

AUSCAP

contains the active ingredient fluoxetine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about AUSCAP.

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 benefits and risks. Your doctor has weighed the risks of you taking AUSCAP against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What AUSCAP is used for

AUSCAP is used to treat:

- depression
- obsessive compulsive disorder (OCD)
- premenstrual dysphoric disorder (PMDD).

AUSCAP belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). SSRIs are thought to work by their action on brain chemicals called amines which are involved in controlling mood.

Your doctor may have prescribed AUSCAP for another reason. Ask your doctor if you have any questions about why AUSCAP has been prescribed for you.

AUSCAP is not recommended for use in children and adolescents under the age of 18 years of age.

AUSCAP is available only with a doctor's prescription.

Before you take AUSCAP

When you must not take it

Do not take AUSCAP if you are allergic to medicines containing fluoxetine or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take AUSCAP if you are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have taken a MAOI within the last 14 days. Check with your doctor or pharmacist if you are unsure as to whether you are taking a MAOI.

If you take AUSCAP while you are taking a MAOI, you may experience tremors, shivering, muscle stiffness, fever, a rapid pulse, rapid breathing or confusion.

Do not take AUSCAP if you are taking another medicine called pimozide to treat disturbances in thinking, feelings and behaviour.

Talking pimozide and AUSCAP together may alter the rhythm of your heart.

Do not take AUSCAP if the expiry date (Exp.) printed on the pack has passed.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking AUSCAP during pregnancy. If AUSCAP is taken during pregnancy, you should be careful, particularly at the end of pregnancy. Transitory withdrawal symptoms have been reported rarely in the newborn after maternal use in the last 3 months of pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking AUSCAP when breastfeeding.

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

- liver problems
- kidney problems
- fits
- diabetes
- a bleeding disorder or a tendency to bleed more than usual.

Tell your doctor if you drink alcohol.

Although drinking alcohol is unlikely to affect your response to AUSCAP, your doctor may suggest avoiding alcohol while you are being treated for depression.

If you have not told your doctor about any of the above, tell them before you start taking AUSCAP.

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 be affected by AUSCAP, or may affect how well it works. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat some types of depression.

You should stop taking MAOIs at least two weeks before starting AUSCAP.

- lithium, a medicine used to treat mood swings and some types of depression
- other medicines for depression, obsessive compulsive disorder or premenstrual dysphoric disorder
- sleeping tablets or sedatives
- medicines used to relieve anxiety
- medicines used to treat certain mental and emotional conditions, also called antipsychotics
- medicines used to treat disturbances in thinking, feelings and behaviour, such as pimozide
- medicines used to control fits
- medicines used to prevent blood clots, such as warfarin
- flecainide, a medicine used to treat some heart conditions
- tryptophan
- St John's Wort
- medicines used to treat pain, such as tramadol
- sumatriptan, a medicine used to treat migraine.
- tamoxifen, a medicine used to treat or prevent breast cancer.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

Do not start taking other medicines for depression without checking with your doctor. Do this even if you have already stopped taking AUSCAP.

Monoamine oxidase inhibitors (MAOIs), which are other medicines used for depression, may interfere with AUSCAP. You should not start taking a MAOI for at least 5 weeks after stopping AUSCAP.

How to take AUSCAP

How much to take

The usual dose is one capsule taken once a day. Your doctor may increase this dose depending on your condition.

For premenstrual dysphoric disorder, AUSCAP may be prescribed to be taken only during a certain part of the month. Your doctor will prescribe the dosing schedule that is right for you.

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

How to take AUSCAP

Swallow the capsules with a glass of water.

If you forget to take AUSCAP

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

Otherwise, take the missed dose as soon as you remember, and then go back to taking your capsules as you would normally.

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

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

How long to take AUSCAP for

Keep taking AUSCAP for as long as your doctor recommends.

The length of treatment will depend on how quickly your symptoms improve.

Most medicines of this type take time to work so don't feel discouraged if you do not feel better right away. While some symptoms may be relieved sooner than others, it commonly takes two to four weeks before improvement is really apparent.

If you take too much AUSCAP (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much AUSCAP. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much AUSCAP, you may feel nauseous, vomit, feel restless, agitated or excited.

While you are taking AUSCAP

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking AUSCAP.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking AUSCAP.

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

Visit your doctor regularly so they can check on your progress.

If you are being treated for depression, be sure to discuss with your doctor any problems you may have and how you feel, especially any feelings of severe sadness or bursts of unusual energy or anger. This will help your doctor to determine the best treatment for you.

If you or someone you know is demonstrating any of the following warning signs, especially if you or they are under 25 years of age, tell your doctor or a mental health professional immediately or go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self harm
- increase in aggressive behaviour, irritability or agitation.

All thoughts or talk of suicide must be taken seriously.

Things you must not do

Do not stop taking AUSCAP, or lower the dose, without checking with your doctor.

Stopping AUSCAP suddenly may cause dizziness, anxiety, headache, nausea or tingling and numbness of your hand or feet. Your doctor may want you to gradually reduce the amount of AUSCAP you are taking before stopping completely.

Do not take the herbal remedy St. John's Wort while you are being treated with AUSCAP. If you are already taking the herbal remedy, stop taking St. John's Wort and mention it to your doctor at your next visit.

Do not use AUSCAP to treat any other conditions unless your doctor tells you to.

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

Things to be careful of

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

AUSCAP may cause drowsiness, dizziness or lightheadedness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

Like all other medicines, AUSCAP may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- nausea, vomiting
- upset stomach, diarrhoea
- loss of appetite, weight loss
- changes in taste
- dry mouth
- trouble sleeping, unusual dreams
- nervousness, anxiety
- drowsiness
- weakness
- dizziness
- excessive sweating, flushing, chills

- lesions of the skin or mucous membrane
- fever and joint aches
- sexual problems
- more frequent urination
- changes in vision.

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

- itching, skin rash or hives
- shortness of breath, wheezing or trouble breathing
- swelling of the face, lips, tongue or other parts of the body
- muscle spasms
- tremors
- twitches
- convulsions or fits
- fast, irregular heart beat
- abnormal bleeding or bruising
- sudden switches of mood to one of overactivity and uninhibited behaviour.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Children and Adolescents

Headaches are very common side effects.

Weight loss and decreased height gain have been observed in association with the use of AUSCAP in children and adolescent patients. This is similar to other medicines that belong to the group of medicines called selective serotonin reuptake inhibitors (SSRIs).

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

After using AUSCAP

Storage

Keep AUSCAP 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.

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

Do not store AUSCAP or any other medicine in the bathroom or near a sink.

Do not leave AUSCAP in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking AUSCAP, or your capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

AUSCAP is a capsule with an opaque light green cap and opaque ivory body containing a white, odourless powder.

Each pack contains 28 capsules.

Ingredients

The active ingredient in AUSCAP is fluoxetine. Each AUSCAP capsule contains 20 mg of fluoxetine.

The capsules also contain:

- lactose
- microcrystalline cellulose
- colloidal anhydrous silica
- magnesium stearate
- gelatin
- titanium dioxide
- iron oxide yellow CI77492

- quinoline yellow CI47005
- indigo carmine CI73015.

The capsules do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Aspen Pharma Pty Ltd
34-36 Chandos Street,
St. Leonards NSW 2065
Australia

Australian registration numbers:
AUSCAP - AUST R 140589

Date of preparation:
June 2011