

ANGELIQ® 1/2

(Anne gel eek)

oestradiol and drospirenone

Consumer Medicine Information

Warning

The Women's Health Initiative (WHI) trial examined the health benefits and risks of combined oestrogen plus progestogen therapy (n=16,608) and oestrogen-alone therapy (n=10,739) in postmenopausal women aged 50 to 79 years. The oestrogen 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 oestrogens (CEE, 0.625 mg/day) and medroxyprogesterone acetate (MPA, 2.5 mg/day) for 5.2 years compared to those receiving placebo.

The oestrogen-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 oestrogens with medroxyprogesterone acetate, and other combinations and dosage forms of oestrogens 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:

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

WHAT IS IN THIS LEAFLET

This leaflet answers some of the common questions about Angeliq 1/2 tablets. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Angeliq 1/2 against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

WHAT ANGELIQ 1/2 IS USED FOR

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 tablets contain oestradiol, an oestrogen hormone and drospirenone, a progestogen hormone. During menopause, the oestradiol 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 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 oestrogen therapy.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE ANGELIQ 1/2

When you must not take it

Do not take Angeliq 1/2 if you have an allergy to:

- oestradiol and/or drospirenone, the active ingredients in Angeliq 1/2
- any of the ingredients listed at the end of this leaflet.

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.

Do not take Angeliq 1/2 if you have:

- undiagnosed vaginal bleeding
- breast cancer or a suspicion of breast cancer
- other tumours (including liver tumours) or a suspicion of other tumours
- severe liver disease
- a history of or have severe renal disease
- had a heart attack and/or stroke
- 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)
- high levels of fat in the blood (triglycerides)

If any of these conditions appear for the first time while taking Angeliq 1/2, stop taking it at once and consult your doctor.

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.

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

Do not take this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after "EXP" (e.g. 11 13 refers to November 2013). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

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

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 oestrogen 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 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)

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).

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.

HRT and cancer

Endometrial cancer

The risk of cancer of the lining of the womb (endometrial cancer) increases when oestrogens 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.

If you have not told your doctor about any of the above, tell him/her before you start taking Angeliq 1/2.

Taking other medicines

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

Some medicines and Angeliq 1/2 may interfere with each other. 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 hydantoins, 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE ANGELIQ 1/2

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.

How to take it

Take one tablet daily at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it. It

does not matter if you take this medicine before or after food.

Swallow the tablets whole with a full glass of water.

When to take it

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 it

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 it

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice, or go to

Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Angeliq 1/2.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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.

WHILE YOU ARE TAKING ANGELIQ 1/2

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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 it immediately

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.

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

Things you must 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.

What to be careful of

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

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Angeliq 1/2.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- abdominal pain
- bloating
- unusual tiredness or weakness
- pain in the limbs
- nausea
- headache
- mood swings
- hot flushes
- nervousness
- benign breast tumour
- breast enlargement
- 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).

Tell your doctor immediately, or go to Accident and Emergency department at your nearest hospital if you notice any of the following:

- 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
- coughing blood, unusual pains or swelling of your arms or legs, sudden shortness of breath, fainting
- lumpy breasts
- tingling, prickling or numbness of the skin
- chest pain

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 that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Also tell your doctor if you have any of the symptoms listed under “While you are taking Angeliq 1/2 - stop taking it immediately”.

AFTER TAKING ANGELIQ 1/2

Storage

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.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

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PRODUCT DESCRIPTION

What it looks like

Angeliq 1/2 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.

Ingredients

Active ingredients per tablet:

- Angeliq 1/2 -1 mg of oestradiol and 2 mg of drospirenone

Inactive ingredients:

- lactose
- maize starch
- pregelatinised maize starch
- povidone
- magnesium stearate
- hypromellose
- macrogol 6000
- purified talc
- titanium dioxide
- iron oxide red

Supplier

Made in Germany for:

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

Australian Registration Number

AUST R 114816

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