

# ELEXA FILM-COATED TABLETS

Escitalopram (as oxalate) (10mg and 20mg)

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## What Elexa is used for

Elexa contains escitalopram and is used to treat:

- depression
- panic disorder with or without agoraphobia (fear of public or open spaces)
- social anxiety disorder / social phobia (fear or avoidance of social situations)
- generalised anxiety disorder (generally feeling very anxious or nervous, even when there is little or no reason to worry about them)
- obsessive-compulsive disorder (OCD) (persistent, obsessive thoughts that make you carry out repetitive behaviour)

## How Elexa works

Elexa contains the active substance escitalopram. Escitalopram belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered important factor in development of depression and related diseases.

## Before you use Elexa

### When you must not use it

Do not take:

- if you are allergic to escitalopram or any of the other ingredients of this medicine (listed in section **Product Description**).

- If you take other medicines which belong to a group called monoamine oxidase inhibitors (MAOIs) (see subsection *Taking other medicines*). Taking Elexa with a MAOI may cause a serious, sometimes fatal, reaction with features resembling serotonin syndrome (see section **Side effects**).
- at the same time as taking pimozide (used in the treatment of mental disorders or nervous system disorders)

### Before you start to use it

If you take Elexa near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor should be aware that you are taking Elexa so they can advise you. Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:

- if you have epilepsy. Treatment with Elexa should be stopped if seizures (fits) occur for the first time, or if there is an increase in the seizure frequency (see also section **Side effects**).
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Elexa may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- if you have a decreased level of sodium in the blood.
- if you have a tendency to easily develop bleedings or bruises, or if you are pregnant (see 'Pregnancy, breast-feeding and fertility').
- if you are receiving electroconvulsive treatment (ECT) (usually used for severe depression).
- if you have coronary heart disease.
- if you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in

the eye).

[see also subsection *Things to be careful of*].

- if you have a history of mania (uncontrollable excitement that causes unusual behaviour) or hypomania (a condition similar to mania but less severe)
- if you have a history of suicide-related events
- if you are currently pregnant, breast-feeding, or trying to get pregnant.

### Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:

- Non-selective MAOIs, e.g. phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Elexa. After stopping, you must allow 7 days before taking any of these medicines:
- Reversible, selective MAO-A inhibitors, e.g. moclobemide (used to treat depression).
- Irreversible MAO-B inhibitors, e.g. selegiline (used to treat Parkinson's disease).
- Lithium (used in the treatment of manic depressive disorder) and tryptophan (an amino acid).
- Desipramine (used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol and similar medicines (used against severe pain). These increase the risk of side effects.
- Cimetidine and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels
- St John's Wort (*Hypericum perforatum* - a herbal remedy used for depression).
- Acetylsalicylic acid, non-steroidal anti-inflammatory drugs (NSAID), warfarin, dipyridamole, and phenprocoumon (medicines used for

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pain relief or to thin the blood). These may increase bleeding-tendency.

- Mefloquin (used to treat Malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat mental disorders) and anti-depressants due to a possible risk of a lowered threshold for seizures.
- Flecainide, propafenone, and metoprolol (used in cardiovascular diseases), clomipramine and nortriptyline (antidepressants), and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of Elexa may need to be adjusted.

## How to use Elexa

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### How much to use

#### Adults

##### *Depression*

The normally recommended dose of Elexa is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

##### *Panic disorder*

The starting dose is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.

##### *Social anxiety disorder*

The normally recommended dose is 10 mg taken as one daily dose. Your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day, depending on how you respond to the medicine.

##### *Generalised anxiety disorder*

The normally recommended dose is 10 mg taken as one daily dose. The dose may be increased by your doctor to a

maximum of 20 mg per day.

##### *Obsessive-compulsive disorder*

The normally recommended dose is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

##### Elder Patients (Above 65 Years Of Age)

Initial treatment with half the usually recommended dose and a lower maximum dose are recommended.

##### Use in children and adolescents

Elexa should not normally be given to children and adolescents (see subsection *Things to be careful of*).

*If necessary, you can divide the tablets by firstly placing the tablet on a flat surface with the score facing upwards. The tablets may then be broken by pressing down on each end of the tablet, using both forefingers as shown in the drawing.*



##### When to use it

You can take Elexa with or without food. Swallow the tablet with some water. As with many medicines, combining Elexa with alcohol is not advisable, although Elexa is not expected to interact with alcohol.

##### How long to use it

It may take a couple of weeks before you start to feel better. Continue to take even if it takes some time before you feel any improvement in your condition for as long as your doctor recommends.

If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

##### If you forget to use it

Do not take a double dose to make up for forgotten doses. If you do forget to take a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose and carry on as usual.

##### If you use too much (overdose)

If you take more than the prescribed dose of Elexa, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion (fits), coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance.

## While you are using it

### Things you must do

- Take Elexa exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Elexa.
- Tell your doctor immediately if you become pregnant while taking Elexa.

### Things you must not do

Do not change the dose of your medicine without talking to your doctor first.

Do not stop taking Elexa until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose is gradually reduced over a number of weeks. When you stop taking Elexa, especially if it is abruptly, you may feel discontinuation symptoms. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Elexa, please contact your doctor. He or she may

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ask you to start taking your tablets again and come off them more slowly.

