

DONEPEZIL GENERICHEALTH

donepezil hydrochloride

What is in this leaflet

This leaflet answers some common questions about DONEPEZIL GENERICHEALTH (donepezil hydrochloride). It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DONEPEZIL GENERICHEALTH against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What DONEPEZIL GENERICHEALTH is used for

DONEPEZIL GENERICHEALTH tablets are used to treat mild, moderate and severe Alzheimer's disease, or dementia of the Alzheimer's type.

DONEPEZIL GENERICHEALTH will not

cure this disease, but should help improve your memory and thinking capacity.

This medicine belongs to a group of medicines called acetylcholinesterase inhibitors. They are thought to work by increasing the level of a chemical called acetylcholine in the brain.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is only available with a doctor's prescription.

Before you take DONEPEZIL GENERICHEALTH

When not to take it

Do not take DONEPEZIL GENERICHEALTH if you have an allergy to:

- any medicine containing donepezil hydrochloride
- piperidine derivatives
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty in

breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Lactose: DONEPEZIL GENERICHEALTH contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking DONEPEZIL GENERICHEALTH.

Do not give DONEPEZIL GENERICHEALTH to children.

The safety and effectiveness of donepezil hydrochloride in children have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should be taking DONEPEZIL GENERICHEALTH, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you plan to go to hospital for

surgery that requires a general anaesthetic.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problems
- stomach problems, particularly gastric or duodenal ulcer
- seizures or fits (epilepsy)
- asthma or obstructive pulmonary disease
- loss of memory or other mental capacity due to stroke or blood vessel problems
- a tendency towards aggressive behaviour.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking donepezil hydrochloride.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and donepezil hydrochloride may interfere with each other. These include:

- any other medicine for treating dementia
- some medicines used to relieve stomach cramps or spasms, Parkinson's disease or travel sickness

- some medicines used to treat difficulty in passing urine
- non-steroidal anti-inflammatory drugs (NSAIDs) - medicines used to treat arthritis, pain or inflammation
- some medicines used to relax muscles
- some medicines used to treat high blood pressure or fast heart beat
- some medicines used to treat irregular heart beat such as quinidine
- some medicines used to treat asthma, diarrhoea, depression, schizophrenia and related mental conditions, or used in general anaesthesia
- carbamazepine, phenobarbitone or phenytoin, medicines used to treat epilepsy
- ketoconazole, a medicine used to treat fungal infections
- rifampicin, an antibiotic used to treat tuberculosis
- dexamethasone, a corticosteroid medicine.

These medicines may be affected by DONEPEZIL GENERICHEALTH or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

If you are not sure if you are taking any of these medicines, ask your doctor or pharmacist.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DONEPEZIL GENERICHEALTH.

Tell your doctor about these other medicines before you take DONEPEZIL GENERICHEALTH.

How to take DONEPEZIL GENERICHEALTH

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

The usual starting dose for donepezil hydrochloride is one 5 mg tablet each day.

After 1 month, your doctor will assess your response and may increase your dose to one 10 mg tablet a day.

However, depending on your condition and how you react to the medicine, your doctor may change your dose.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take the tablet every night just before you go to bed.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

DONEPEZIL
GENERICHEALTH can be
taken with or without food.

How long to take it for

**Continue taking
DONEPEZIL
GENERICHEALTH for as
long as your doctor tells
you.**

DONEPEZIL
GENERICHEALTH helps to
control your condition, but
does not cure it. It is
important to keep taking
DONEPEZIL
GENERICHEALTH even if
you feel well.

It may take several weeks for
DONEPEZIL
GENERICHEALTH to take
effect, so do not be
discouraged if you do not see
an improvement straight
away.

If you take too much

**Immediately telephone your
doctor or the Poisons
Information Centre (tel. 131
126) or go to Accident and
Emergency (Casualty) at
your nearest hospital, if
you think that you or
anyone else may have
taken too much
DONEPEZIL
GENERICHEALTH. Do this
even if there are no signs
of discomfort or poisoning.
You may need urgent
medical attention.**

If you take more DONEPEZIL
GENERICHEALTH than you
should, you may feel sick in
the stomach, vomit, sweat or
produce more saliva than
usual. You may also have a
slow heart beat, feel dizzy,
have trouble breathing, faint,
have fits, feel weak or not be

able to control your bowel
motions or passing of urine.

While you are taking DONEPEZIL GENERICHEALTH

Things you must do

Tell all doctors, dentists and
pharmacists who are treating
you that you are taking
DONEPEZIL
GENERICHEALTH.

**If you are about to be
started on any new
medicine, remind your
doctor and pharmacist that
you are taking DONEPEZIL
GENERICHEALTH.**

**If you are going to have
surgery, tell the surgeon or
anaesthetist that you are
taking this medicine.**

It may affect other medicines
used during surgery. Your
doctor may ask you to stop
taking DONEPEZIL
GENERICHEALTH a few
days before you have
surgery.

