

ESPRAN TABLET

Escitalopram Oxalate (5mg, 10 mg, 20 mg)

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What Espran is used for

It is indicated for the treatment of more severe form of depression.

How Espran works

Espran contains an active substance called Escitalopram. Espran belongs to a group of antidepressants called Selective Serotonin Reuptake Inhibitors (SSRIs).

Espran act by increasing the serotonin level in the brain. Disturbances in the serotonin level are considered an important factor in the development of depression and related diseases.

Before you use Espran

- When you must not use it

Do not take Espran if:

- You are allergic (hypersensitive) to Escitalopram or Citalopram or any of the other ingredients of Espran (see section **Product description**).
- You take other medicines that belong to a group called monoamine oxidase inhibitors (MAOIs) used for the treatment or within 14 days of discontinuing treatment with an MAOI.

Pregnancy and breastfeeding

Do not take Espran if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Espran if you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

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 Espran should be stopped if seizures occur for the first time, or if there is an increase in the seizure frequency.
- If you have diabetes. Treatment with Espran may alter glucose control. Insulin and/or oral anti-diabetic 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.
- If you are receiving electroconvulsive treatment (usually used in severe depression).
- Some people 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. If you experience this, contact your doctor.

- 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.

- Caution should be used when it is taken in combination with other centrally acting medicines.
- The use of alcohol by people taking Espran is not recommended.
- Caution should be exercised when Escitalopram and lithium are co-administered.
- Concomitant treatment of tramadol, sumatriptan and an SSRI is clinically warranted, appropriate observation of the individual is advised.
- Co-administration of Escitalopram with the tricyclic antidepressant desipramine or medicines metabolized by enzyme CYP2D6 Caution is indicated.
- St. John's Wort (used in the treatment of anxiety).
- Metoprolol (used to treat high blood pressure).

- Ketoconazole (antifungal medication).

How to use Espran

- How much to use

Espran is administered as a single daily dose and may be taken with or without food.

Major depressive episodes

Usual dosage is 10mg once daily. Depending on individual response, the dose may be increased to a maximum of 20 mg daily.

Elderly (> 65 years of age)

Initial treatment with half of the usually recommended dose and a lower maximum dose should be considered.

Children and Adolescents (<18 years)

Espran should not be used in the treatment of children and adolescents under the age of 18 years.

Reduced Kidney or liver Function or poor Metabolizers of liver enzyme, CYP2C19

An initial dose of 5 mg daily during the first two weeks of treatment is recommended. Depending on individual response, the dose may be increased to 10mg daily.

- When to use it

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.

Use as directed by your doctor or pharmacist.

- How long to use it

Usually 2-4 weeks are necessary to obtain antidepressant response. After the symptoms resolve, treatment for at least 6 months is required for consolidation of the response.

Continue taking Espran tablets for as long as your doctor recommends.

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- 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.

Symptoms seen in reported overdose of escitalopram include:

- Dizziness.
- Tremor and agitation to rare cases of serotonin syndrome.
- Convulsion and coma.
- Nausea/vomiting.
- Low blood pressure.
- Faster than normal heart rate at rest.
- Abnormal heart rhythms.
- Irregular heartbeat.
- Electrolyte/fluid balance conditions (Condition of low potassium or sodium level in blood stream).

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 Espran.
- 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.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give Espran to anyone else, even if they have the same symptoms or condition as you.
- Discontinuation symptoms:
 - When stopping treatment with ESPRAN the dose should be

gradually reduced over a period of at least one to two weeks in order to avoid possible discontinuation symptoms.

- Possible discontinuation symptoms are dizziness, sensory disturbances (including Sensation of tingling, trickling, pricking or burning or electric shock sensations of the skin), sleep disturbances (including sleeping difficulty and intense dreams), agitation or anxiety, nausea and/or vomiting, shakiness, confusion, sweating, headache, diarrhea, palpitations, emotional instability, irritability and visual disturbances.

- Things to be careful of

- 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.
- Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in children and adolescents with major depressive disorder (MDD) and other psychiatric disorders.
- If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

People who are started on therapy should be observed closely for clinical worsening, suicidality, or unusual changes in behavior.

Families and caregivers should be advised to closely observe the individual and to communicate with the prescriber.

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, Escitalopram can cause side effects, although not everybody gets them.

The most commonly observed adverse events in people taking Escitalopram are:

- Sleeping difficulty.
- Ejaculation disorder (primarily ejaculatory delay).
- Nausea.
- Sweating increased.
- Fatigue and feeling sleepy.

The other side effects are:

- Palpitation (feeling of having rapid, fluttering or pounding heart).
- High blood pressure.
- Sensation of tingling, trickling, pricking or burning of a person's skin.
- Migraine or headache.
- Vomiting.
- Heartburn.
- Inflammation on stomach and intestines.
- Abdominal pain.
- Allergy including rash.
- Increased anxiety symptoms. This usually subsides within the first two weeks of treatment.
- Fever.
- Chest pain.
- Increased or decreased weight.
- Joint pain.
- Muscle cramp or shakiness.
- Appetite increased.
- Lethargy.
- Inflammation of the airway which carry air to and from lungs).
- Stuffy nose.
- Coughing.
- Vision blurred.
- Ear ache.
- Noise or ringing in the ears.
- Urinary tract infection or frequency.

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

Tell your doctor if you get any side effect that bothers you or that does not go away.

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You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects (ConSERF) or Vaccine (AEFI)).

Storage and Disposal of Espran

- Storage

- Store below 30°C.
- Keep out of reach and sight of children.

- 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

ESPRAN 5MG TABLET

White to off white, round, biconvex, film coated tablets debossed with “135” on one side and ‘5’ on other side.

ESPRAN 10MG TABLET

White to off – white, round, biconvex, film coated tablets debossed with break line on both sides, separating ‘11’ and ‘36’ on one side and ‘10’ on other side.

ESPRAN 20MG TABLET

White to off – white, round, biconvex, film coated tablets debossed with break line on both sides, separating ‘11’ and ‘37’ on one side and ‘20’ on other side.

- Ingredients

Active ingredient:

- Escitalopram Oxalate.

Inactive ingredients:

- Cellulose Microcrystalline (PH 102)
- Croscarmellose Sodium
- Colloidal Silicon dioxide
- Povidone K-30
- Isopropyl alcohol
- Talc
- Magnesium Stearate
- Hypromellose-2910
- Titanium dioxide
- Macrogol 400

- MAL number(s):

ESPRAN 5 MG TABLET:

MAL10070579AZ

ESPRAN 10 MG TABLET:

MAL10070578AZ

ESPRAN 20 MG TABLET:

MAL10070577AZ

Manufacturer

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Product Registration Holder

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