

ANGELIQ® 1/2

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using ANGELIQ® 1/2?

ANGELIQ® 1/2 contains the active ingredients estradiol and drospirenone. ANGELIQ® 1/2 provides hormone replacement therapy (HRT) for the treatment of menopausal complaints in postmenopausal women.

ANGELIQ® 1/2 is not a contraceptive. It will not prevent you from falling pregnant.

For more information, see Section [1. Why am I using ANGELIQ® 1/2?](#) in the full CMI.

2. What should I know before I use ANGELIQ® 1/2?

Do not use if you have ever had an allergic reaction to estradiol, drospirenone, or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant, plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ANGELIQ® 1/2?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ANGELIQ® 1/2 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ANGELIQ® 1/2?

Take one tablet daily at about the same time each day. Swallow the tablets whole with a full glass of water. It does not matter if you take this medicine before or after food.

More instructions can be found in Section [4. How do I use ANGELIQ® 1/2?](#) in the full CMI.

5. What should I know while using ANGELIQ® 1/2?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using ANGELIQ® 1/2.Check your breasts each month and report any changes promptly to your doctor.
Things you should not do	<ul style="list-style-type: none">Do not take ANGELIQ® 1/2 to treat any other complaints unless your doctor tells you to.Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">No effects on the ability to drive and use machines have been observed.
Drinking alcohol	<ul style="list-style-type: none">Tell your doctor if you drink alcohol.Excess intake of alcohol during use of HRT has an influence on the treatment.
Looking after your medicine	<ul style="list-style-type: none">Store below 30°C. Store it in a cool dry place away from moisture, heat or sunlight.Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while using ANGELIQ® 1/2?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention. Ask your doctor or pharmacist if you have any further questions about side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: The Women’s Health Initiative (WHI) trial examined the health benefits and risks of combined *estrogen plus progestogen* therapy (n=16,608) and *estrogen-alone* therapy (n=10,739) in postmenopausal women aged 50 to 79 years.

The estrogen plus progestogen arm of the WHI trial indicated an increased risk of *myocardial infarction (MI)*, *stroke*, *invasive breast cancer*, *pulmonary embolism and deep vein thrombosis* in postmenopausal women receiving treatment with combined conjugated equine estrogens (CEE, 0.625 mg/day) and medroxyprogesterone acetate (MPA, 2.5 mg/day) for 5.2 years compared to those receiving placebo.

The estrogen-alone arm of the WHI trial indicated an increased risk of stroke and deep vein thrombosis in hysterectomized women treated with CEE-alone (0.625 mg/day) for 6.8 years compared to those receiving placebo.

Other doses of oral conjugated estrogens with medroxyprogesterone acetate, and other combinations and dosage forms of estrogens and progestogens were not studied in the WHI clinical trials and, in the absence of comparable data, these risks should be assumed to be similar.

Therefore, the following should be given serious consideration at the time of prescribing:

- Estrogens with or without progestogens should not be prescribed for primary or secondary prevention of cardiovascular diseases.
- Estrogens with or without progestogens should be prescribed at the lowest effective dose for the approved indication.
- Estrogens with or without progestogens should be prescribed for the shortest period possible for the approved indication.
- For the prevention of osteoporosis, estrogen treatment should be considered in light of other available therapies.

ANGELIQ® 1/2 (Anne-gel-eeek)

Active ingredient(s): *estradiol and drospirenone*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ANGELIQ® 1/2. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ANGELIQ® 1/2.**

Where to find information in this leaflet:

- [1. Why am I using ANGELIQ® 1/2?](#)
- [2. What should I know before I use ANGELIQ® 1/2?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ANGELIQ® 1/2?](#)
- [5. What should I know while using ANGELIQ® 1/2?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ANGELIQ® 1/2?

ANGELIQ® 1/2 contains the active ingredients **estradiol and drospirenone**. Estradiol is an estrogen hormone and drospirenone is a progestogen hormone. During menopause, the estradiol production of the ovaries declines. Although menopause is natural, it often causes distressing symptoms, which are connected with the gradual loss of the hormones produced by the ovaries. ANGELIQ® 1/2 replaces the hormones that the body no longer makes and prevents or relieves symptoms such as hot flushes, sweats, sleep disturbances and nervousness.

