

# AJALOPRAM ORODISPERSIBLE TABLET

Escitalopram 5mg, 10mg, 15mg & 20mg.

## What is in this leaflet

1. What Ajalopram Orodispersible Tablet is used for
2. How Ajalopram Orodispersible Table works
3. Before you use Ajalopram Orodispersible Tablet
4. How to use Ajalopram Orodispersible Tablet
5. While you are using Ajalopram Orodispersible Tablet
6. Side Effects
7. Storage and Disposal Ajalopram Orodispersible Tablet
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

## What Ajalopram Orodispersible Tablet is used for:

Escitalopram is indicated for the treatment of:

- Major depressive disorders
- Panic disorder with or without agoraphobia (e.g., fear of leaving the house, entering shops, being in crowds and in public places).
- Social anxiety disorder (social phobia).
- Generalized anxiety disorder.
- Obsessive-compulsive disorder.

## How Ajalopram Orodispersible Tablet works:

Escitalopram is an antidepressant which belongs to the 'SSRI' group (selective serotonin reuptake inhibitors).

## Before you use Ajalopram Orodispersible Tablet:

*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, including moclobemide (used in the treatment of depression) and linezolid (an antibiotic).

- If you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning).
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm.

*Before you start to use it:*

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

*Taking other medicines* Tell your healthcare provider if you take any of the following:

- Reversible, selective MAO-A inhibitor: Moclobemide (used to treat depression).
- Reversible, non-selective MAO-inhibitor: Linezolid
- Irreversible selective MAO-B inhibitors: selegiline (used to treat Parkinson's disease).
- Serotonergic medicinal products e.g. Sumatriptan (used to treat migraine), tramadol (used against severe pain) and other triptans.
- St. John's wort (*hypericum perforatum*)
  - a herbal remedy used for depression.
- Non-steroidal anti-inflammatory drugs (NSAIDs).
- SSRIs can lower the seizure threshold. Caution is advised when concomitantly using other medicinal products capable of lowering the seizure threshold (e.g., antidepressants (tricyclics, SSRIs), neuroleptics (phenothiazines, thioxanthenes and butyrophenones), mefloquin, bupropion and tramadol).
- Lithium and tryptophan.
- Altered anti-coagulant effects may occur when Ajalopram Orodispersible Tablet is combined with oral anticoagulants. If you are receiving oral anticoagulant therapy should receive careful

coagulation monitoring when Ajalopram Orodispersible Tablet is started or stopped.

- Medicines that decrease blood levels of potassium or magnesium, as these conditions increase the risk of life-threatening heart rhythm disorders.
- As with other psychotropic medicinal products, the combination with alcohol is not advisable.
- Do not take Ajalopram Orodispersible Tablet if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, such as Class IA and III antiarrhythmics, antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (e.g. astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

## How to use Ajalopram Orodispersible Tablet

*How much to use*

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Place the tablet on your tongue. The tablet will rapidly disintegrate and can be swallowed without water.

Major Depression: The normally recommended dose of Ajalopram Orodispersible Tablet 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 with or without agoraphobia:

The starting dose of Ajalopram Orodispersible Tablet 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 of Ajalopram Orodispersible Tablet 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.

Generalized anxiety disorder:

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

Use in the elderly (>65 years of age):

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

Children and adolescents (< 18 years):

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

Reduced renal function: Dosage adjustment is not necessary if you are with mild or moderate renal impairment. Caution is advised if you are with severely reduced renal function (CLCR less than 30ml/min).

Reduced hepatic function: An initial dose of 5mg daily for the first 2 weeks of treatment if you are with mild or moderate hepatic impairment.

Depending on individual response, the dose may be increased to 10mg daily. Caution and extra careful advised if you are with severely reduced hepatic function.

Poor metabolisers of CYP2C19:

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

*When to use it*

It may take a couple of weeks before you start to feel better. Continue to take Ajalopram Orodispersible Tablet 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.

*How long to use it*

Continue to take Ajalopram Orodispersible Tablet for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. When stopping treatment with Ajalopram Orodispersible Tablet the dose should be gradually reduced over a period of at least one to two weeks in order to reduce the risk of discontinuation symptoms.

