

Important Safety Information About **YAZ**®

What Is YAZ Prescribed for?

YAZ®(drospirenone and ethinyl estradiol) 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 three 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.

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 (greater than 1%) adverse events in women using **YAZ** during the contraception clinical trials include: upper respiratory infection, headache, breast pain, vaginal yeast infection, and excessive vaginal discharge.

The most frequent (greater than 1%) adverse events, reported with the use of **YAZ** during the PMDD clinical trials include: intermenstrual bleeding, headache, nausea, breast pain, upper respiratory infection, and loss of strength.

The most frequent (greater than 1%) adverse events reported with the use of **YAZ** during the acne clinical trials include: upper respiratory infection, bleeding between periods, headache, suspicious Pap smear, and nausea.

Who Shouldn't Take YAZ?

YAZ®(drospirenone and ethinyl estradiol) contains a different kind of hormone, drsp®, 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 daily long-term treatment for a chronic condition such as cardiovascular disease or chronic inflammatory disease. Women who take certain drugs (see safety information) should have their potassium level 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.

Motrin is the registered trademark of Johnson & Johnson Company. Advil is the registered trademark of Wyeth Consumer Healthcare Inc. Naprosyn is the registered trademark of Hoffmann-La Roche Inc. Aleve is the registered trademark of Bayer Healthcare LLC. Capoten is the registered trademark of Par Pharmaceutical, Inc. Vasotec is the registered trademark of Merck & Company, Inc. Zestril is the registered trademark of AstraZeneca Pharmaceutical. Cozaar is the registered trademark of E.I. du Pont de Nemours and Company. Diovan is the registered trademark of Novartis Corporation. Avapro is the registered trademark of Sanofi-Synthelabo.