

ANGELIQ FILM-COATED TABLET

Estradiol hemihydrate / Drospirenone (1.0mg/2.0 mg)

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What Angeliq Tablet is used for

Angeliq Tablet is a hormone replacement therapy (HRT) for women who have reached menopause and still have their uterus. It is used to relieve symptoms caused by low estrogen levels during and after menopause, such as hot flushes, night sweats, trouble sleeping, mood swings, vaginal dryness, discomfort during sex, and urinary issues. These symptoms can occur naturally with age or due to early menopause caused by surgery or certain medical conditions.

Angeliq is also used to help prevent osteoporosis (bone thinning) in postmenopausal women who are at higher risk of fractures and are unable to use other medications for bone health.

How Angeliq Tablet works

Angeliq contains two active ingredients which are estradiol hemihydrate (a form of estrogen) and drospirenone (a type of progestin), which work together to treat symptoms of menopause and help prevent bone loss. After menopause, the body makes much less estrogen, leading to symptoms like hot flushes, night sweats, mood swings, trouble sleeping, and vaginal dryness. Estradiol replaces the missing estrogen, helping to relieve these symptoms and maintain bone strength, which reduces the risk of osteoporosis and fractures.

However, taking estrogen alone can cause the lining of the womb (uterus) to thicken too much, which increases the risk of womb cancer in women who still have a uterus. Drospirenone balances the

effects of estrogen by protecting the womb lining. Together, this combination makes Angeliq effective in managing menopausal symptoms and preventing osteoporosis.

Before you use Angeliq Tablet

- When you must not use it

Do not take Angeliq if you have, or have ever had any of the conditions listed below. If any of these apply to you, tell your doctor who will be able to advise you further.

- you are allergic to estradiol hemihydrate and drospirenone or any other ingredients of this medicine (listed in Product Description)
- if you have unexplained vaginal bleeding.
- if you have or suspected of having breast cancer.
- if you have or suspected of having cancer that is sensitive to sex hormones.
- if you have or have had liver tumors (non-cancerous or cancerous).
- if you have severe liver or kidney disease and your laboratory values are abnormal
- if you recently had a heart attack and/or stroke caused by blood clot.
- if you have or have had a blood clot in the legs (deep venous thrombosis) or the lungs (pulmonary embolism).
- if you have a high risk of developing blood clots.
- if you have high levels of fat in your blood (triglycerides)
- if you are pregnant or breast-feeding.

- Before you start to use it

Check with your doctor or pharmacist before taking Angeliq if you have:

- Have or had blood clots, or anyone in your close family has had them (especially in the legs or lungs).
- Are overweight or have varicose veins.
- Are going to have surgery, be on bed rest, or have had a serious injury (risk of clotting increases).
- Have high blood pressure, high cholesterol, or high triglycerides (fat in the blood).
- Have diabetes, asthma, epilepsy

(seizures), or migraines.

- Have liver problems, gallstones, or had jaundice during pregnancy or hormone use.
- Have kidney disease and are taking potassium-sparing medication.
- Have or had uterine fibroids, endometriosis, or breast lumps.
- Have any skin conditions like chloasma (brown patches), especially if you sunburn easily.
- Have rare conditions like lupus (SLE), porphyria, otosclerosis (hearing issue), or chorea minor (involuntary movements).
- Have a hormone-related condition called hereditary angioedema.
- Are aged 65 or older, due to a possible increased risk of memory loss or dementia.

Your doctor will help you weigh the benefits and risks before starting Angeliq.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

You should not take Angeliq if you are pregnant. It is only meant for women who have gone through menopause. If you accidentally become pregnant while using Angeliq, stop taking it immediately and speak to your doctor.

Angeliq should not be used while breastfeeding. This is because small amounts of the medicine may pass into breast milk, which could affect your baby. Always talk to your doctor if you are breastfeeding or planning to.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may:

- have an influence on the blood levels of Angeliq,
- stop Hormone Replacement Therapy (HRT) from working properly,
- cause unexpected bleeding.

Inform your doctor or pharmacist if you are taking:

- Phenytoin, carbamazepine, primidone, barbiturates, oxcarbazepine, topiramate, felbamate (to treat seizures/epilepsy)
- Rifampicin (to treat tuberculosis and bacterial infections)
- Griseofulvin, fluconazole, itraconazole, ketoconazole, voriconazole (to treat fungal infections)
- John's wort (herbal supplement used for low mood and mild depression)
- Verapamil, diltiazem (to treat high blood pressure or heart rhythm problems)
- Clarithromycin, erythromycin (to treat bacterial infections)
- HIV and Hepatitis C medicines (to treat viral infections)
- Enalapril, lisinopril (to treat high blood pressure and heart failure – ACE inhibitors)
- Losartan, valsartan (to treat high blood pressure and protect the heart – angiotensin II blockers)
- Spironolactone (to treat fluid retention and high blood pressure)
- Ibuprofen, naproxen (to relieve pain, inflammation, and fever)
- Grapefruit juice (may interfere with hormone metabolism)

How to use Angeliq Tablet

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- If you haven't used estrogen before, or if you are switching from a continuous

combination hormone treatment, you can start Angeliq anytime.