ANGELIQ® 1/2 provides hormone replacement therapy (HRT) for the treatment of menopausal complaints in postmenopausal women. It is also used to treat symptoms due to decreased activity from the sexual organs (hypogonadism), after removal of the ovaries (ovariectomy) or when the ovaries do not work (primary ovarian failure).

ANGELIQ® 1/2 is only intended for short term use.

ANGELIQ® 1/2 should only be used by women who have not had their uterus removed (hysterectomy). If you have had a hysterectomy, your doctor will prescribe another form of estrogen therapy.

ANGELIQ® 1/2 is not a contraceptive. It will not prevent you from falling pregnant.

2. What should I know before I use ANGELIQ® 1/2?

Warnings

Do not use ANGELIQ® 1/2 if you:

- are allergic to estradiol and/or drospirenone, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- have undiagnosed vaginal bleeding.
- have breast cancer or a suspicion of breast cancer.
- have other tumours (including liver tumours) or a suspicion of other tumours.
- have severe liver disease.
- have a history of or have severe renal disease.
- have had a heart attack and/or stroke.

- have a history of or are at a high risk of a blood clot in the blood vessels of the legs (deep venous thrombosis) or the lungs (pulmonary embolism).
- have high levels of fat in the blood (triglycerides).

Tell your doctor if you:

- are overweight.
- have varicose veins.
- or anyone in your immediate family has had blood clots in the legs (thrombosis).
- have any hospitalisation, surgery or prolonged immobilization.

If you have any of the above risk factors, you have an increased risk of a blood clot while you are taking ANGELIQ® 1/2. The risk also increases with age.

Taking ANGELIQ® 1/2 may increase your risk of coronary heart disease. Tell your doctor if you experience chest pain or discomfort.

Taking ANGELIQ® 1/2 may increase your risk of gall bladder disease. This is because estrogen stimulates the liver to remove more cholesterol from blood and divert it to the gall bladder.

Before starting ANGELIQ® 1/2, your doctor should conduct a thorough medical and gynaecological examination (including the breasts). Your doctor should conduct this examination periodically. If you have liver disease, your doctor will also conduct liver function tests from time to time. Your doctor will also note your family medical history and exclude pregnancy.

Tell your doctor if you have any of the following medical conditions:

- high blood pressure
- kidney or liver disease
- jaundice (yellowing of the skin and/or eyes) during pregnancy or while on other hormone treatments
- high levels of fat in the blood
- diabetes
- abnormal vaginal bleeding
- tumours in your womb or pituitary gland
- endometriosis (the presence of tissue of the lining of the womb in places in the body where it is not normally found)
- chloasma (yellow brown patches on the skin)
- epilepsy
- lumpy or painful breasts (benign breast disease)
- asthma
- porphyria (an inherited disease where the body cannot convert naturally occurring compounds into haem, which contains iron)
- hearing loss caused by an abnormal bone growth in the ear (otosclerosis)
- systemic lupus erythematosus (SLE; a chronic inflammatory disease)
- chorea minor (involuntary movement disorder)
- hereditary angioedema (repeated episodes of severe swelling)

If HRT is used in the presence of any of the conditions listed above you will need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to take ANGELIQ® 1/2.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

ANGELIQ® 1/2 contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking it. Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Elderly, adolescents, and paediatric use

Tell your doctor if you are 65 years or older when HRT is initiated. The reason is that there is limited evidence from clinical studies that hormonal treatment may increase the risk of significant loss of intellectual abilities such as memory capacity (dementia).

Do not take this medicine if you are under 18 years old.

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant. It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine. The active ingredient in ANGELIQ® 1/2 passes into breast milk and there is a possibility that your baby may be affected.

Endometrial cancer

The risk of cancer of the lining of the womb (endometrial cancer) increases when estrogens are used alone for prolonged periods. The progestogen in ANGELIQ® 1/2 opposes this risk.

Please inform your doctor if you have frequent bleeding irregularities or persistent bleeding during the treatment with ANGELIQ® 1/2.

Breast cancer

Please inform your doctor if you have suffered from fibrocystic disease of the breasts (lumpy or painful breasts) or if you have first degree relatives (mother, sisters, daughters) who have had breast cancer.

Breast cancer has been diagnosed slightly more often in women who have used Hormone Replacement Therapy (HRT) for several years than in women of the same age who have never used HRT. The risk increases with duration of treatment. If you are concerned about this information you should discuss this with your doctor.

