

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

### **Donepezil Teva 5 mg Film-coated Tablets** **Donepezil Teva 10 mg Film-coated Tablets** donepezil hydrochloride (as monohydrate)

**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. See section 4.

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

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

#### **1. What Donepezil Teva is and what it is used for**

Donepezil (donepezil hydrochloride) belongs to a group of medicines called acetylcholinesterase inhibitors. Donepezil Teva increases the levels of a substance (acetylcholine) in the brain involved in memory function by slowing down the breakdown of acetylcholine.

It is used to treat the symptoms of dementia in people diagnosed as having mild and moderately severe Alzheimer's Disease. The symptoms include increasing memory loss, confusion and behavioural changes. As a result, sufferers of Alzheimer's disease find it more and more difficult to carry out their normal daily activities. It is for use in adult patients only.

#### **2. What you need to know before you take Donepezil Teva**

##### **Do not take Donepezil Teva**

- if you are allergic to donepezil hydrochloride, or to piperidine derivatives, or any of the other ingredients of this medicine (listed in section 6).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Donepezil Teva if you have or have had:

- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart condition (such as irregular or very slow heart beat, heart failure, myocardial infarction)
- a heart condition called 'prolonged QT interval' or a history of certain abnormal heart rhythms called Torsade de Pointes or if anyone in your family has 'prolonged QT interval'
- low levels of magnesium or potassium in your blood
- asthma or other long term lung disease
- liver problems or hepatitis
- difficulty passing urine or mild kidney disease

Also tell your doctor if you are pregnant or think you might be pregnant.

### **Children and adolescents**

Donepezil Teva is not recommended for use in children and adolescents younger than 18 years of age.

### **Other medicines and Donepezil Teva**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that your doctor has not prescribed for you but which you have bought yourself from a chemist/pharmacist. It also applies to medicines you may take sometime in the future if you continue to take Donepezil Teva. This is because these medicines may weaken or strengthen the effects of Donepezil Teva. In particular it is important to tell your doctor if you are taking any of the following types of medicines:

- medicines for heart rhythm problems e.g. amiodarone, sotalol
- medicines for depression e.g. citalopram, escitalopram, amitriptyline, fluoxetine
- medicines for psychosis e.g. pimozide, sertindole, ziprasidone
- medicines for bacterial infections e.g. clarithromycin, erythromycin, levofloxacin, moxifloxacin, rifampicin
- anti-fungal medicines e.g. ketoconazole
- other Alzheimer's disease medicines, e.g. galantamine
- pain killers or treatment for arthritis e.g. aspirin, non-steroidal anti-inflammatory (NSAID) drugs such as ibuprofen, or diclofenac sodium
- anticholinergics medicines, e.g. tolterodine
- anticonvulsants e.g. phenytoin, carbamazepine
- medication for a heart condition e.g. quinidine, beta-blockers (propranolol and atenolol)
- muscle relaxants e.g. diazepam, succinylcholine
- general anaesthetic
- medicines obtained without a prescription e.g. herbal remedies

If you are going to have an operation that requires you to have a general anaesthetic, you should tell your doctor and the anaesthetist that you are taking Donepezil Teva. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil Teva can be used in patients with kidney disease or mild to moderate liver disease. Tell your doctor first if you have kidney or liver disease. Patients with severe liver disease should not take Donepezil Teva.

Tell your doctor or pharmacist the name of your caregiver. Your caregiver will help you to take your medicine as it is prescribed.

### **Donepezil Teva with food and alcohol**

Food will not influence the effect of Donepezil Teva. Donepezil Teva should not be taken with alcohol because alcohol may change its effect.

### **Pregnancy breast-feeding**

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.

Donepezil Teva should not be used while breast-feeding.

### **Driving and using machines**

Alzheimer's disease may impair your ability to drive or operate machinery and you must not perform these activities unless your doctor tells you that it is safe to do so.

Also, your medicine can cause tiredness, dizziness and muscle cramp. If you experience any of these effects you must not drive or operate machinery.

### **Donepezil Teva contains lactose**

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

### **Donepezil Teva contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

## **3. How to take Donepezil Teva**

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

### **How much Donepezil Teva should you take?**

Initially the recommended dose is 5 mg (one white tablet) every night before you go to bed. After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night before you go to bed.

The tablet strength you will take may change depending on the length of time you have been taking the medicine and on what your doctor recommends. The maximum recommended dose is 10 mg each night.

Always follow your doctor's, or pharmacist's advice about how and when to take your medicine.

Do not alter the dose yourself without your doctor's advice.

### **How to take your medicine**

Swallow your Donepezil Teva tablet with a drink of water before you go to bed at night.

If you experience abnormal dreams, nightmares or difficulty in sleeping (see section 4) your doctor may advise you to take Donepezil hydrochloride in the morning.

### **Use in children and adolescents**

Donepezil Teva is not recommended for use in children and adolescents (younger than 18 years of age).

### **If you take more Donepezil Teva than you should**

Contact your doctor or the nearest hospital emergency department immediately if you take more of the medicine than you should. Take this leaflet and any remaining tablets with you.

