

NOUMED ESCITALOPRAM

escitalopram (as oxalate) tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NOUMED ESCITALOPRAM.

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 taking this medicine against the benefits it is expected to 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 NOUMED ESCITALOPRAM is used for

NOUMED ESCITALOPRAM tablets contain the active ingredient escitalopram.

Escitalopram belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRI). They work by acting on brain chemicals called amines which are involved in controlling mood.

Imbalances in these chemicals can cause emotional and physical symptoms including being low in spirit, lacking interest in activities, inability to enjoy life, poor appetite or overeating, disturbed sleep or waking up too early, loss of sex drive, lack of energy and feelings of guilt.

Depression is longer lasting or more severe than the "low moods" that everyone has from time to time due to the stress of everyday life.

Escitalopram helps correct this brain chemical imbalance to relieve the symptoms of major depression.

NOUMED ESCITALOPRAM may also be used to treat obsessive-compulsive disorder (OCD), which involves having both obsessions and compulsions. Obsessions are unwanted thoughts that occur over and over again, while compulsions are ongoing needs to repeat certain actions as a result of these thoughts.

NOUMED ESCITALOPRAM should not be used by children or adolescents below 18 years old.

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

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.

NOUMED ESCITALOPRAM is not addictive, but you may get side effects if you stop taking it suddenly.

Before you take it

When you must not take it

Do not take this medicine if you have an allergy to escitalopram, citalopram, similar medicines (e.g. SSRI), or to any of the other ingredients listed at the end of this leaflet under Product Description.

Some of the symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty in

breathing; swelling of the face, lips tongue or other parts of the body; rash, itching or hives on the skin.

Do not take NOUMED ESCITALOPRAM if you are also taking the following medicines:

- pimozide, a medicine used to treat mental disorders
- monoamine oxidase inhibitors (MAOIs), such as phenelzine, tranylcypromine and moclobemide which are also used to treat depression; linezolid (an antibiotic); or selegiline (used for Parkinson's disease).

Taking escitalopram with MAOIs may cause a sudden increase in body temperature, extremely high blood pressure and severe convulsions.

Allow at least 1 day to elapse after taking your last dose of moclobemide, or at least 14 days for other MAOIs, before you start taking NOUMED ESCITALOPRAM.

Allow at least 14 days after stopping NOUMED ESCITALOPRAM treatment before starting on a MAOI, including moclobemide.

Your doctor can advise you when it is safe to start one treatment after stopping the other.

- medicines that are known to prolong the QT-interval.
Do not take NOUMED ESCITALOPRAM if you have a known QT-interval prolongation or congenital long QT syndrome.

Do not take this medicine after the expiry date printed on the pack or

if the packaging is torn or shows signs of tampering.

If you take it after the expiry date has passed, it may not work as well.

If it has expired or is damaged, return the pack 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 pregnant or plan to become pregnant.

If it is necessary for you to take this medicine, your doctor can discuss with you the potential risks and benefits.

If used during pregnancy, Noured Escitalopram should never be stopped abruptly.

Make sure your doctor and/or midwife knows you are taking NOUMED ESCITALOPRAM.

When taken during pregnancy, particularly in the last three months, medicines like escitalopram may affect the general condition of your newborn baby and may increase the risk of a serious condition called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born.

If this happens to your baby, you should contact your doctor and/or midwife immediately.

Discuss the risks and benefits with your doctor if you are breastfeeding or plan to breastfeed.

Escitalopram may appear in breast milk and it is not recommended to breastfeed while taking this medicine.

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

- a tendency to bleed or bruise easily
- diabetes
- heart disease
- kidney disease
- liver disease
- bipolar disorder (manic depression)
- a history of seizures or fits
- restlessness and/or a need to move often, difficulty sitting still
- raised intraocular pressure (fluid pressure in the eye), or if you are at risk of angle-closure glaucoma.

Tell your doctor if you are receiving electroconvulsive therapy.

Remind your doctor if you are over 65 years of age.

A lower dosage is recommended in the elderly.

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

Do not give NOUMED ESCITALOPRAM to a child or adolescent.

Its safety and use in children or adolescents under 18 years old have not been studied.