Discontinuation symptoms include: Feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

## *Things to be careful of*

### *Pregnancy, breast-feeding and fertility*

Do not take Elexa if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved. Make sure your midwife and/or doctor know you are on Elexa. If used during pregnancy Elexa should never be stopped abruptly.

If you take Elexa during your pregnancy you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. When taken during pregnancy, medicines like Elexa may increase the risk of a serious condition in babies, 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 your newborn baby has

any of these symptoms, please contact your midwife and/or doctor immediately.

If you take Elexa near the end of your pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Elexa so they can advise you. It is expected that Elexa will be excreted into breast milk. Breastfeeding is not recommended during treatment.

Citalopram, a medicine like escitalopram, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet. Ask your doctor or pharmacist for advice before taking any medicine.

### *Children and adolescents*

Elexa should normally not be used for children and adolescents under 18 years. Also you should know that patients under 18 have an increased risk of side-effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behavior and anger) when they take this class of medicines. Despite this, your doctor may prescribe Elexa for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Elexa for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Elexa. Also, the long term safety effects concerning growth, maturation and cognitive and behaviour development of Elexa in this age group have not yet been demonstrated.

### *Driving and using machines*

You are advised not to drive a car or operate machinery until you know how

Elexa affects you.

### *Please note:*

Some patients with manic-depressive illness may enter into a manic phase. This is characterised by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor. Symptoms such as restlessness or difficulty to sit or stand still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

### *Thoughts of suicide and worsening of your depression or anxiety disorder*

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer. You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a young adult. Information from clinical trials have shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

You may find it helpful to tell a relative or close friend that you are depressed or have anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

### **Side Effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects usually disappear

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after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

**If you experience the following side effects you should contact your doctor or go to the hospital straight away:**

*Uncommon (may affect up to 1 in 100 people):*

- Unusual bleeds, including gastrointestinal bleeds

*Rare (may affect up to 1 in 1,000 people):*

- If you experience swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction), contact your doctor or go to a hospital straight away.
- If you have a high fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome. If you feel like this contact your doctor.

*Not known (frequency cannot be estimated from the available data):*

- Difficulties urinating
- Seizures (fits)
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/ hepatitis

**In addition to above the following side effects have been reported:**

*Very common (may affect more than 1 in 10 people):*

- Feeling sick (nausea)

*Common (may affect up to 1 in 10 people):*

- Blocked or runny nose (sinusitis)
- Decreased or increased appetite
- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
- Diarrhoea, constipation, vomiting, dry mouth
- Increased sweating

- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
- Fatigue, fever
- Increased weight

*Uncommon (may affect up to 1 in 100 people):*

- Nettle rash (urticaria), rash, itching (pruritus)
- Grinding one's teeth, agitation, nervousness, panic attack, confusion state
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Excessive menstrual bleeding
- Irregular menstrual period
- Decreased weight
- Fast heart beat
- Swelling of the arms or legs
- Nosebleeds

*Rare (may affect up to 1 in 1,000 people):*

- Aggression, depersonalization (feelings of unreality and strangeness concerning oneself or the environment), hallucination (hearing voices or seeing things which are not there)
- Slow heart beat

*Not known (frequency cannot be estimated from the available data):*

- Thoughts of harming yourself or thoughts of killing yourself (see also subsection *Things to be careful of*)
- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused)
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension)
- Abnormal liver function test (increased amounts of liver enzymes

in the blood)

- Movement disorders (involuntary movements of the muscles)
- Painful erections (priapism)
- Bleeding disorders including skin and mucous bleeding (ecchymosis) and low level of blood platelets (thrombocytopenia)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breast-feeding and fertility' in section **While you are using it** for more information
- Sudden swelling of skin or mucosa (angioedemas)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Flow of milk in men and in women that are not nursing
- Mania
- An increased risk of bone fractures has been observed in patients taking this type of medicines.

In addition, a number of side effects are known to occur with drugs that work in a similar way to escitalopram (the active ingredient of Elexa). These are:

- Motor restlessness (akathisia)
- Anorexia

If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <http://www.npra.gov.my> (Consumers→ Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI)).

## Storage and Disposal of Elexa

### Storage

Keep this medicine out of the sight and reach of children.

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Do not use this medicine after the expiry date, which is stated on the label or carton after EXP. The expiry date refers to the last day of that month. Do not store above 30°C.

## Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **Product Description**

### *What it looks like*

Elexa is presented as film-coated tablet.

10 mg: White, elliptic, convex film-coated tablets, scored on both sides.

20mg: White, oblong, convex film-coated tablets, scored on one side and embossed with a "+" on the other side.

The tablets can be divided into equal doses.

### *Ingredients*

- Active ingredient:

The active substance is escitalopram. Each Elexa tablet contains 10 mg or 20 mg escitalopram (as oxalate).

- Inactive ingredients:

Core: microcrystalline cellulose, colloidal anhydrous silica, talc, croscarmellose sodium and magnesium stearate.

Film Coating: hypromellose, macrogol 400 and titanium dioxide (E-171), Opadry OY-S-28849 White

- MAL No.:

10mg: MAL25086011ACZ

20mg: MAL25086012ACZ

## **Manufacturer**

Atlantic Pharma Producoes

Farmaceuticas S.A.

Rua de Tapada Grande 2, Abrunheira, Sintra, 2710-228 Portugal.

## **Product Registration Holder**

Intega Sdn Bhd

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## **Date of Revision**

August 2025

## **Serial Number**

NPRA (R2) 23/233