

Angeliq®

tablets

(Drospirenone/Estradiol)

(an"jū-lēk')

PATIENT INFORMATION

Read this **PATIENT INFORMATION** before you start taking **ANGELIQ** and read what you get each time you refill **ANGELIQ**. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ANGELIQ (a combination of estrogen and a progestin)?

Do not use estrogens with or without progestins to prevent heart disease, heart attacks, or strokes.

Using estrogens with or without progestins may increase your chances of getting heart attack, strokes, breast cancer, and blood clots. Using estrogens with or without progestins may increase your risk of dementia. You and your healthcare provider should talk regularly about whether you still need treatment with **ANGELIQ**.

What is ANGELIQ?

ANGELIQ is a medicine that contains two kinds of hormones, estrogen and progestin.

What is ANGELIQ used for?

ANGELIQ is used after menopause to:

- **reduce moderate to severe hot flashes.** Estrogens are hormones made by a woman's ovaries. The ovaries normally stop making estrogens when a woman is between 45 to 55 years old. This drop in body estrogen levels causes the "change of life" or menopause (the end of monthly menstrual periods). Sometimes, both ovaries are removed during an operation before natural menopause takes place. The sudden drop in estrogen levels causes "surgical menopause." When the estrogen levels begin dropping, some women develop very uncomfortable symptoms, such as feelings of warmth in the face, neck, and chest, or sudden strong feelings of heat and sweating ("hot flashes" or "hot flushes"). In some women, the symptoms are mild, and they will not need estrogens. In other women, symptoms can be more severe. You and your healthcare provider should talk regularly about whether you still need treatment with **ANGELIQ**.
- **treat moderate to severe dryness, itching, and burning in or around the vagina.** You and your healthcare provider should talk regularly about whether you still need treatment with **ANGELIQ** to control these problems. If you use **ANGELIQ** only to treat dryness, itching, and burning in and around your vagina, talk with your healthcare provider about whether a topical vaginal product would be better for you.

Who should not use ANGELIQ?

Do not use **ANGELIQ** if you have had your uterus removed (hysterectomy).

ANGELIQ contains a progestin to decrease the chances of getting cancer of the uterus. If you do not have a uterus, you do not need a progestin and you should not use **ANGELIQ**.

Do not start taking ANGELIQ if you:

- **have unusual vaginal bleeding.**
- **currently have or have had certain cancers.** Estrogens may increase the chances of getting certain types of cancers, including cancer of the breast or uterus. If you have or had cancer, talk with your healthcare provider about whether you should take **ANGELIQ**.
- **had a stroke or heart attack in the past year.**
- **currently have or have had blood clots.**

- **have kidney disease, liver disease, or disease of your adrenal glands.**
- **are allergic to ANGELIQ or any of its ingredients.** See the end of this leaflet for a list of ingredients in **ANGELIQ**.
- **think you may be pregnant.**

Tell your healthcare provider:

- **if you are breastfeeding.** The hormone in **ANGELIQ** can pass into your milk.
- **about all of your medical problems.** Your healthcare provider may need to check you more carefully if you have certain conditions, such as asthma (wheezing), epilepsy (seizures), migraine, endometriosis, lupus, hypertension (high blood pressure) or problems with your heart, liver, thyroid, kidneys, or have high calcium levels in your blood.
- **about all the medicines you take,** including prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may affect how **ANGELIQ** works. **ANGELIQ** may also affect how your other medicines work.
- **if you are going to have surgery or will be on bed rest.** You may need to stop taking estrogens.

How should I take ANGELIQ?

1. Take one tablet every day.
2. Estrogens should be used only as long as needed. The lowest effective dose of **ANGELIQ** has not been determined. You and your healthcare provider should talk regularly (for example, every 3 to 6 months) about whether you still need treatment with **ANGELIQ**.

What are the possible side effects of ANGELIQ?

ANGELIQ is different from other hormonal medicines for menopausal symptoms because it contains drospirenone, and drospirenone may increase the potassium or lower the sodium in your blood.

You should not take **ANGELIQ** if you have kidney, liver or adrenal disease because these conditions may also increase the potassium in your blood. Some other medicines also increase potassium. If you regularly take another medicine that increases potassium levels, talk with your healthcare provider about whether **ANGELIQ** is right for you. In some situations, your healthcare provider may recommend testing your blood for potassium.

Less common but serious side effects include the following and should be discussed with your healthcare provider to assess your personal risks:

- Breast cancer
- Cancer of the uterus
- Stroke
- Heart attack
- Blood clots
- Dementia
- Gallbladder disease
- Ovarian cancer

These are some of the warning signs of serious side effects:

- Breast lumps
- Unusual vaginal bleeding
- Dizziness and faintness
- Changes in speech
- Severe headaches
- Chest pain
- Shortness of breath
- Pains in your legs
- Changes in vision
- Vomiting

Call your healthcare provider right away if you get any of these warning signs, or any other unusual symptom that concerns you.

Common side effects include:

- Headache
- Breast pain
- Irregular vaginal bleeding or spotting
- Stomach/abdominal cramps, bloating
- Nausea and vomiting
- Hair loss

Other side effects include:

- High blood pressure
- Liver problems
- High blood sugar
- Fluid retention
- Enlargement of benign tumors of the uterus ("fibroids")
- Vaginal yeast infection

These are not all the possible side effects of **ANGELIQ**. For more information, ask your healthcare provider or pharmacist.

What can I do to lower my chances of a serious side effect with ANGELIQ?

Talk with your healthcare provider regularly about whether you should continue taking **ANGELIQ**.

See your healthcare provider right away if you get vaginal bleeding while taking **ANGELIQ**.

Have a breast exam and mammogram (breast X-ray) every year unless your healthcare provider tells you something else. If members of your family have had breast cancer or if you have ever had breast lumps or an abnormal mammogram, you may need to have breast exams more often.

If you have high blood pressure, high cholesterol (fat in the blood), diabetes, are overweight, or if you use tobacco, you may have higher chances for getting heart disease. Ask your healthcare provider for ways to lower your chances for getting heart disease.

General information about safe and effective use of ANGELIQ.

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use **ANGELIQ** for conditions for which it was not prescribed. Do not give **ANGELIQ** to other people, even if they have the same symptoms you have. It may harm them.

Keep ANGELIQ out of the reach of children

This leaflet summarizes the most important information about **ANGELIQ**. If you would like more information, talk with your healthcare provider or pharmacist. You can ask for information about **ANGELIQ** that is written for health professionals. You can get more information by calling our toll free number (1-888-237-5394) or visit www.angeliq-us.com

What are the ingredients in ANGELIQ?

The active ingredients in **ANGELIQ** are drospirenone (a progestin) and estradiol. **ANGELIQ** also contains lactose monohydrate NF, corn starch NF, modified starch NF, povidone USP, magnesium stearate NF, hydroxylpropylmethyl cellulose USP, macrogol NF, talc USP, titanium dioxide USP, and ferric oxide pigment NF.

Do not store above 86°F (30°C).



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