

Elicea film-coated tablet

Escitalopram (10mg)

What is in this leaflet

1. What *Elicea* is use for
2. How *Elicea* works
3. Before you use *Elicea*
4. How to use *Elicea*
5. While you are using it
6. Side effects
7. Storage and Disposal of *Elicea*
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What *Elicea* is used for

Elicea contains escitalopram and is used to treat depression (major depressive episodes).

It may take a couple of weeks before you start to feel better. You must talk to a doctor if you do not feel better or if you feel worse.

How *Elicea* works

Elicea 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 an important factor in the development of depression and related diseases.

Before you use *Elicea*

- When you must not use it

- If you are allergic to escitalopram or any of the other ingredients of this medicine.
- If you take other medicines which belong to a group called MAO inhibitors,

Pregnancy and lactation

Do not take *Elicea* if you are pregnant, trying to get pregnant or think you may be pregnant. If you get pregnant while taking *Elicea*, stop taking it immediately and contact your doctor.

If you take *Elicea* during the last 3 months of 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.

If your newborn baby has any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor know you are on *Elicea*.

It is expected that *Elicea* will be excreted into breast milk. Do not take *Elicea* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start use it

Talk to your doctor or pharmacist before taking *Elicea*. 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 *Elicea* should be stopped if seizures occur for the first time, or if there is an increase in the seizure frequency.
- If you suffer from impaired liver or kidney function.
- If you have diabetes. If you have a decreased level of sodium in the blood.
- If you have a tendency to easily develop bleedings or bruises.
- If you are receiving electroconvulsive treatment.
- If you have problem with your heart
- If you take *Elicea* 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 *Elicea* so they can advise you.

Please note

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity.

Symptoms such as restlessness or difficulty in sitting or standing 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.

If you are depressed 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.

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

Suicidality in children and adolescents

- Antidepressants increase the risk of suicidal thinking and behaviour (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.
- Anyone considering the use of an antidepressant in a child or adolescent for any clinical use must balance the risk of increased suicidality with the clinical need.
- Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behaviour.
- Families and caregivers should be advised to closely observe the patient and to communicate with the prescriber.
- The indication(s) approved in paediatric for the particular drug should be clearly stated / included.

Elicea contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription. Tell your doctor if you are taking any of the following medicines: phenelzine, iproniazid, isocarboxazid, nialamide, pimozide and tranylcypromine as active ingredients. (if you have taken any of these medicines you will need to wait 14 days before you start taking

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Elicea. After stopping Elicea you must allow 7 days before taking any of these medicines), moclobemide, selegiline, lithium, tryptophan, imipramine and desipramine, sumatriptan and similar medicines, tramadol, buprenorphine, cimetidine, lansoprazole, omeprazole, fluconazole, fluoxetine, fluvoxamine, ticlopidine, St. John's wort (hypericum perforatum), acetylsalicylic acid (aspirin), non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood), warfarin, dipyridamole, phenprocoumon, mefloquine, bupropion, neuroleptics (medicines to treat schizophrenia, psychosis like risperidone, thioridazine, haloperidol), tricyclic antidepressants and SSRIs, flecainide, propafenone, metoprolol, clomipramine, and nortriptyline.

If you have any further questions about this you should speak to your doctor.

How to use Elicea

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Depression

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

Elderly patients (above 65 years of age)

The recommended starting dose of Elicea is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Children and adolescents (below 18 years of age)

Elicea should not normally be given to children and adolescents.

- When to use it

For oral use.

Elicea should be taken as one daily dose. You can take Elicea with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter. The tablet can be divided into equal doses. Use as directed by your doctor or pharmacist.

- How long to use it

It may take a couple of weeks before

you start to feel better. Continue to take Elicea even if it takes some time before you feel any improvement in your condition.

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

Continue to take Elicea 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

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Elicea box with you when you go to the doctor or hospital.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

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

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

When you have completed your course of treatment, it is generally advised that the

dose of Elicea is gradually reduced over a number of weeks.

When you stop taking Elicea, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Elicea is stopped. The risk is higher, when Elicea has been used for a long time or in high doses or when the dose is reduced too quickly. 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 Elicea, please contact your doctor. He or she may 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).

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side Effects

Like all medicines, Elicea can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine. The side effects usually disappear after a few weeks of treatment.

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If you experience any of the following symptoms you should contact your doctor or go to the hospital straight away:

Uncommon:

- Unusual bleeds, including gastrointestinal bleeds

Rare:

- Swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction).
- High fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome.

Not known:

- Seizures (fits),
- signs of liver function impairment/hepatitis
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as torsade de pointes
- Thoughts of harming or killing yourself

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

Very common: feeling sick (nausea).

Common: blocked or runny nose, 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, sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm), fatigue, fever, increased weight.

Uncommon: nettle rash, rash, itching, grinding one's teeth, agitation, nervousness, panic attack, confusion, disturbed sleep, taste disturbance, fainting, enlarged pupils visual, disturbance, ringing in the ears, loss of hair, excessive menstrual bleeding, irregular menstrual period, decreased weight, fast heartbeat, swelling of the arms or legs, nosebleeds.

Rare: aggression, depersonalisation, hallucination, slow heartbeat.

Not known: 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 Abnormal liver function test (increased amounts of liver enzymes in the blood), involuntary movements of the muscles, Painful erections, signs of increased bleeding e.g. from skin and mucous membranes, sudden swelling of skin or mucosa, increase in the amount of urine excreted, flow of milk in men and in women that are not nursing, mania, increased risk of bone fractures, alteration of the heart rhythm, motor restlessness, loss of appetite.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Elicea

- Storage

Keep out of the sight and reach of children. Do not store above 30 °C. Store in the original package in order to protect from light and moisture. Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Tablets are white, oval, biconvex film-coated tablets, scored on one side. The tablet can be divided into equal doses.

Blisters packs: 30 film-coated tablets in a folding box.

- Ingredients

Active ingredient

Each film-coated tablet contains 10 mg escitalopram (as 12.780 mg escitalopram oxalate).

Inactive ingredients

In the tablet core are: lactose monohydrate, crospovidone, povidone K30, microcrystalline cellulose, pregelatinised maize starch and magnesium stearate.

In the film-coating are hypromellose, titanium dioxide (E171), lactose monohydrate, macrogol 3000 and triacetin.

- MAL number:

MAL18086141AZ

Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Mile Off Jalan Meru, Klang,
Selangor, Malaysia.

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