Taking other medicines

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

Some medicines and NOUMED ESCITALOPRAM may interfere with each other. See above section on 'Before you take it'. Other medicines that may interfere with escitalopram include:

- bupropion, used to treat nicotine dependence

- medicines used to treat reflux and stomach ulcers, such as cimetidine, omeprazole, esomeprazole and lansoprazole
- medicines known to prolong bleeding, e.g. aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- ticlopidine or warfarin, medicines used to prevent blood clots
- fluconazole, an anti-fungal medicine
- mefloquine, an anti-malaria medicine
- sumatriptan, used to treat migraines
- tramadol, used to relieve pain
- some heart medications, e.g. flecainide, propafenone, metoprolol
- tryptophan, an amino-acid
- St John's Wort (*Hypericum perforatum*), a herbal remedy
- lithium, used to treat mood swings and some types of depression
- antipsychotic medicines used to treat certain mental and emotional conditions, e.g. risperidone, thioridazine and haloperidol
- tricyclic antidepressants, e.g. imipramine, desipramine
- any other medicines for depression, anxiety, obsessive-compulsive disorder or premenstrual dysphoric disorder.

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

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

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

How to take NOUMED ESCITALOPRAM

How much to take

Your doctor will determine the dose that is suitable for you.

The usual dose is 10 mg per day, but your doctor can increase it to 20 mg per day.

For elderly patients, the recommended maximum dose is 10 mg per day.

For patients with liver disease, the dose may start at 5 mg per day for the first 2 weeks then increased to 10 mg per day.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you or do not understand the instructions.

They will tell you exactly how much to take.

Follow all directions they give you carefully.

If you take the wrong dose, NOUMED ESCITALOPRAM may not work as well and your condition may not be adequately controlled.

How to take it

Swallow the tablet with plenty of water. Do not chew them.

When to take it

Take your medicine as a single dose either in the morning or in the evening.

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

You can take the tablets with or without food.

How long to take it

Like other medicines used to treat these depression or OCD, it may take a few weeks before you feel any improvement.

Since individuals respond differently to treatment, your doctor will check your progress at regular intervals. Treatment usually lasts for at least 6 months.

You should continue taking NOUMED ESCITALOPRAM as long as your doctor tells you, even if you begin to feel better.

If you stop treatment too soon, your symptoms may return.

Do not stop taking this medicine suddenly.

If stopped suddenly, you may experience symptoms, usually mild and temporary, such as dizziness, pins and needles, electric shock sensations, disturbed sleep (vivid dreams, inability to sleep), feeling anxious or agitated, headaches, feeling sick (nausea), vomiting, sweating, tremor (shaking), feeling confused, feeling emotional or irritable, diarrhoea, visual disturbances, or fast or irregular heart beats.

Before you complete your treatment, the dose will be gradually reduced over a couple of weeks rather than stopped abruptly.

Your doctor will tell you how to lower your dose so that you do not get these unwanted effects.

If you forget to take it

If you realise that you have missed your dose within the past 12 hours, take it straight away, then continue to take it as you would normally.

Otherwise, 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 that you missed.

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

If you have missed more than one dose, or are not sure what to do, ask your doctor 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 (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else has taken too much NOUMED ESCITALOPRAM. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep this telephone number handy.

Symptoms of an overdose may include dizziness, low blood pressure, nausea (feeling sick), vomiting, agitation, tremor (shaking) and rarely convulsions and coma.

While you are taking it

Things you must do

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking NOUMED ESCITALOPRAM.

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

Tell your doctor immediately if you become pregnant while taking NOUMED ESCITALOPRAM.

Tell your doctor immediately if you have thoughts about harming or killing yourself, or if you know someone using NOUMED ESCITALOPRAM who talks about or shows signs of killing him or herself.

All mentions of suicide or violence must be taken seriously.

People taking escitalopram may be more likely to think about killing themselves or actually trying to do so, especially when treatment is first

started, the dose is changed, or soon after treatment is stopped.

Occasionally, symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur in young adults, i.e. 18 to 24 years old who have not used antidepressant medicines before.

