PATIENT & CAREGIVER EDUCATION Ethinyl Estradiol, Drospirenone, and Levomefolate

This information from Lexicomp[®] explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Beyaz; Safyral; Tydemy

Brand Names: Canada

YAZ Plus

Warning

• Smoking cigarettes while using this drug raises the chance of severe heart and blood-related side effects. This chance is raised with age (mainly older than 35 years of age). It is also raised with the number of cigarettes smoked. It is strongly advised not to smoke. Do not use this drug if you smoke and are older than 35 years of age.

What is this drug used for?

- It is used to prevent pregnancy.
- It is used to treat premenstrual dysphoric disorder (PMDD).
- It is used to treat pimples (acne).
- Levomefolate is a vitamin used to aid the diet needs of people who may get pregnant.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

• If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your

doctor about the allergy and what signs you had.

- If you have had any of these health problems: Blood clots, blood clotting problem, breast cancer or other cancer where hormones make it grow, diseased blood vessels in the brain or heart, heart valve problems, heart disease, a certain type of abnormal heartbeat (atrial fibrillation), chest pain caused by angina, heart attack, stroke, high blood pressure, liver tumor or other liver problems, severe headache or migraine, or diabetes.
- If you have any of these health problems: Adrenal gland problems, high potassium levels, or kidney problems.
- If you have had any of these health problems: Endometrial cancer, cancer of the cervix or vagina, or vaginal bleeding where the cause is not known.
- If you have taken ombitasvir, paritaprevir, and ritonavir (with or without dasabuvir) within the past 2 weeks.
- If you turned yellow while pregnant or with estrogen use like hormonal birth control.
- If you are pregnant or may be pregnant. Do not take this drug if you are pregnant.
- If you are breast-feeding or plan to breast-feed.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists. This drug may need to be stopped before certain types of surgery as your doctor has told you. If this drug is stopped, your doctor will tell you when to start taking this drug again after your surgery or procedure.
- This drug may raise the chance of blood clots, a stroke, or a heart attack. Talk with the doctor.
- This drug has the hormone drospirenone. The chance of blood clots may be greater with birth control that has drospirenone than with other birth control pills. Talk with the doctor.
- Talk with your doctor if you will need to be still for

long periods of time like long trips, bedrest after surgery, or illness. Not moving for long periods may raise your chance of blood clots.

- If you have high blood sugar (diabetes), talk with your doctor. This drug may raise blood sugar.
- Check your blood sugar as you have been told by your doctor.
- If you are taking a salt substitute that has potassium in it, a potassium-sparing diuretic, or a potassium product, talk with your doctor.
- High blood pressure has happened with drugs like this one. Have your blood pressure checked as you have been told by your doctor.
- High cholesterol and triglyceride levels have happened with this drug. If you have high cholesterol or triglycerides, talk with your doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Be sure to have regular breast exams and gynecology check-ups. You will also need to do breast self-exams as you have been told.
- This drug may cause dark patches of skin on your face. Avoid sun, sunlamps, and tanning beds. Use sunscreen and wear clothing and eyewear that

protects you from the sun.

- Certain drugs, herbal products, or health problems may cause hormone-based birth control to not work as well. Be sure your doctor knows about all of your drugs and health problems. You will need to see if you also need to use a non-hormone form of birth control like condoms.
- This drug does not stop the spread of diseases like HIV or hepatitis that are passed through having sex.
 Do not have any kind of sex without using a latex or polyurethane condom. If you have questions, talk with your doctor.
- The chance of getting cervical cancer may be higher in people who take hormone-based birth control. However, this may be due to other reasons. If you have questions, talk with the doctor.
- Some studies have shown the risk of breast cancer is raised when taking hormone-based birth control for a long time. However, other studies have not shown this risk. If you have questions, talk with the doctor.
- Do not use in children who have not had their first menstrual period.
- If you have any signs of pregnancy or if you have a positive pregnancy test, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of liver problems like dark urine, tiredness, decreased appetite, upset stomach or stomach pain, light-colored stools, throwing up, or yellow skin or eyes.
- Signs of high potassium levels like a heartbeat that does not feel normal; feeling confused; feeling weak, lightheaded, or dizzy; feeling like passing out; numbness or tingling; or shortness of breath.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.

- Signs of gallbladder problems like pain in the upper right belly area, right shoulder area, or between the shoulder blades; yellow skin or eyes; fever with chills; bloating; or very upset stomach or throwing up.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Depression or other mood changes.
- Not able to pass urine or change in how much urine is passed.
- A lump in the breast, breast pain or soreness, or nipple discharge.
- Vaginal itching or discharge.
- Eyesight changes or loss, bulging eyes, or change in how contact lenses feel.
- Call your doctor right away if you have signs of a blood clot like chest pain or pressure; coughing up blood; shortness of breath; swelling, warmth, numbness, change of color, or pain in a leg or arm; or trouble speaking or swallowing.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Appetite changes.
- Weight gain.
- Headache.
- Upset stomach or throwing up.
- Cramps.
- Bloating.
- Period (menstrual) changes. These include spotting or bleeding between cycles.
- Enlarged breasts.
- Tender breasts.
- Feeling tired or weak.
- Lowered interest in sex.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-

1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

For all uses of this drug:

- Take this drug at the same time of day.
- Take after the evening meal or at bedtime.
- Take with or without food. Take with food if it causes an upset stomach.
- If you drink grapefruit juice or eat grapefruit often, talk with your doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.

Birth control:

- After starting this drug, you may need to use a nonhormone type of birth control like condoms to prevent pregnancy for some time. Follow what your doctor has told you to do about using a non-hormone type of birth control.
- Do not skip doses, even if you do not have sex very

often.

- If you throw up or have diarrhea, this drug may not work as well to prevent pregnancy. If this happens within 3 to 4 hours after you take an active tablet, take another tablet. If it goes on for more than 1 day, use an extra form of birth control and call your doctor. Call your doctor if you throw up or have diarrhea and are not sure what to do.
- If you miss 2 periods in a row, take a pregnancy test before starting a new dosing cycle.

What do I do if I miss a dose?

• If a dose is missed, check the package insert or call the doctor to find out what to do. If using this drug to prevent pregnancy, a non-hormone form of birth control like condoms may need to be used for some time to prevent pregnancy.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told

to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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