Overdose symptoms may include nausea (feeling sick) and vomiting (being sick), drooling, sweating, slow heart rate, low blood pressure (light-headedness or dizziness when standing), breathing problems, losing consciousness and seizures (fits) or convulsions.

### **If you forget to take Donepezil Teva**

If you forget to take your medicine, just take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

If you forget to take your medicine for more than one week, call your doctor before taking any more medicine.

### **If you stop taking Donepezil Teva**

Do not stop taking the tablets unless told to do so by your doctor. If you stop taking Donepezil Teva, the benefits of your treatment will gradually fade away.

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

### **For how long should you take Donepezil Teva**

Your doctor or pharmacist will advise you on how long you should continue to take your tablets. You will need to see your doctor from time to time to review your treatment and assess your symptoms.

## **4. Possible side effects**

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

The following side effects have been reported by people taking Donepezil Teva.  
Tell your doctor if you have any of these effects while you are taking Donepezil Teva.

**Serious side effects:**

You must tell your doctor immediately if you notice these serious side effects mentioned. You may need urgent medical treatment.

- liver damage e.g. hepatitis. The symptoms of hepatitis are nausea (feeling sick) or vomiting (being sick), loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine (may affect up to 1 in 1000 people).
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (may affect up to 1 in 100 people).
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (may affect up to 1 in 100 people).
- seizures (fits) or convulsions (may affect up to 1 in 100 people).
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome") (may affect up to 1 in 10,000 people).
- muscle weakness, tenderness or pain and particularly, if at the same time, you feel unwell, have a high temperature or have dark urine. They may be caused by an abnormal muscle breakdown which can be life threatening and lead to kidney problems (a condition called rhabdomyolysis) (may affect up to 1 in 10,000 people).
- fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes (frequency cannot be estimated from the available data).

**Other side effects**

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

- diarrhoea
- headache

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

- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)
- the common cold
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmare
- agitation
- aggressive behaviour
- fainting
- dizziness
- stomach feeling uncomfortable
- rash
- passing urine uncontrollably
- pain
- accidents (patients may be more prone to falls and accidental injury)

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

- slow heart beat
- salivary hypersecretion

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

- changes in the heart activity which can be seen on an electro-cardiogram (ECG) called 'prolonged QT interval'

- libido increased, hypersexuality
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side)

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

- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Donepezil Teva**

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 or blister after ‘EXP’. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Donepezil Teva contains**

- The active substance is donepezil hydrochloride. Each film-coated tablet contains 5 mg or 10 mg of donepezil hydrochloride (as monohydrate)
- The other ingredients of the tablet core are maize starch, lactose monohydrate, cellulose, microcrystalline, sodium starch glycollate, type A, silica, colloidal anhydrous, magnesium stearate.

The film-coating contains:

Donepezil Teva 5 mg film-coated tablets:

lactose monohydrate, hypromellose 15 cp, titanium dioxide (E171) and macrogol 4000

Donepezil Teva 10 mg film-coated tablets:

lactose monohydrate, hypromellose 15 cp, titanium dioxide (E171) and macrogol 4000 and yellow iron oxide (E172)

**What Donepezil Teva looks like and contents of the pack**

Donepezil Teva 5 mg Film-coated Tablets are white to off-white, round, biconvex film-coated tablets debossed “DN 5” on one side.

Donepezil Teva 10 mg Film-coated Tablets are yellow, round, biconvex film-coated tablets debossed “DN 10” on one side.

The film-coated tablets are supplied in blister packs of 7, 28, 30, 50, 56, 60, 84, 90, 98 or 120 film-coated tablets.

The film-coated tablets are supplied in blister calendar pack of 7, 28, 56, 84 or 98 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder**

Teva Pharma B.V.  
Swensweg 5  
2031GA Haarlem  
The Netherlands

**Manufacturer**

Teva Operations Poland Sp. z.o.o., Mogilska 80. 31-456, Krakow, Poland  
PLIVA Hrvatska d.o.o. (Pliva Croatia Ltd.), Prilaz baruna Filipovića 25, 10000 Zagreb, Croatia  
Merckle GmbH, Ludwig-Merckle-Str. 3, 89143 Blaubeuren, Germany

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium	Donepezil Teva 5 mg filmomhulde tabletten Donepezil Teva 10 mg filmomhulde tabletten
Germany	Donepezil-HCl AbZ 5 mg Filmtabletten Donepezil-HCl AbZ 10 mg Filmtabletten
France	Donépézil TEVA 5 mg comprimé pelliculé Donépézil TEVA 10 mg comprimé pelliculé
Ireland	Donepezil Teva 5 mg Film-coated Tablets Donepezil Teva 10 mg Film-coated Tablets
Italy	Donepezil Teva
Portugal	Donepezilo Teva
Slovenia	Donepezil Pliva 5mg filmsko obložene tablete Donepezil Pliva 10mg filmsko obložene tablete
Spain	Donepezilo Teva 5 mg comprimidos recubiertos con película EFG Donepezilo Teva 10 mg comprimidos recubiertos con película EFG

**This leaflet was last revised in October 2022.**