

DUAVIVE® 0.45/20

Conjugated estrogens/bazedoxifene

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DUAVIVE. It does not contain all 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 DUAVIVE 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 DUAVIVE is used for

This medicine is used for the treatment of symptoms, such as "hot flushes" and sweating, which are associated with menopause in women who still have their uterus (womb).

How DUAVIVE works

This medicine contains two active substances called conjugated estrogens and bazedoxifene. Conjugated estrogens belong to a group of medicines called menopausal hormone therapy (MHT), also known as hormone replacement therapy (HRT). Bazedoxifene belongs to a group of non-hormonal medicines called selective estrogen receptor modulators (SERMs).

Menopause occurs naturally in women, typically between the ages of 45 and 55. During menopause, your body produces less estrogen than it did beforehand. This can cause symptoms such as "hot flushes".

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.

This medicine is not addictive.

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

Before you take DUAVIVE

When you must not take it

DUAVIVE should only be taken if you have been fully informed of the risks.

The decision to take DUAVIVE should be based on your particular needs and health and made after a careful medical evaluation.

Talk regularly with your doctor about whether you still need treatment with DUAVIVE.

Do not take DUAVIVE if you have an allergy to:

- any medicine containing conjugated estrogens or bazedoxifene
- any of the ingredients listed at the end of this leaflet
- any other similar medicines.

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 DUAVIVE if you have, or have had, any of the following medical conditions:

- breast cancer or suspected breast cancer
- estrogen-dependent cancers or suspected estrogen-dependent cancers. Examples include endometrial cancer

- recent unexplained vaginal bleeding
- excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated
- blood clot in a vein (thrombosis), such as in the legs (deep vein thrombosis, DVT), the lungs (pulmonary embolism) or eyes
- blood clotting disorder (such as protein C, protein S, or antithrombin deficiency)
- disease caused by blood clots in the arteries, such as a heart attack, stroke or angina
- liver disease or where your liver function tests have not returned to normal
- rare blood problem called porphyria, which is passed down in families (inherited).

This medicine is for use only by postmenopausal women with a uterus. Do not take this medicine if you are pregnant, or if you think you might be pregnant. Do not take this medicine if you are breast-feeding.

Do not give DUAVIVE to a child.

This medicine is not suitable for use in children.

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or the package 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

You must have a thorough medical check-up before starting DUAVIVE for the first time or if you are taking it again after a break.

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

Tell your doctor if you are taking other menopausal hormonal therapy (e.g., other estrogens, progestogens) or other SERMS e.g., raloxifene (a medicine used to prevent or treat osteoporosis), clomiphene or tamoxifen.

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

- fibroids inside your womb
- growth of womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- increased risk of developing blood clots

- have or are at increased risk of getting an estrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure
- any problems with your liver
- diabetes
- gallstones
- migraine or severe headaches
- a rare disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- seizures (epilepsy)
- asthma
- a disease affecting the eardrum and hearing (otosclerosis)
- a high level of fat in your blood (triglycerides)
- fluid retention due to heart or kidney problems.
- problems with your parathyroid gland
- angioedema (a condition where fluid build-up causes swelling under the skin particularly on the face, hands, feet, eyes and lips)

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

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains lactose monohydrate, sucrose, sorbitol, glucose (in maltitol liquid, a type of sugar).

There is no experience in treating women with premature menopause (due to ovarian failure or surgery).

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, naturopath or health food shop. In particular, other menopausal hormonal therapy (e.g., other estrogens, progestogens) or other SERMS e.g., raloxifene (a medicine used to prevent or treat osteoporosis), clomiphene or tamoxifen).

Some medicines and DUAVIVE may interfere with each other. These include:

- medicines to treat epilepsy such as phenobarbital, phenytoin, carbamazepine
- some antibiotics and anti-infectives such as rifampicin, rifabutin, erythromycin, clarithromycin
- anti-fungal agents such as ketoconazole and itraconazole
- anti-virals such as ritonavir, efavirenz and nevirapine

- St John's Wort (*Hypericum perforatum*).

These medicines may be affected by DUAVIVE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Avoid grapefruit juice, as it may also affect how well DUAVIVE works.

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

How to take DUAVIVE

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 on the box, ask your doctor or pharmacist for help.

How much to take

The recommended dose is one tablet taken once daily.

How to take it

Swallow the tablet whole with a full glass of water. Do not divide, crush, chew, or dissolve the tablet in your mouth.

