

SAFYRAL[®]
(drospirenone/ethinyl estradiol/levomefolate
calcium tablets and levomefolate calcium tablets)
3 mg/0.03 mg/0.451 mg and 0.451 mg

YASMIN[®]
(drospirenone and ethinyl estradiol tablets) 3.0 mg/0.030 mg

Beyaz[®]
(drospirenone/ethinyl estradiol/levomefolate
calcium tablets and levomefolate calcium tablets)
3 mg/0.02 mg/0.451 mg and 0.451 mg

YAZ[®] (drospirenone &
ethinyl estradiol)

FDA Advisory Committees affirm positive benefit-risk profile and recommend an update of labels to reflect information from available studies

On December 8, 2011, the Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the U.S. Food and Drug Administration (FDA) held a meeting to discuss the available scientific evidence on the safety of drospirenone-containing oral contraceptives.

The majority of Advisory Committee members voted (15 to 11) that the benefits of drospirenone-containing combination oral contraceptives (COCs) in the prevention of pregnancy outweigh the potential risks. The Committee members also voted (21 to 5) that the current labels for Bayer's drospirenone-containing combination oral contraceptives do not adequately reflect the risk benefit profile for these products and should be revised to include additional information from available studies.

Recommendations from the Committees will be considered by the FDA in making its final decision.

"We thank the Committee members for their efforts and participation in the discussion on the benefit-risk profile for drospirenone-containing combination oral contraceptives," said Pamela A. Cyrus, M.D., Vice President and Head of U.S. Medical Affairs, Bayer HealthCare Pharmaceuticals.

Bayer has consistently worked with the FDA and other regulatory authorities around the world as new data have become available regarding drospirenone-containing COCs, and has worked with the agencies to make label updates as appropriate. Bayer will continue to do so.

What are SAFYRAL[®] and YASMIN[®] prescribed for?

For women who choose the Pill for birth control, SAFYRAL and YASMIN are approved to:

- Prevent pregnancy - 99% effective when taken as directed

SAFYRAL is also approved for women who choose the Pill for birth control to:

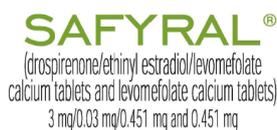
- Provide a daily dose of folate supplementation, which is recommended for women in their reproductive years. Folate lowers the risk of having rare neural tube birth defects in a pregnancy occurring during SAFYRAL use or shortly after stopping

Who should not take SAFYRAL or YASMIN?

Do not use SAFYRAL or YASMIN if you smoke and are over age 35. Smoking increases your risk of serious side effects from the Pill, which can be life-threatening, including blood clots, stroke or heart attack. This risk increases with age and the number of cigarettes smoked.

Do not use SAFYRAL or YASMIN if you have kidney, liver or adrenal disease because this could cause serious heart and health problems, or if you have or have had blood clots, certain cancers, a history of heart attack or stroke, or if you are or may be pregnant.

Please see additional Important Safety Information about SAFYRAL, YASMIN, Beyaz[®] and YAZ[®] including Boxed Warning, below.



What are the most serious risks of taking SAFYRAL® and YASMIN®?

SAFYRAL and YASMIN increase the risk of serious conditions, including blood clots, stroke and heart attack. The risk of blood clots is highest during the first year of use.

In addition, SAFYRAL and YASMIN each contain drospirenone, a different kind of hormone that for some may increase potassium too much. Consult your healthcare provider if you are on daily, long-term treatment for a chronic condition with medications that may also increase potassium (see below), as you should have a blood test to check your potassium level during the first month of taking SAFYRAL or YASMIN.

What medications may increase potassium?

NSAIDs – ibuprofen (Motrin®, Advil®), naproxen (Aleve® and others) when taken long-term and daily for arthritis or other problems, 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 the most common side effects?

In contraception and folate clinical trials, the most common side effects were premenstrual syndrome, headache/migraine, breast pain/tenderness/discomfort, nausea/vomiting and abdominal pain/discomfort/tenderness.

SAFYRAL and YASMIN do not protect against HIV infection (AIDS) or other STDs.

What is Beyaz® prescribed for?