- If you are switching from a hormone treatment that is taken in cycles, finish your current cycle before starting Angeliq.

How much to use

Each blister pack is for 28 days of treatment. You have to take one tablet daily.

When to use it

Take one tablet daily, every day without breaks between packs, preferably at the same time every day.

- How long to use it

Take this medicine for the duration that your doctor recommends.

- If you forget to use it

If you are less than 24 hours late, take your tablet as soon as possible. Take the next one at your normal time.

But if you are more than 24 hours late, leave the forgotten tablet in the blister pack. Continue to take the remaining tablets at the usual time every day.

If you miss several tablets in a row, unexpected bleeding or spotting may occur. If this happens, tell your doctor, as they may need to check your treatment or give you advice on what to do next.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea and vomiting and light or period-like bleeding. No specific treatment is necessary but you should consult your doctor if you are concerned.

While you are using Angeliq Tablet

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using Angeliq.

Tell your doctor immediately if you become pregnant while using this medication.

Take Angeliq only with a doctor's prescription

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give Angeliq to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Inform the nurse or lab that you are on hormone therapy before doing any blood tests, as it may affect the results.

Do not take/drink alcohol while using Angeliq.

Stop Angeliq immediately and see a doctor if you experience:

- Your first-ever migraine or worse-than-usual migraines
- Severe or frequent headaches
- Sudden changes in vision or hearing
- Painful, swollen veins (possible phlebitis)
- Signs of a blood clot such as coughing up blood, unusual pain or swelling in your arms or legs, sudden shortness of breath, fainting.
- If you experience bleeding after a long time without periods
- You develop jaundice (yellowing of the skin or eyes)
- Show signs of gallbladder or liver issues, like stomach pain or dark urine.
- Feel a lump in your breast or notice any breast changes
- Develop or worsen depression, anxiety, or mood changes.

You should also have regular check-ups (e.g., breast exams, blood pressure checks, and possibly pelvic exams) while using Angeliq.

Side effects

Like all medicines, Angeliq can cause side effects, although not everybody gets them.

Possible side effects are:

Very common side effects:

- Breast pain or discomfort
- Bleeding from the vagina
- Stomach pain or cramps

Common side effects

- Feeling emotionally unstable (mood swings).

Uncommon or other possible side effects:

- Blood clots in the legs, lungs, heart (can lead to stroke or heart attack)
- Migraine headaches
- Possible memory problems if started after age 65
- Breast cancer (slight increase in risk)
- Cervical polyps
- Growth of fibroids
- Reactivated endometriosis
- Abnormal vaginal bleeding
- Gallstones
- Liver problems or yellowing of the skin (jaundice)
- Pancreatitis due to high fat levels in the blood
- Brown patches on face (chloasma)
- Rash, itching or allergic reactions
- Increased blood fat (triglycerides)

- Possible changes in blood sugar control (especially in diabetics)
- Weight gain or loss
- Swelling of face or body (angioedema)
- Increased size of benign tumors like prolactinoma
- Worsening of conditions like asthma, epilepsy, lupus, porphyria, or migraines

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nppra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Angeliq Tablet

- Storage

Keep this medicine out of the sight and reach of children.

Store below 30°C

Do not use this medicine after the expiry date which is stated on the box.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Medium red film-coated tablet.

- Ingredients

- Active ingredients
 - Estradiol hemihydrate
 - Drospirenone

- Ingredients

- Inactive ingredients
 - Ferric Oxide Pigment, Red E172
 - Talc
 - Titanium Dioxide E171
 - Magnesium Stearate
 - Hydroxypropyl Methylcellulose
 - Maize Starch
 - Povidone 25000
 - Lactose Monohydrate
 - Modified Starch
 - Purified Water
 - Macrogol 6000

- MAL number(s):

MAL20061594ARZ

Manufacturer

Bayer Weimar GmbH und Co. KG
Dobereinerstrasse 20
99427 Weimar
Germany

Product Registration Holder

Bayer Co. (Malaysia) Sdn. Bhd.
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