PATIENT & CAREGIVER EDUCATION

Ethinyl Estradiol and Levonorgestrel

This information from UpToDate® Lexidrug™ 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

Afirmelle; Altavera; Amethia [DSC]; Amethyst; Ashlyna; Aubra EQ; Aubra [DSC]; Aviane; Ayuna; Balcoltra; Camrese; Camrese Lo; Chateal EQ; Chateal [DSC]; Daysee; Delyla; Dolishale; Enpresse-28 [DSC]; Falmina; Fayosim [DSC]; Iclevia; Introvale; Jaimiess; Jolessa; Joyeaux; Kurvelo; Lessina; Levonest; Levora 0.15/30 (28) [DSC]; LoJaimiess; LoSeasonique [DSC]; Lutera; Marlissa; Minzoya; Portia-28; Quartette [DSC]; Rivelsa; Rosyrah; Seasonique [DSC]; Setlakin; Simpesse; Sronyx [DSC]; Trivora (28) [DSC]; Twirla; Tyblume; Vienva

Brand Names: Canada

Alesse 21; Alesse 28; Alysena 21; Alysena 28; Audrina 21; Audrina 28; Aviane; Indayo; Laylaa 21; Laylaa 28; Min Ovral 21; Min Ovral 28; Ovima 21; Ovima 28; Portia 21; Portia 28; Seasonale; Seasonique; Triquilar 21; Triquilar 28

Warning

All products:

- 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.

Patch:

- Be sure you know your child's body mass index (BMI). If you do not know, talk with the doctor. If your child's BMI is 25 or more, this drug may not work as well. Your child must not use this drug with a BMI of 30 or more. The risk of blood clots may be higher.

What is this drug used for?

- It is used to prevent pregnancy. If your child has been given this drug for some other reason, talk with the doctor for more information.

What do I need to tell the doctor BEFORE my child takes this drug?

- If your child is allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell the doctor about the allergy and what signs your child had.
- If your child has 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, endometrial cancer, cancer of the cervix or vagina, liver disease, liver tumor, very bad headache or migraine, diabetes, or vaginal bleeding where the cause is not known.
- If your child has turned yellow while pregnant or with estrogen use like hormonal birth control.
- If your child has taken ombitasvir, paritaprevir, and ritonavir (with or without dasabuvir) within the past 2 weeks.

- If your child is taking glecaprevir and pibrentasvir.

If your child is pregnant:

- Do not give this drug to your child during pregnancy.

If your child is breast-feeding a baby:

- Talk with the doctor if your child is breast-feeding a baby or plans to breast-feed a baby.

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

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

What are some things I need to know or do while my child takes this drug?

All products:

- Tell all of your child's health care providers that your child is taking this drug. This includes your child's doctors, nurses, pharmacists, and dentists. This drug may need to be stopped before certain types of surgery

as the doctor has told you. If this drug is stopped, the doctor will tell you when to start giving this drug again after your child's surgery or procedure.

- This drug may raise the chance of blood clots, a stroke, or a heart attack. Talk with the doctor.
- Talk with the doctor if your child 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 the chance of blood clots.
- If your child has high blood sugar (diabetes), talk with the doctor. This drug can raise blood sugar.
- Check your child's blood sugar as you have been told by the doctor.
- High blood pressure has happened with drugs like this one. Have your child's blood pressure checked as you have been told by the doctor.
- Have your child's blood work and other lab tests checked as you have been told by the doctor.
- Be sure your child has regular breast exams and gynecology check-ups. Your child will also need to do breast self-exams as the doctor has told you.
- This drug may affect certain lab tests. Tell all of your child's health care providers and lab workers that your child takes this drug.

- Certain drugs, herbal products, or health problems may cause hormone-based birth control to not work as well. Be sure the doctor knows about all of your child's drugs and health problems. You will need to see if your child also needs to use a non-hormone form of birth control like condoms.
- If your child is allergic to tartrazine (FD&C Yellow No. 5), talk with your child's doctor. Some products have tartrazine.
- This drug may cause high cholesterol and triglyceride levels. 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.
- Do not use in children who have not had their first menstrual period.

If your child is or may be sexually active:

- This drug does not stop the spread of diseases like HIV or hepatitis that are passed through having sex. Be sure your child does not have any kind of sex without using a latex or polyurethane condom.

If your product has iron in it:

- Accidental overdose of drugs that have iron in them is a leading cause of deadly poisoning in children younger than 6 years of age. Keep away from children. If this drug is taken by accident, call a doctor or poison control center right away.