It is recommended that yearly breast examinations are conducted and regular breast self-examination (monthly)

should be carried out. HRT has been reported to result in an increased number of abnormal mammograms requiring further evaluation.

HRT increases the density of mammographic images. This may complicate the mammographic detection of breast cancer in some cases. Therefore your doctor may choose to use other breast cancer screening techniques as well.

Ovarian Cancer

Some observational studies have shown a slightly increased overall risk of developing ovarian cancer in women who have used HRT compared to women who have never used HRT. In women currently using HRT, this risk was further increased. These associations have not been shown in all studies. There is no consistent evidence that the risk of developing ovarian cancer is related to the duration of use of HRT. However, the risk may be more relevant with long-term use (for several years).

Liver tumour

During or after the use of hormones such as those that are contained in ANGELIQ® 1/2, benign liver tumours have rarely occurred, and malignant liver tumours even more rarely. In isolated cases, bleeding has occurred from such tumours into the abdominal cavity.

Although such events are rare, you should inform your doctor about any unusual pain in your upper abdomen that does not disappear within a short time.

3. What if I am taking other medicines?

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

Some medicines may interfere with ANGELIQ® 1/2 and affect how it works. These include:

- medicines to treat high blood pressure, chest pain and/or irregular heart beats such as ACE inhibitors, verapamil, diltiazem
- medicines used to treat epilepsy such as hydantoin, barbituates, primidone, carbamazepine
- rifampicin for the treatment of tuberculosis
- macrolide antibiotics (e.g. clarithromycin, erythromycin)
- herbal medicines containing St John's Wort
- medicines used to treat HIV such as ritonavir or nevirapine
- some medicines used to treat Hepatitis C Virus (HCV) such as boceprevir, telaprevir
- anticoagulants, medicines used to thin blood and to treat or prevent blood clots
- medicines used to treat fungal infections such as ketoconazole, itraconazole, voriconazole, fluconazole
- medicines used to treat pain and inflammation (e.g. ibuprofen, diclofenac)
- grapefruit juice

These medicines may be affected by ANGELIQ® 1/2 or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ANGELIQ® 1/2.

4. How do I use ANGELIQ® 1/2?

How much to take

- Take one tablet daily at about the same time each day.
- Swallow the tablets whole with a full glass of water. It does not matter if you take this medicine before or after food.
- Follow the instructions provided and use ANGELIQ® 1/2 until your doctor tells you to stop.

When to take ANGELIQ® 1/2

- If you are using HRT for the first time or if you change from a continuous combination HRT product (each of the tablets contains the same ingredients), you may begin taking ANGELIQ® 1/2 at any time.
- If you are changing from a sequential combined HRT treatment (tablets differ in their ingredients, which is made visible with different colours), you should start ANGELIQ® 1/2 at the end of the scheduled bleeding.

How long to take ANGELIQ® 1/2

- ANGELIQ® 1/2 is only intended for short term use. Your doctor will advise you on how long to use ANGELIQ® 1/2. Your doctor should discuss with you the risks and benefits with extended use of this product and your treatment with hormone therapy should also be re-evaluated at regular intervals.
- You may have an increased risk of developing breast cancer, heart disease, stroke, blood clots including clots in the lungs, and dementia. On the other hand, the risk of hip fractures and bowel cancer may be reduced. Your doctor can discuss these risks and benefits with you, taking into account your particular circumstances.

If you forget to take ANGELIQ® 1/2

ANGELIQ® 1/2 should be used regularly at the same time each day. If you are less than 24 hours late take your tablet as soon as possible, and take the next one at the normal time.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you miss tablets for several days, irregular bleeding may occur.

If you use too much ANGELIQ® 1/2

If you think that you have used too much ANGELIQ® 1/2, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ANGELIQ® 1/2?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using ANGELIQ® 1/2.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ANGELIQ® 1/2.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

The use of HRT may affect the results of certain laboratory tests. If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

See your doctor at least once a year for a check-up. Some women will need to go more often. Your doctor will:

- check your breasts and order a mammogram at regular intervals.
- check your uterus and cervix and do a pap smear at regular intervals.
- monitor your blood pressure.

Check your breasts each month and report any changes promptly to your doctor. Your doctor or nurse can show you how to check your breasts properly.

Stop taking ANGELIQ® 1/2 immediately

Call your doctor straight away if you become pregnant while taking this medicine.

