

PACKAGE LEAFLET: INFORMATION FOR THE USER

Donepezil Jubilant 5 mg film-coated tablets
Donepezil Jubilant 10 mg film-coated tablets
donepezil hydrochloride

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

1. What Donepezil Jubilant is and what it is used for

Donepezil Jubilant (donepezil hydrochloride) belongs to a group of medicines called acetylcholinesterase inhibitors.

Donepezil 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.

Donepezil Jubilant is for use in adult patients only.

2. What you need to know before you take Donepezil Jubilant

Do not take Donepezil Jubilant

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Donepezil Jubilant if you have or have had any of the following conditions:

- 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 have '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 is not recommended for use in children and adolescents (younger than 18 years of age).

Other medicines and Donepezil Jubilant

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 Jubilant. This is because these medicines may weaken or strengthen the effects of Donepezil Jubilant.

In particular, it is important to tell your doctor or pharmacist if you are taking any of the following types of medicines:

- medicines for heart rhythms 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 infection 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 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 Jubilant. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil Jubilant 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 Jubilant.

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

Donepezil Jubilant with food, drink and alcohol

Food will not influence the effect of Donepezil Jubilant.

Donepezil Jubilant should not be taken with alcohol because alcohol may change its effect.

Pregnancy and breast-feeding

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

Donepezil Jubilant should not be used while breast-feeding.

Driving and using machines

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

Alzheimer's disease may also 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.

Donepezil Jubilant **contains lactose**.

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 Donepezil Jubilant

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. 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 white tablet) every night before you go to bed.

Swallow your Donepezil Jubilant 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 Jubilant in the morning.

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 or pharmacist's advice about how and when to take your medicine. Do not alter the dose yourself without your doctor's advice.

For how long should you take Donepezil Jubilant?

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.

If you take more Donepezil Jubilant than you should

Contact your doctor or the nearest hospital emergency department immediately if you take more than you should. Take the remaining tablets, the leaflet and/or the carton with you to the hospital so that the doctor knows what has been taken.

Symptoms of overdosing 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 Jubilant

If you forget to take your medicine, 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 Jubilant

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

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

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 Jubilant.

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 effect up to 1 in 1,000 people).
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (may effect 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 effect up to 1 in 100 people).
- seizures (fits) or convulsions (may effect up to 1 in 100 people).
- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder known as “Neuroleptic Malignant Syndrome”) (may effect 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 effect up to 1 in 10,000 people).
- fast, irregular heart beat and fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes (frequency cannot be estimated from the available data)

Other possible side effects:

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

- diarrhoea
- feeling or being sick
- headaches

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

- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)
- common cold
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- 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 heartbeat

Rare side effects (may affect up to 1 in 1,000 people):

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

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, hyper sexuality.
- Pisa syndrome (a condition involving involuntary muscle contraction with abnormal bending of the body and head to one side).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Donepezil Jubilant

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 and 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 any medicines you no longer use. These measures will

help protect the environment.

6. Contents of the pack and other information

What Donepezil Jubilant contains

- The active substance is donepezil hydrochloride.

Donepezil Jubilant 5 mg, film-coated tablets

Each tablet contains 5 mg donepezil hydrochloride.

Donepezil Jubilant 10 mg, film-coated tablets

Each tablet contains 10 mg donepezil hydrochloride.

- The other ingredients are:

Tablet core: lactose monohydrate, microcrystalline cellulose (E460), maize starch, hydroxypropyl cellulose (E463), magnesium stearate (470b).

Tablet coating: hypromellose (E464), macrogol, talc, titanium dioxide (E171).

What Donepezil Jubilant looks like and contents of the pack

Donepezil Jubilant 5 mg, film-coated tablets

White to off-white, round film-coated tablets, debossed with J on one side and 5 on the other side. The size of the tablet is 7.7 x 3.4 mm.

Donepezil Jubilant 10 mg, film-coated tablets

White to off-white, round film-coated tablets, debossed with J on one side and 10 on the other side. The size of the tablet is 8.5 x 4.5 mm.

Pack sizes:

Blisters of 28, 50, 56, 98 or 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<To be completed nationally>

Manufacturer:

PSI supply nv

Axxes Businesspark

Guldensporenpark 22 – Block C

9820 Merelbeke

Belgium

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

Sweden	Donepezil Jubilant 5 mg filmdragerade tabletter Donepezil Jubilant 10 mg filmdragerade tabletter
Denmark	Donepezil Jubilant 5 mg filmovertrukne tabletter Donepezil Jubilant 10 mg filmovertrukne tabletter
Italy	Lizidra 5 mg compresse rivestite con film Lizidra 10 mg compresse rivestite con film
Cyprus	Donepezil Jubilant 5 mg επικαλυμμένα με λεπτό υμένιο δισκία Donepezil Jubilant 10 mg επικαλυμμένα με λεπτό υμένιο δισκία
Malta	Donepezil Jubilant 5 mg film-coated tablets Donepezil Jubilant 10 mg film-coated tablets

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