

#### PATIENT & CAREGIVER EDUCATION

# **Ethinyl Estradiol and Norethindrone**

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**

Alyacen 1/35; Alyacen 7/7/7; Aranelle; Aurovela 1.5/30; Aurovela 1/20; Aurovela 24 FE; Aurovela Fe 1.5/30; Aurovela FE 1/20; Balziva; Blisovi 24 Fe; Blisovi Fe 1.5/30; Blisovi FE 1/20; Briellyn; Charlotte 24 Fe; Cyclafem 1/35 [DSC]; Cyclafem 7/7/7 [DSC]; Dasetta 1/35 (28); Dasetta 7/7/7; Estrostep Fe [DSC]; Feirza 1.5/30; Feirza 1/20; Femhrt [DSC]; Femlyv; Finzala; Fyavolv; Galbriela; Gemmily; Generess FE [DSC]; Hailey 1.5/30; Hailey 24 Fe; Hailey FE 1.5/30; Hailey FE 1/20; Jinteli; Junel 1.5/30; Junel 1/20; Junel FE 1.5/30; Junel FE 1/20; Junel Fe 24; Kaitlib Fe; Larin 1.5/30; Larin 1/20; Larin 24 FE; Larin Fe 1.5/30; Larin Fe 1/20; Layolis FE [DSC]; Leena; Lo Loestrin Fe; Loestrin 1.5/30 (21); Loestrin 1/20 (21); Loestrin Fe 1.5/30; Loestrin Fe 1/20; Luizza 1.5/30; Luizza 1/20; Merzee [DSC]; Mibelas 24 Fe; Microgestin 1.5/30; Microgestin 1/20; Microgestin 24 Fe [DSC]; Microgestin FE 1.5/30; Microgestin FE 1/20; Minastrin 24 Fe [DSC]; Necon 0.5/35 (28); Nortrel 0.5/35 (28); Nortrel 1/35 (21); Nortrel 1/35 (28); Nortrel 7/7/7; Nylia 1/35; Nylia 7/7/7; Philith; Pirmella 1/35 [DSC]; Pirmella 7/7/7 [DSC]; Tarina 24 Fe; Tarina FE 1/20 EQ; Tarina FE 1/20 [DSC]; Taysofy; Taytulla; Tilia Fe; Tri-Legest Fe; Vyfemla; Wera; Wymzya Fe; Xarah Fe; Xelria Fe

#### **Brand Names: Canada**

Brevicon 0.5/35; Brevicon 1/35; Loestrin 1.5/30 [DSC]; Lolo; Minestrin 1/20 [DSC]; Select 1/35; Synphasic

# Warning

#### Birth control:

• 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.

### Menopausal hormone therapy (MHT):

- Do not use this drug to prevent heart disease or dementia. A study of women taking an estrogen with a progestin showed a raised chance of heart attack, stroke, blood clot, breast cancer, and dementia. The chance of stroke, blood clot, and dementia was also raised when the estrogen was taken alone. Not all products and doses were studied. It is not known if the same effects may happen with this drug.
- The chance of endometrial cancer may be raised with the use of estrogen alone in patients with a uterus. Use of a progestin along with estrogen may lower the risk. Call your doctor right away if you have unexplained or long-lasting vaginal bleeding.
- Use this drug for the shortest time needed at the lowest useful dose. Your doctor will talk with you on a regular basis to see if you need to keep taking this drug.

# What is this drug used for?

- It is used to prevent pregnancy.
- It is used to prevent soft, brittle bones (osteoporosis) after menopause.
- It is used to treat signs caused by menopause.
- It is used to treat pimples (acne).
- 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? All products:

- 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, certain types of abnormal heartbeats like 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 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 a health problem called hereditary angioedema.
- If you have had dark patches on your skin (chloasma) or a raised sensitivity to the sun or radiation.
- If you have taken ombitasvir, paritaprevir, and ritonavir (with or without dasabuvir) within the past 2 weeks.
- If you are taking glecaprevir and pibrentasvir.
- 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.
- If you turned yellow while pregnant or with estrogen use like hormonal birth control.

