

Important Safety Information About YAZ®

What is YAZ Prescribed For?

YAZ is indicated for the prevention of pregnancy in women who elect to use an oral contraceptive. YAZ is also indicated for the treatment of 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).

YAZ is indicated for the 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 acne only if the patient desires an oral contraceptive for birth control.

Who Shouldn't Take YAZ®

YAZ contains a different kind of hormone, drsp® (drospirenone), which may increase potassium. Therefore, you should not take YAZ if you have kidney, liver, or adrenal disease because this could cause serious heart and health problems. Tell your doctor if you are on 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.

What are some examples of cardiovascular or chronic inflammatory drugs that may increase potassium? NSAIDs—ibuprofen (Motrin®, Advil®), naproxen (Naprosyn®, Aleve®, 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®, Vasotec®, Zestril®, and others), angiotensin-II receptor antagonists (Cozaar®, Diovan®, Avapro®, and others), aldosterone antagonists, and heparin.

What Are Possible Side Effects Involved With Taking YAZ?

What are the risks involved with taking any oral contraceptive (OC)? OCs can be associated with increased risks of several serious side effects. OCs do not protect against HIV infection or other STDs. **Women, especially those 35 and over, are strongly advised not to smoke because it increases the risk of serious cardiovascular side effects including blood clots, stroke, and heart attack.**

The most frequent (>1%) treatment-emergent adverse events, listed in descending order, reported with the use of YAZ in the contraception clinical trials, which may or

may not be drug-related, included: upper respiratory infection, headache, breast pain, vaginal moniliasis, leukorrhea, diarrhea, nausea, vomiting, vaginitis, abdominal pain, flu syndrome, dysmenorrhea, moniliasis, allergic reaction, urinary tract infection, accidental injury, cystitis, tooth disorder, sore throat, infection, fever, surgery, sinusitis, back pain, emotional lability, migraine, suspicious Papanicolaou smear, dyspepsia, rhinitis, acne, gastroenteritis, bronchitis, pharyngitis, skin disorder, intermenstrual bleeding, decreased libido, weight gain, pain, depression, increased cough, dizziness, menstrual disorder, pain in extremity, pelvic pain, and asthenia.

The most frequent (>1%) treatment-emergent adverse events, listed in descending order, reported with the use of YAZ in the PMDD clinical trials, which may or may not be drug-related, included: intermenstrual bleeding, headache, nausea, breast pain, upper respiratory infection, asthenia, abdominal pain, decreased libido, emotional lability, suspicious Papanicolaou smear, nervousness, menorrhagia, pain in extremity, depression, menstrual disorder, migraine, sinusitis, weight gain, vaginal moniliasis, vaginitis, hyperlipidemia, back pain, diarrhea, increased appetite, enlarged abdomen, accidental injury, acne, dysmenorrhea, and urinary tract infection.

The most frequent (>1%) treatment-emergent adverse events, listed in descending order, reported with the use of YAZ in the acne clinical trials, which may or may not be drug-related, included: upper respiratory infection, metrorrhagia, headache, suspicious Papanicolaou smear, nausea, sinusitis, vaginal moniliasis, flu syndrome, menorrhagia, depression, emotional lability, abdominal pain, gastroenteritis, urinary tract infection, tooth disorder, infection, vomiting, pharyngitis, breast pain, dysmenorrhea, menstrual disorder, accidental injury, asthenia, sore throat, weight gain, arthralgia, bronchitis, rhinitis, amenorrhea, and urine abnormality.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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