

# Do Not Use!

## The New Birth Control Pill Drospirenone With Ethinyl Estradiol (YASMIN)

The combination birth control pill of ethinyl estradiol with drospirenone (YASMIN) was approved by the Food and Drug Administration (FDA) in April 2001. Combination birth control pills contain the hormones estrogen and progestin. These products are referred to as combined hormonal oral contraceptives. In the case of Yasmin, ethinyl estradiol is the estrogen and drospirenone is the progestin. The difference between Yasmin and the other birth control pills on the market is that drospirenone has never before been marketed in the U.S. and is unlike other progestins that have been available here.

Drospirenone is a close chemical cousin of spironolactone (ALDACTONE), a diuretic or water pill that causes the body to retain potassium. Spironolactone is known as a potassium sparing diuretic and a 3-milligram dose of drospirenone, the amount in a daily pill, is equivalent to 25 milligrams of spironolactone. Two facts cause us to list Yasmin as a *Do Not Use* drug: (1) drospirenone causes elevated blood levels of potassium that may cause serious heart and other health problems such as a change in acid balance of the blood and muscle weakness; and (2) there is no evidence that Yasmin is superior in any way to older contraceptive products.

The use of Yasmin is contraindicated (should not be used) in women with the following

conditions:

- \* Kidney problems;
- \* Liver problems;
- \* Adrenal disease;
- \* Disorders that lead to the formation of blood clots;

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- \* A past history of blood clots;
- \* Cerebral-vascular or coronary artery disease;
- \* Known or suspected cancer of the breast;
- \* Cancer of the endometrium or other known or suspected estrogen-dependent cancer;
- \* Undiagnosed abnormal genital bleeding;
- \* Cholestatic jaundice (yellowing of the skin or eyes) of pregnancy or jaundice with prior pill use;

- \* Liver tumor (benign or malignant) or active liver disease;
- \* Known or suspected pregnancy;
- \* Heavy smoking (more than 15 cigarettes per day); and
- \* Being over age 35.

A number of prescription and nonprescription drugs can contribute to increased blood levels of potassium. These include:

- \* Nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (MOTRIN), naproxyn (ALEVE), and celecoxib (CELEBREX) when taken long term and daily for the treatment of arthritis and other problems;
- \* Potassium sparing diuretics such as spironolactone, triamterene (DYRENIUM), and amiloride (MIDAMOR);
- \* Potassium supplementation that includes the use of unregulated dietary supplements labeled as containing potassium;
- \* Angiotensin converting enzyme (ACE) inhibitors such as captopril (CAPOTEN) and enalapril (VASOTEC);
- \* Angiotensin receptor blockers, also known as angiotensin-II receptor antagonists, such as losartan (COZAAR) and valsartan (DIOVAN);
- \* Heparin, which is an injectable anticoagulant (blood thinner) that is rarely used outside of the hospital.

The professional product labeling, or "package insert," for

Yasmin specifies that a blood test be done during the first month of use, in order to check potassium level if any of the above listed drugs are also being taken. This blood test is not required for any other birth control pill currently on the market.

Yasmin is required to contain the following bold-faced warning:

**Yasmin contains 3 mg of the progestin drospirenone that has antimineralocorticoid activity, including the potential for hyperkalemia [elevated blood levels of potassium] in high-risk patients, comparable to a 25 mg dose of spironolactone. Yasmin should not be used in patients with conditions that predispose to hyperkalemia (i.e. renal insufficiency, hepatic dysfunction and adrenal insufficiency). Women receiving daily, long term treatment for chronic conditions or diseases with medications that may increase serum potassium, should have their serum potassium level checked during the first treatment cycle. Drugs that may increase serum potassium include ACE inhibitors, angiotensin-II receptor antagonists, potassium-sparing diuretics, heparin, aldosterone antagonists, and NSAIDs.**

Yasmin and other birth control pills may interact with the following drugs:

\* Rifampin (RIMACTANE, RIFADIN), a drug used for tuberculosis. The breakdown (metabolism) of ethinyl estradiol and some progestins is increased by rifampin. A reduction in

contraceptive effectiveness and an increase in menstrual irregularities have been associated with concomitant use of rifampin.

\* Anticonvulsants such as phenobarbital (LUMINAL, SOLFOTON), phenytoin (DILANTIN), and carbamazepine (TEGRETOL) have been shown to increase the metabolism of ethinyl estradiol and/or some progestins, which could result in a reduction of contraceptive effectiveness.

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\* Antibiotics. Pregnancy while taking birth control pills has been reported when oral contraceptives were taken with antibiotics such as ampicillin (AMOXIL), tetracycline (ACHROMYCIN, SUMYCIN), and griseofulvin (FULVICIN, GRIFULVIN V, GRISACTIN, GRIS-PEG).

\* Atorvastatin (LIPITOR), a cholesterol lowering "statin" drug. Coadministration of atorvastatin and an oral

contraceptive increased the absorption of the progestin norethindrone and ethinyl estradiol by approximately 30 percent and 20 percent, respectively.

\* ST. JOHN'S WORT. Herbal supplement preparations containing St. John's Wort (*hypericum perforatum*) may induce liver enzymes that may reduce the effectiveness of oral contraceptives and emergency contraceptive pills. This may also result in breakthrough bleeding.

\* Other. Ascorbic acid (vitamin C) and acetaminophen (TYLENOL) may increase plasma levels of some synthetic estrogens, possibly by inhibition of their metabolism.

In the May 1999 issue of *Worst Pills, Best Pills* we listed another type of combined birth control pill as *Do Not Use*. These are products containing ethinyl estradiol and the progestin desogestrel (DESOGEN, ORTHO-CEPT). Birth control pills containing desogestrel are referred to as third generation oral contraceptives and women that use these pills have a doubling in their risk of developing blood clots compared to second generation oral contraceptives. The second generation oral contraceptives contain the progestins norgestrel, levonorgestrel or norethindrone.

### **What You Can Do**

There is no medical reason that you should be using Yasmin rather than one of the older pills containing the progestins norgestrel, levonorgestrel or norethindrone.