

## **Package leaflet: Information for the patient**

### **Amizal 45 mg Coated tablets**

Idebenone

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### **What is in this leaflet:**

1. What Amizal is and what it is used for
2. What you need to know before you take Amizal
3. How to take Amizal
4. Possible side effects
5. How to store Amizal
6. Contents of the pack and other information

### **1. What is Amizal and what it is used for**

Amizal is a medicine that acts in the Central Nervous System (CNS), which is indicated in the treatment of hypobulia (decreased voluntary processes), affective disorders and logopathy (disturbance of reasoning and language), associated with sequelae of cerebral infarction, cerebral haemorrhage and cerebral atherosclerosis.

### **2. What you need to know before you take Amizal**

#### **Do not take Amizal**

- If you are allergic (hypersensitive) to idebenone or any of the other ingredients of this medicine (listed in section 6).

#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Amizal.

#### **Other medicines and Amizal**

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

No cases of drug interaction with Amizal have been reported.

#### **Amizal with food, drink and alcohol**

Take the tablets after meals in order to increase the absorption of the medicine.

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant, think you may be pregnant or breast-feeding, tell your doctor or pharmacist.

#### **Driving and using machines**

Amizal does not interfere with the ability to drive and use machines.

#### **Amizal contains lactose monohydrate**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **3. How to take Amizal**

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

The usual dose is 1 tablet 2 times a day (90 mg/day).

You should take the tablets after meals.

#### **If you take more Amizal than you should**

Given the low toxicity of idebenone, it is not expected that ingestion of a high amount of the medicine will cause severe intoxication. However, if this happens you should talk to your doctor.

#### **If you forget to take Amizal**

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Amizal**

Do not stop taking Amizal even if you feel better. You should continue to take the medicine as prescribed by your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

### **4. Possible side effects**

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

Idebenone is generally well tolerated. The reported side effects were always transient and reversible in nature.

Rare side effects (may affect up to 1 in 1000 people):

- Hypersensitivity reactions
- Gastrointestinal disorders
- Vertigo
- Anxiety
- Sleep disorders

The relationship between the occurrence of these side effects and treatment with idebenone has not been confirmed.

Slight transient and reversible changes of some laboratory parameters (blood count and transaminases) have also been reported.

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

## **5. How to store Amizal**

Store below 25°C.

Store in the original package in order to protect from light and moisture.

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

Do not use this medicine after the expiry date which is stated on the carton, after EXP. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration.

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.

## **6. Contents of the pack and other information**

### **What Amizal contains**

- The active substance is idebenone. Each coated tablet contains 45 mg.
- The other ingredients are pregelatinized starch, carmellose calcium, microcrystalline cellulose, magnesium stearate, lactose monohydrate and yellow coating suspension containing hypromellose, titanium dioxide (E171), talc, polyethylene glycol 3350, hydroxypropyl cellulose and yellow iron oxide (E172).

### **What Amizal looks like and contents of the pack**

Amizal is presented as yellow, circular, coated tablets, packed in blisters, in packs of 20, 40 and 60 units.

Not all pack sizes may be marketed.

### **Marketing Authorization Holder and Manufacturer**

Laboratórios Atral, S.A.

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