*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 Ajalopram Orodispersible Tablet, contact your doctor or nearest hospital emergency department immediately.

## **While you are using Ajalopram Orodispersible Table**

*Things you must do*

It may take a couple of weeks before you start to feel better. Continue to take Ajalopram Orodispersible Tablet even if it takes some time before you feel any improvement in your condition.

*Things you must not do*

- Ajalopram Orodispersible Tablet not be used in the treatment if you are children or adolescents under the age of 18.
- You should not take Ajalopram Orodispersible Tablet if you have seizure.
- If you are in mania phase should be discontinued the treatment with Ajalopram Orodispersible Tablet.

*Things to be careful of*

- Inform your doctor if you are pregnant or planning to become pregnant. Do not take Ajalopram Orodispersible Tablet if you are pregnant or breast-feeding, unless you and your doctor have discussed the risks and benefits involved.
- If you are a diabetic patient. Ajalopram Orodispersible Tablet may alter glycaemic control (hypoglycaemia or hyperglycaemia).
- If you have anxiety, may experience increased anxiety symptoms at the beginning of treatment. This reaction usually subsides within two weeks during continued treatment. A low starting dose is advised.
- May increased risk of suicidal thoughts, self-harm, and suicide. Therefore, need closely monitored until such improvement occurs.
- If you feel movement disorder characterized by a feeling of inner restlessness and inability to stay still.
- If you taking SSRIs, particularly in concomitant use with oral anticoagulants, which can affect

platelet function and if you have bleeding tendencies.

- There is limited clinical experience of concurrent administration of SSRI and ECT, therefore caution is advisable.
- If you are taking medicinal products with serotonergic effects such as sumatriptan or other triptans, tramadol and tryptophan. May cause symptoms such as agitation, tremor, myoclonus and hyperthermia. If this occurs treatment with the SSRI and the serotonergic medicinal product should be discontinued immediately and symptomatic treatment initiated.
- Due to limited clinical experience, caution is advised if you have coronary heart disease.
- Caution is advised if you have lower heart beat rate compare to the normal beat rate.
- If you have angle-closure glaucoma or history of glaucoma.

#### Side Effect

Blocked or runny nose (sinusitis), decreased or increased appetite, anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, pricking 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 and increased weight.

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

#### Storage and Disposal of Ajalopram Orodispersible Tablet

##### Storage

Store below 30°C in the original package to protect from light

##### Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

#### Product Description

##### What it looks like

5mg: White to off-white round, flat tablets with beveled edges and engraved with “5” on one side.

10mg: White to off-white round, flat tablets with beveled edges and engraved with “10” on one side.

15mg: White to off-white round, flat tablets with beveled edges and engraved with “15” on one side.

20mg: White to off-white round, flat tablets with beveled edges and engraved with “20” on one side.

##### Ingredients

Active Ingredient Escitalopram Oxalate equivalent to Escitalopram 5mg.

Escitalopram Oxalate equivalent to Escitalopram 10mg.

Escitalopram Oxalate equivalent to Escitalopram 15mg.

Escitalopram Oxalate equivalent to Escitalopram 20mg.

Inactive Ingredient Polacrillin potassium, Hydrochloric acid, concentrated, Lactose monohydrate (spray-dried), Cellulose, microcrystalline, Croscarmellose sodium, Acesulfame potassium, Neohesperidine-dihydrochalcone, Flavor peppermint, Magnesium stearate and Purified Water.

##### MAL no:

Ajalopram 5mg Orodispersible Tablet: MAL18086105ACZ

Ajalopram 10mg Orodispersible Tablet: MAL18086106ACZ

Ajalopram 15 Mg Orodispersible Tablet: MAL18086104ACZ

Ajalopram 20 Mg Orodispersible Tablet: MAL18086103ACZ

##### Manufacturer:

Genepharm S.A  
18 Km Marathon Avenue  
-15351 Pallini Greece

##### Product Registration Holder:

AJ Research & Pharma Sdn.Bhd.  
Unit 27.1, Level 27, Menara Felda,  
Platinum Park, No. 11, Perisaran  
KLCC, 50088 Kuala Lumpur Malaysia.

##### Date of revision:

December 2022

##### Serial Number

NPRA (R1/1) 24022023/055