You should stop treatment at once and consult your doctor if you have any of the following conditions:

- your very first attack of migraine (typically a throbbing headache and nausea preceded by visual disturbances).
- worsening of pre-existing migraine, any unusually frequent or unusually severe headaches.
- sudden disturbances of vision or hearing.
- swollen veins (phlebitis).
- if you have existing benign tumours in your womb, your doctor will organise scans to monitor your tumours as ANGELIQ® 1/2 can increase the size of tumours.

If you get a blood clot while you are taking ANGELIQ® 1/2 or if you suspect this has happened, you should stop taking it immediately and contact your doctor. Warning signs to look out for are:

- coughing blood
- unusual pains or swelling of your arms or legs
- sudden shortness of breath
- fainting.

ANGELIQ® 1/2 must also be stopped at once if you develop jaundice (yellowing of the skin and/or eyes). Tell your doctor immediately if this occurs.

Things you should not do

- Do not take ANGELIQ® 1/2 to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine without checking with your doctor. If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If your bleeding pattern seems different

ANGELIQ® 1/2 has been made to provide you with hormone replacement therapy without cyclical bleeding. You may, however, get some bleeding during the first few months of treatment. It could occur at any time but it is unlikely to be heavy. Bleeding episodes should eventually get less and finally stop.

If significant bleeding continues or if at any time bleeding or spotting becomes unacceptable for you, ask your doctor whether you should discontinue treatment or change to a sequential therapy.

If bleeding occurs after a prolonged interval of not having period like bleeding, talk to your doctor, as this may need to be investigated.

Drinking alcohol

Tell your doctor if you drink alcohol.

Excess intake of alcohol during use of HRT has an influence on the treatment. Your doctor will advise you.

Looking after your medicine

- Store below 30°C.
- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

During the first few months of treatment you may experience some vaginal bleeding at unexpected times (breakthrough bleeding and spotting). These are usually temporary and normally subside with continued use. If they do not, contact your doctor. Breast pain was a very common symptom.

Less serious side effects

Less serious side effects	What to do
<p>General disorders:</p> <ul style="list-style-type: none"> • abdominal pain • bloating • unusual tiredness or weakness • pain in the limbs <p>Digestive:</p> <ul style="list-style-type: none"> • nausea <p>Nervous system:</p> <ul style="list-style-type: none"> • headache • mood swings • hot flushes • nervousness <p>Skin and appendages:</p> <ul style="list-style-type: none"> • benign breast tumour • breast enlargement <p>Urogenital:</p> <ul style="list-style-type: none"> • tumours in the womb enlarged • tumour of the neck of the uterus (cervix) • white vaginal discharge • urinary tract infections or incontinence (uncontrollable, involuntary passing of urine). 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Immune system disorders:</p> <ul style="list-style-type: none"> • signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing <p>General disorders:</p> <ul style="list-style-type: none"> • coughing blood, unusual pains or swelling of your arms or legs, sudden shortness of breath, fainting <p>Skin and appendages:</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

<ul style="list-style-type: none"> • lumpy breasts • tingling, prickling or numbness of the skin <p>Cardiovascular system:</p> <ul style="list-style-type: none"> • chest pain 	
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Rarely, skin disorders have been reported in women receiving hormone replacement therapy. Tell your doctor if you notice itchy, reddish, painful lumps (erythema nodosum, erythema multiforme, haemorrhagic dermatitis) or yellow-brown patches on the skin (chloasma)

Occurrences of inflammatory bowel disease (an inflammatory disease that can affect any part of the gastrointestinal tract) have been reported in a study with women using HRT. However, based on current scientific knowledge, there is no clear evidence if HRT use causes inflammatory bowel disease.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ANGELIQ® 1/2 contains

Active ingredient (main ingredient)	1 mg of estradiol 2 mg of drospirenone
Other ingredients (inactive ingredients)	lactose monohydrate maize starch pregelatinised maize starch povidone magnesium stearate hypromellose macrogol 6000 purified talc titanium dioxide iron oxide red

Do not take this medicine if you are allergic to any of these ingredients.

What ANGELIQ® 1/2 looks like

ANGELIQ® 1/2 (Aust R 114816) is available in a calendar pack consisting of 7 or 28 red coloured tablets. Each tablet is marked with “DL” in a regular hexagon on one side.

Who distributes ANGELIQ® 1/2

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

www.bayer.com.au

This leaflet was prepared in December 2021.

See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.



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