What are some side effects that I need to call my child's 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 child's doctor or get medical help right away if your child has 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 gallbladder problems like pain in the upper right belly area, right shoulder area, or between the shoulder blades; change in stools; dark urine or yellow skin or eyes; or fever with chills.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- New or worse migraines.
- Depression or other mood changes.
- A lump in the breast, breast pain or soreness, or nipple discharge.
- Vaginal itching or discharge.
- Spotting or vaginal bleeding that is very bad or does not go away.
- Eyesight changes or loss, bulging eyes, or change in how

contact lenses feel.

- This drug may cause your child to swell or keep fluid in the body. Tell your child's doctor if swelling, weight gain, or trouble breathing happens after this drug is given.
- Call the doctor right away if your child has 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 child's doctor or get medical help if any of these side effects or any other side effects bother your child or do not go away:

Tablets and chewable tablets:

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

- Enlarged breasts.
- Tender breasts.
- Period (menstrual) changes. These include spotting or bleeding between cycles.
- Back pain.
- This drug may cause dark patches of skin on your child's face. Avoid lots of sun, sunlamps, and tanning beds. Use sunscreen and dress your child in clothing and eyewear that protects from the sun.

Patch:

- Irritation where this drug was used.
- Headache.
- Weight gain.
- Stomach cramps.
- Upset stomach.

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

You may report side effects to your national health agency.

How is this drug best given?

Give this drug as ordered by your child's doctor. Read all information given to you. Follow all instructions closely.

All products:

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

Tablets:

- Give this drug with or without food. Give with food if it causes an upset stomach.

Chewable tablets:

- Have your child chew and swallow with a full glass of water or swallow the tablet whole.
- Give on an empty stomach.

Tablets and chewable tablets:

- Give this drug at the same time of day.
- If your child also takes colesevelam, give it at least 4

hours before or after your child takes this drug.

- If your child throws up or has diarrhea, this drug may not work as well to prevent pregnancy. If this happens within 3 to 4 hours after your child takes an active tablet, give another tablet. If it goes on for more than 1 day, your child must use an extra form of birth control and you must call the doctor. Call the doctor if your child throws up or has diarrhea and you are not sure what to do.
- If your child's monthly cycle is 28 days and she misses 2 periods in a row, have your child take a pregnancy test before starting a new dosing cycle.
- If your child has a cycle longer than 91 days and she misses one period, have your child take a pregnancy test before starting a new dosing cycle.

Patch:

- Put patch on once a week for 3 weeks. Put it on the same day each week. Do not use patch on the 4th week.
- Put patch on clean, dry, healthy skin on the buttock, stomach, or upper back.
- Move the site with each patch.
- Do not put on the breast.
- Do not put the patch on the waistline or under a bra strap.

- Do not put on skin that is irritated or damaged. Do not put on an area with skin folds or skin that will be rubbed by tight clothes.
- Do not cut or divide patches. Do not use patches that are damaged.
- Do not use adhesives or wraps to hold the patch in place.
- Do not put on skin where you have just used creams, oils, lotions, powder, or other skin products. The patch may not stick as well.
- Do not put on more than 1 patch at a time.
- If your child misses 2 periods in a row, have your child take a pregnancy test before starting a new dosing cycle.
- If this drug has not been used the right way and 1 monthly period is missed, have your child take a pregnancy test.
- If your child swims or often has contact with water, the patch may not stick as well. Talk with the doctor if your child is a swimmer or often has contact with water for more than 30 minutes.
- If the patch loosens at the edges, press the edges firmly.
- Put the same patch on the same place if it falls off and has been off for less than 24 hours.

- Put on a new patch if the patch being used is no longer sticky or if it is sticking to itself or some other surface.
- If a patch has been off for more than 1 day, your child may not be protected from pregnancy. Have your child put a new patch on to start a new 4-week cycle. Have her use another type of birth control like a condom during the first week of the new cycle.

What do I do if my child misses 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?

Tablets and chewable tablets:

- Store at room temperature protected from light. Store in a dry place. Do not store in a bathroom.

Chewable tablets:

- Protect from heat.

Patch:

- Store at room temperature. Do not refrigerate or freeze.
- Store in pouch until ready for use.

- After you take off a skin patch, be sure to fold the sticky sides of the patch to each other. Throw away used patches where children and pets cannot get to them.

All products:

- 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 child's symptoms or health problems do not get better or if they become worse, call your child's doctor.
- Do not share your child's drug with others and do not give anyone else's drug to your child.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your child's 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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