When to take it

Take your medicine 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.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

DUAVIVE should be taken for the shortest time possible and only for as long as treatment is needed. You and your doctor should talk regularly about whether you still need treatment with DUAVIVE.

If you forget to take it

If you forget to take a tablet, take it as soon as you remember.

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

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

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 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 DUAVIVE.

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

You may need urgent medical attention.

Symptoms of an overdose may include:

- feeling sick or vomiting
- breast tenderness
- dizziness
- stomach pain
- feeling sleepy or tired
- a short period of vaginal bleeding.

While you are taking DUAVIVE

Things you must do

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

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

If you are going to have surgery (or your movement is restricted), tell the surgeon or anaesthetist that you are taking this medicine.

You may need to stop taking DUAVIVE about 4 to 6 weeks before the operation, to reduce the risk of a blood clot. Ask your doctor when you can start taking this medicine again.

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

DUAVIVE should not be taken while you are pregnant.

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.

Keep all of your doctor's appointments so that your progress can be checked.

Once you have started this medicine you should see your doctor for regular check-ups (at least once a year). During

these check-ups, discuss with your doctor the benefits and risks of continuing with DUAVIVE. You are advised to:

- go for regular breast screening (mammograms), pelvic exams and cervical smear (pap) tests, as recommended by your doctor.
- regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple, or any lumps you can see or feel.

Tell your doctor right away if you get any unusual vaginal bleeding while you are taking DUAVIVE.

Vaginal bleeding after menopause may be a warning sign of cancer of the uterus (womb).

Things you must not do

Do not take DUAVIVE 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 or lower the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how DUAVIVE affects you.

This medicine may cause drowsiness, blurred vision or a reduction in the sharpness of your vision in some people. If

you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DUAVIVE.

This medicine helps most people with menopausal symptoms, but it may have unwanted side effects in a few people. 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 list of side effects. You may not experience any of them.

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

Go to hospital if...

Stop taking DUAVIVE and tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- any of the conditions mentioned under the section 'Do not take DUAVIVE...' above
- a severe allergic reaction - symptoms may include sudden wheezing and chest pain or tightness, swelling of the

eyelids, face, lips, mouth, tongue or throat, difficulty breathing, collapse

- if you have swelling of the eyes, nose, lips, mouth, tongue or throat, difficulty in breathing, severe dizziness or fainting, skin rash (symptoms of angioedema)
- a large increase in your blood pressure (symptoms may be headache, tiredness, dizziness)
- you notice signs of a blood clot, such as painful swelling and redness of the legs, sudden chest pain, or difficulty in breathing.
- loss of vision, pain and swelling of the eye or eyelid, especially if sudden.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of liver disease.
- blurred vision
- reduction in the sharpness of your vision
- dry eyes

- difficulty in opening your eyes.
- you see a halo around lights, sparks or lights when your eyes are closed.

The above list includes serious side effects that may require medical attention. Serious side effects are uncommon.

Tell your doctor if...

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

- abdominal pain (stomach ache)
- muscle spasms
- constipation
- diarrhoea
- nausea
- thrush (vaginal yeast infection).

The above list includes the more common side effects of your medicine.

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

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

Some of these side effects (for example, changes in thyroid function, blood pressure or cholesterol level) can only be found when your doctor does tests from time to time to check your progress.

After taking DUAVIVE

Storage

Keep your tablets in the blister pouch until it is time to take them.

If you take the tablets out of the blister pouch they may not keep well.

After opening the blister pouch, use all tablets within 60 days.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

Product description

What it looks like

The DUAVIVE 0.45 mg/20 mg modified-release tablet is a pink, oval-shaped, tablet marked on one side with "0.45/20".

The tablets are provided in PVC/Aclar[®]/PVC/Al blister packs containing 28 tablets.

Ingredients

DUAVIVE contains 0.45 mg of conjugated estrogens and bazedoxifene acetate equivalent to 20 mg bazedoxifene as active ingredients.

It also contains:

- lactose monohydrate
- microcrystalline cellulose
- powdered cellulose
- hypromellose
- magnesium stearate

- calcium phosphate
- sucrose
- hypolose
- macrogol 400
- sucrose palmitate
- ascorbic acid
- Opadry pink
- Opaglos 2 clear
- Opacode black ink.

Supplier

DUAVIVE is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney, NSW.

Toll Free Number: 1800 675 229.

www.pfizermedicalinformation.com.au/

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