**Tell your doctor
immediately if you become
pregnant while taking
DONEPEZIL
GENERICHEALTH.**

If you are a woman of child-
bearing age, you should
avoid becoming pregnant
while taking DONEPEZIL
GENERICHEALTH.

**Keep all of your doctor's
appointments so that your
progress can be checked.**

Your doctor may do some
tests from time to time to
make sure the medicine is

working and to prevent
unwanted side effects.

If you forget to take it

**If you forget to take a
tablet, take one tablet the
following day at the usual
time then continue as
normal.**

**Do not take a double dose
to make up for the dose
you missed.**

This may increase the
chance of you getting
unwanted side effects.

**If you are not sure what to
do, ask your doctor or
pharmacist.**

**If you forget to take it for
more than 1 week, call your
doctor before taking any
more.**

**If you have trouble
remembering to take your
medicine, ask your
pharmacist for some hints.**

Things you must not do

**Do not give this medicine
to anyone else, even if they
have the same condition as
you.**

**Do not use DONEPEZIL
GENERICHEALTH to treat
any other complaints
unless your doctor says to.**

Things to be careful of

**Be careful driving or
operating machinery until
you know how DONEPEZIL
GENERICHEALTH affects
you.**

This medicine may cause
fatigue, dizziness and muscle
cramps, especially at the start
of treatment or when the

dose is increased. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

In addition, Alzheimer's disease may affect your ability to drive or operate machinery. Ask your doctor whether it is safe for you to continue to drive or operate machinery.

Side Effects

Like other medicines, DONEPEZIL GENERICHEALTH may cause some unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Tell your doctor as soon as possible if you do not feel well while you are taking DONEPEZIL GENERICHEALTH. Your doctor may decide to adjust the dose of DONEPEZIL GENERICHEALTH or may change to a different medicine.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- heartburn, indigestion, or stomach pain
- headache, dizziness
- difficulty in sleeping
- unusual tiredness
- feeling sick, diarrhoea, vomiting

- loss of appetite, weight loss
- bruising
- muscle cramps, joint pain
- tingling or numbness of the hands or feet
- depression, unusual dreams
- agitation, aggressive behaviour
- difficulty passing urine or passing more often

The above side effects are more common and are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- seeing, feeling or hearing things that are not there, abnormal thoughts
- trembling and shaking of the hands and fingers, shuffling walk and stiffness of the arms and legs
- severe upper stomach pain, often with nausea, vomiting and fever

The above list includes serious side effects which may require medical attention.

If any of the following happens, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- any breathing problems
- sudden signs of allergy such as rash, itching or hives, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty in breathing
- fainting, especially if you have a slow or irregular heart beat

- chest pain (angina)
- vomiting blood or material that looks like coffee grounds
- black sticky bowel motions (stools)
- convulsions or fits
- weakness, shortness of breath, yellowing of the skin, dark brown urine and stomach pain
- sudden increase in body temperature, extremely high blood pressure and severe convulsions

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

How to store DONEPEZIL GENERICHEALTH

Storage

Keep DONEPEZIL GENERICHEALTH where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep DONEPEZIL GENERICHEALTH in a cool, dry place where the temperature stays below 25 degrees C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

**Keep DONEPEZIL
GENERICHEALTH tablets
in the original blister pack
until it is time to take them.**

If you take the tablets out of the pack they may not keep well.

Disposal

If your doctor tells you to stop taking donepezil hydrochloride, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

Product description

What DONEPEZIL GENERICHEALTH tablets look like

- DONEPEZIL
GENERICHEALTH 5 mg
tablets – yellow, circular,
biconvex film-coated
tablets debossed with
'RC25' on one side.
Available in packs of 28
tablets.
- DONEPEZIL
GENERICHEALTH 10 mg
tablets – yellow, capsule-
shaped, film-coated
tablets debossed with
'RC' and '26' on either
side of the break line on
one side and a break line
on the other side.
Available in packs of 28
tablets.

Ingredients

Active ingredients

- DONEPEZIL
GENERICHEALTH 5 mg
- 5 mg donepezil
hydrochloride/tablet.

- DONEPEZIL
GENERICHEALTH 10 mg
- 10 mg donepezil
hydrochloride/tablet.

Inactive ingredients

The inactive ingredients are:

- lactose
- maize starch
- hydroxypropylcellulose
- microcrystalline cellulose
- sodium starch glycollate
type A
- magnesium stearate
- hypromellose
- titanium dioxide
- macrogol 400
- purified talc
- iron oxide yellow

DONEPEZIL
GENERICHEALTH tablets do
not contain gluten.

Sponsor

Generic Health Pty Ltd
Level 1, 1102 Toorak Road
Camberwell VIC 3124

Australian Registration Numbers

Donepezil hydrochloride 5 mg
– 172750

Donepezil hydrochloride 10
mg – 172753

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