMIN, please see the full prescribing information.

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