Patients and care givers should pay attention to any of the following warning signs of suicide-related behaviour while taking NOUMED ESCITALOPRAM. Tell your doctor 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 a aggressive behaviour, irritability or agitation.

Tell your doctor immediately if you experience symptoms such as restlessness or difficulty in sitting or standing still.

These symptoms can occur during the first week of treatment.

Contact your doctor as soon as possible if you suddenly experience an episode of mania.

Some patients with bipolar disorder (manic depression) may enter into a manic phase, where signs include profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity.

Sometimes you may be unaware of these symptoms. You may find it helpful to ask a friend or relative to help you notice possible signs of a change in your behaviour.

Things you must not do

Do not take NOUMED ESCITALOPRAM to treat any other complaints unless your doctor tells you to.

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

Do not increase the dosage without checking with your doctor, even if you become more anxious.

At the beginning of treatment, some patients may experience increased anxiety which will disappear during continued treatment.

Do not stop taking NOUMED ESCITALOPRAM, or lower the dosage, without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

If you stop taking NOUMED ESCITALOPRAM suddenly, you may experience unwanted effects (see above section on *'How long to take it'*).

Things to be careful of

Make sure you know how NOUMED ESCITALOPRAM affects you before you drive or operate machinery.

It may cause blurred vision, nausea, fatigue and dizziness in some people, especially early in the treatment. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Avoid alcohol while you are taking this medicine.

It is not advisable to drink alcohol while you are being treated for depression.

Side effects

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

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. The side effects are, in general, mild and go away after a short period of time.

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

- loss of appetite
- dry mouth
- diarrhoea
- nausea (feeling sick)
- sleeplessness
- fatigue, sleepiness or drowsiness, yawning
- increased sweating
- nose bleeding
- decreased sexual drive; problems with ejaculation or erection; women may have difficulty achieving orgasm.

These are the more common side effects of NOUMED ESCITALOPRAM.

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

- agitation, confusion, panic attacks, anxiety, restlessness
- dizziness
- dizziness when you stand up (which may be due to low blood pressure)
- changes to heartbeat (fast, decreased or irregular)
- difficulty in passing urine
- unusual secretion of breast milk
- unusual bleeding, bruising
- rash, itching, swollen patches
- bone fracture.

Abnormalities may also occur in blood tests that your doctor has arranged.

These are rare but serious side effects of NOUMED ESCITALOPRAM or other medicines that work in a

similar way. You may need urgent medical attention.

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

- thoughts of suicide or harming yourself (see section on 'Things you must do')
- symptoms of a serious allergic reaction, which include hives, swelling of the face, lips, mouth or throat causing difficulty in swallowing or breathing
- symptoms of serotonin syndrome, which include high fever, agitation, confusion, trembling and abrupt contractions of muscles
- manic symptoms, including elevated mood
- hallucinations
- seizures, tremors, involuntary movement of muscles
- fast, irregular heartbeat with feelings of dizziness or difficulty breathing.

These are very serious side effects that may need urgent medical attention or hospitalisation.

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.

If you notice any unwanted effects after stopping treatment with NOUMED ESCITALOPRAM, tell your doctor and ask them for advice on how to manage these effects.

After taking it

Storage

Keep your medicine in the original container until it is time to take them.

If you take the tablets out of its container, they may not keep well.

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

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine 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 its expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

NOUMED ESCITALOPRAM is available in 2 strengths that are supplied in blister packs of 28 tablets each.

10 mg: white, oval, film-coated tablets with a breaking notch on one side.

20 mg: white, round, film-coated tablets with a cross-breaking notch both sides.

Ingredients

Active ingredient

NOUMED ESCITALOPRAM tablets contain either 10 mg or 20 mg of escitalopram (as the oxalate form).

Inactive ingredients

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium
- hypromellose
- colloidal anhydrous silica

- magnesium stearate
- macrogol 6000
- purified talc
- titanium dioxide

NOUMED ESCITALOPRAM does not contain sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

Avalon Pharmaceuticals Pty Ltd
Level 5, 7 Eden Park Drive
Macquarie Park NSW 2113
Telephone 1800 930 999

Australian registration numbers

10 mg: AUST R 298285
20 mg: AUST R 298286

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