

Donepezil Niche 5mg and 10mg 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.

The name of your medicine is Donepezil Niche 5 mg and 10 mg Film-coated Tablets. It will be called Donepezil Niche for ease from here on.

What is in this leaflet:

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

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

The active ingredient in your tablets is donepezil hydrochloride. It works by increasing the amount of a substance called acetylcholine in the brain.

It is used to treat the symptoms of dementia (changes in the way the brain works) in people with mild to moderately severe Alzheimer's disease. These symptoms include increasing memory loss, confusion and changes in the way you behave, making it more difficult to carry out normal daily activities.

Donepezil Niche is only for use in adult patients.

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

Do NOT take Donepezil Niche:

- if you are allergic to Donepezil hydrochloride (which is a piperidine derivative), or to other 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 Niche if you have or have had:

- stomach or duodenal ulcers
- seizures (fits) or convulsions (uncontrollable shaking movements)
- problems with your heart such as irregular or very slow heart beat
- asthma or other long term lung disease
- liver problems including hepatitis (where your skin and whites of the eyes go yellow)
- difficulty passing urine or mild kidney disease

Children

Donepezil Niche is not recommended for use in children.

Other medicines and Donepezil Niche

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. These medicines may alter the effects of Donepezil Niche if they are taken together.

In particular, tell your doctor if you are taking any of the following types of medicines:

- other Alzheimer's disease medicines, such as galantamine
- pain killers or treatment for arthritis e.g. aspirin, non-steroidal anti-inflammatory (NSAID) drugs such as ibuprofen, or diclofenac sodium
- anticholinergics medicines, such as tolterodine
- antibiotics, such as erythromycin, rifampicin
- medicines used to treat fungal infections, such as ketoconazole, itraconazole
- anti-depressants, such as fluoxetine
- medicines to control fits or convulsions, such as phenytoin, carbamazepine
- medication for a heart condition, such as quinidine, beta-blocker (propranolol and atenolol)
- muscle relaxants, such as diazepam, succinylcholine
- general anaesthetic
- medicines obtained without a prescription, such as 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 Niche. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil Niche with food, drink and alcohol

Donepezil Niche can be taken with or without food.

You should avoid drinking alcohol while you are taking Donepezil Niche because the alcohol may change the effect of Donepezil Niche.

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 Niche should not be taken if you are pregnant, planning to become or think you could be pregnant unless your doctor decides that it is clearly necessary.
- Donepezil Niche must 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 affected you must not drive or operate machinery.

Donepezil Niche 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.

3. How to take Donepezil Niche

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Tell your doctor the name of your caregiver. Your caregiver will help you take your medicine as it has been prescribed.

- 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.
- Usually, you will start by taking 5 mg (one white tablet) every night.
- After one month, your doctor may tell you to take 10 mg (one yellow tablet) every night.
- The maximum recommended dose is 10 mg each night.

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

DO NOT alter the dose yourself without your doctor's advice.

Patients with kidney problems

You can take the usual dose as described above. No dose adjustment is needed.

Patients with liver problems

Your doctor will monitor you before increasing the dose if you have mild or moderate liver problems. If you have severe liver problems, your doctor will decide if Donepezil Niche is suitable for you.

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 Niche than you should

DO NOT take more than one tablet each day. Contact your doctor or nearest hospital casualty department immediately if you take more than you should. Take any remaining tablets, the carton and/or leaflet with you to the hospital so that the doctor knows what has been taken.

If you do take more than you should, you might get symptoms such as feeling and 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 Niche

If you forget to take a tablet, just take one tablet the following day 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 Niche

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

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 Niche.

Tell your doctor or pharmacist if you have any of these effects while you are taking Donepezil Niche.

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 feeling or 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 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 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 (back passage) (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 1,000 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).

Other side effects:

Very common: may affect more than 1 in 10 people

- diarrhoea
- feeling or being sick
- headaches

Common: may affect up to 1 in 10 people

- muscle cramp
- tiredness
- difficulty in sleeping (insomnia)
- the common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- unusual dreams including nightmares
- agitation
- aggressive behaviour
- fainting
- dizziness
- stomach feeling uncomfortable
- rash
- itching
- inability to control passing water (incontinence)
- general pain occurring over the body
- accidents (patients may be more prone to falls and accidental injury)

Uncommon: may affect up to 1 in 100 people

- slow heart beat
- minor increases in blood levels of muscle enzyme (creatin kinase), as shown by blood tests

Rare: 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
- irregular heartbeat, e.g. feeling your heart beat faster or slower

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Donepezil Niche

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

Do not store above 30°C.

DO NOT use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

If your doctor tells you to stop taking your medicine, you should return any you have not used to your pharmacist. 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 Niche contains

- The active substance is Donepezil hydrochloride. The 5 mg tablet contains 5 mg of Donepezil hydrochloride and the 10 mg tablet contains 10 mg of Donepezil hydrochloride.
- The other ingredients are lactose monohydrate, cellulose microcrystalline, magnesium stearate, croscarmellose sodium, talc, macrogol, polyvinyl alcohol, titanium dioxide (E171).
- Additionally, the 10 mg tablet contains synthetic iron oxide yellow (E172).

What Donepezil Niche looks like and contents of the pack

- 5 mg white tablets marked ‘D5’ on one side and plain on the other.
- 10 mg yellow tablets marked ‘D10’ on one side and plain on the other.

The tablets are supplied in packs of 7, 14, 28, 30, 50, 56, 60, 84, 98, 112 or 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation Holder is:
Niche Generics Ltd
1 The Cam Centre
Wilbury Way
Hitchin
Hertfordshire
SG4 0TW
United Kingdom

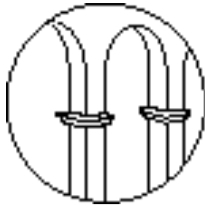
The Manufacturer is:
Niche Generics Ltd
Unit 5
151 Baldoyle Industrial Estate
Dublin 13
Ireland

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

UK: Donepezil Niche 5mg/10mg Film-Coated Tablets

Ireland: Donepezil Niche 5mg/10mg Film-Coated Tablets

This leaflet was last revised in November 2015.



Niche Generics Limited,
Unit 5, 151 Baldoyle Industrial Estate, Baldoyle,
Dublin 13, Ireland
Tel: +353 (0)18167300
e-mail: artwork@nichegenerics.ie

Title:	Donepezil 5mg and 10mg Film-Coated Tablets Niche IE
MA Number/s:	IE: PA 1063/43/1, 1063/43/2
Date of Origination:	16/07/2009
Dimensions:	480mm x 145mm
Colours:	Black ■
Item Code:	N/A
Pharmacode:	TBD
Version Number:	15
Revision Date:	26/11/2015
Reason for Revision:	30/09/15 - addition of risk on rhabdomyoysis, to align with current QRD template and to split joint IE/UK leaflet into 2 separate leaflets. 26/11/15 - addition of revision date

Software: QuarkXpress 4.1