For women who choose the Pill for birth control, Beyaz is approved to:

- Prevent pregnancy – 99% effective when taken as directed
- Provide a daily dose of folate supplementation, which is recommended for women in their reproductive years. Folate lowers the risk of having rare neural tube defects in a pregnancy occurring during Beyaz use or shortly after stopping
- Treat premenstrual dysphoric disorder (PMDD)
 - Beyaz is not approved to treat Premenstrual Syndrome (PMS), a less serious set of symptoms occurring before your period
- Treat moderate acne in women at least 14 years of age

Who should not take Beyaz?

Do not use Beyaz if you smoke and are over age 35. Smoking increases your risk of serious side effects from the Pill, which can be life-threatening, including blood clots, stroke, or heart attack. This risk increases with age and number of cigarettes smoked.

Do not use Beyaz if you have kidney, liver, or adrenal disease because this could cause serious heart and health problems, or if you have or have had blood clots, certain cancers, history of heart attack or stroke, or if you are or may be pregnant.

What are the most serious risks of taking Beyaz?

Beyaz increases the risk of serious conditions including blood clots, stroke, and heart attack. The risk of blood clots is highest during the first year of use.

In addition, Beyaz contains drospirenone, a different kind of hormone that for some may increase potassium too much. Consult your healthcare provider if you are on daily long-term treatment for a chronic condition with medications that may also increase potassium (see below), as you should have a blood test to check your potassium level during the first month of taking Beyaz.

Please see additional Important Safety Information about Beyaz and YAZ® including Boxed Warning, below.

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YAZ[®] (drospirenone &
ethinyl estradiol)

What medications may increase potassium?

NSAIDs – ibuprofen (Motrin[®], Advil[®]), naproxen (Aleve[®] and others) when taken long-term and daily for arthritis or other problems, 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 the most common side effects?

In clinical trials, the most common side effects were headache/migraine, menstrual irregularities, nausea/vomiting, breast pain/tenderness, fatigue, irritability, decreased libido, weight gain, and mood changes.

Beyaz[®] does not protect against HIV infection (AIDS) or other STDs.

What is YAZ[®] prescribed for?

For women who choose the Pill for birth control, YAZ is approved to:

- Prevent pregnancy - 99% effective when taken as directed
- Treat premenstrual dysphoric disorder (PMDD)
 - YAZ is not approved to treat Premenstrual Syndrome (PMS), a less serious set of symptoms occurring before your period
- Treat moderate acne in women at least 14 years of age

Who should not take YAZ?

Do not use YAZ if you smoke and are over age 35. Smoking increases your risk of serious side effects from the Pill, which can be life-threatening, including blood clots, stroke or heart attack. This risk increases with age and number of cigarettes smoked.

Do not use YAZ if you have kidney, liver, or adrenal disease because this could cause serious heart and health problems, or if you have or have had blood clots, certain cancers, history of heart attack or stroke, or if you are or may be pregnant.

What are the most serious risks of taking YAZ?

YAZ increases the risk of serious conditions including blood clots, stroke, and heart attack. The risk of blood clots is highest during the first year of use. This risk is greatest when first starting the Pill and when restarting the same or a different Pill after a 4 week or greater break.

In addition, YAZ contains drospirenone, a different kind of hormone that for some may increase potassium too much. Consult your healthcare provider if you are on daily long-term treatment for a chronic condition with medications that may also increase potassium (see below), as you should have a blood test to check your potassium level during the first month of taking YAZ.

What medications may increase potassium?

NSAIDs—ibuprofen (Motrin[®], Advil[®]), naproxen (Aleve[®] and others) when taken long-term and daily for arthritis or other problems, 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.

Please see additional Important Safety Information about YAZ below.

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What are the most common side effects?

In the contraception and moderate acne clinical trials, the most common side effects were headache/migraine, menstrual irregularities, nausea/vomiting, breast pain/tenderness, and mood changes.

In the PMDD clinical trials, the most common side effects were menstrual irregularities, nausea, headache, breast tenderness, fatigue, irritability, decreased libido, weight gain, and mood changes.

YAZ[®] does not protect against HIV infection (AIDS) or other STDs.

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.

For important risk and use information for SAFYRAL[®], please see the [full Prescribing Information](#).

For important risk and use information for YASMIN[®], please see the [full Prescribing Information](#).

For important risk and use information for Beyaz[®], please see the [full Prescribing Information](#).

For important risk and use information for YAZ, please see the [full Prescribing Information](#).

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