#### Menopausal hormone therapy (MHT):

• If you have had your uterus removed.

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?

## All products:

- 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.
- 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.
- 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 your blood work and other lab tests checked as you have been told by your 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.
- If you are allergic to tartrazine (FD&C Yellow No. 5), talk with your doctor. Some products have tartrazine.
- 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:

- Certain drugs, herbal products, or health problems may cause hormonebased 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 protect against infections that are spread through having sex like HIV or hepatitis. To protect against these infections, use a latex or polyurethane condom.
- This drug may raise the chance of blood clots, a stroke, or a heart attack.
   Talk with the doctor.
- This drug may raise the chance of blood clots. The chance is highest during the first year of using this drug. The chance is also highest when starting to use hormone-based birth control again after not using it for 4 weeks or more. Talk with the 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.
- If you are taking this drug for pimples (acne), you need to be at least 15 years of age.
- 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.

### Menopausal hormone therapy (MHT):

- This drug works best when used with calcium/vitamin D and weight-bearing workouts like walking or PT (physical therapy).
- Follow the diet and exercise plan that your doctor told you about.
- Limit your drinking of alcohol.
- Do not smoke. Smoking raises the chance of heart disease. Talk with your doctor.
- The risk of certain side effects like heart attack, stroke, breast cancer, ovarian cancer, and others may not be the same for everyone. Factors like how long an estrogen is taken, if it is taken with or without a progestin, and other factors may affect the risk for certain side effects. Talk with your doctor about the benefits and risks of using this drug.
- Do not give to a child. Talk with your doctor.

# 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:

#### All products:

- 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 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.
- 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.
- Spotting or vaginal bleeding that is very bad or does not go away.
- This drug may cause you to swell or keep fluid in your body. Tell your doctor if you have swelling, weight gain, or trouble breathing.
- 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.

# Menopausal hormone therapy (MHT):

- Signs of low calcium levels like muscle cramps or spasms, numbness and tingling, or seizures.
- High calcium levels have happened with drugs like this one in some people
  with cancer. Call your doctor right away if you have signs of high calcium
  levels like weakness, confusion, feeling tired, headache, upset stomach or
  throwing up, constipation, or bone pain.

# 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:

#### All products:

- Appetite changes.
- Weight gain or loss.
- Dizziness or headache.
- Upset stomach or throwing up.
- Stomach cramps.
- Bloating.
- Enlarged breasts.
- Tender breasts.
- 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.

#### Birth control:

 Period (menstrual) changes. These include spotting or bleeding between cycles.

## Menopausal hormone therapy (MHT):

- Diarrhea.
- Vaginal bleeding or spotting.

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.

#### All products:

- Take this drug at the same time of day.
- Take with or without food. Take with food if it causes an upset stomach.
- If you also take colesevelam, take it at least 4 hours before or after you take this drug.

#### Birth control:

- After starting this drug, you may need to use a non-hormone 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.

#### Chewable tablets:

- Chew well before swallowing.
- Some brands may be swallowed whole. Check with your pharmacist to see if your brand may be swallowed whole.
- Some brands need to be taken with a full glass of water. Some brands need to be taken without water. Check with your pharmacist to see if you need to take your drug with water.

#### **Oral-disintegrating tablet:**

- Place on your tongue and let it dissolve. After it has dissolved, drink 8 oz (240 mL) of water.
- This drug may also be swallowed whole with 8 oz (240 mL) of water.

# What do I do if I miss a dose? Birth control:

 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.

### Menopausal hormone therapy (MHT):

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
- If you miss taking this drug for a few days in a row, call your doctor before you start taking it again.

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

- Store at room temperature protected from light. Store 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 https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.

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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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