

DONEPEZIL RBX

Donepezil hydrochloride 5/10 mg Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DONEPEZIL RBX (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 RBX 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 RBX is used for

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

DONEPEZIL RBX 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 RBX

When you must not take it

Do not take DONEPEZIL RBX 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 RBX contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking DONEPEZIL RBX .

Do not give DONEPEZIL RBX 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 RBX, 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 RBX 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 RBX.

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

How to take DONEPEZIL RBX

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 RBX can be taken with or without food.

How long to take it

Continue taking DONEPEZIL RBX for as long as your doctor tells you.

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

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

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.

If you take too much (overdose)

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 RBX. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take more DONEPEZIL RBX 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 RBX

Things you must do

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

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

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 RBX a few days before you have surgery.

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

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

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.

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 RBX 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 RBX 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 RBX 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 RBX.

Your doctor may decide to adjust the dose of DONEPEZIL RBX 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.

After taking DONEPEZIL RBX

Storage

Keep DONEPEZIL RBX 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 RBX in a cool, dry place where the temperature stays below 25°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 RBX 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 it looks like

- DONEPEZIL RBX 5 mg tablets - yellow, circular, biconvex film-coated tablets debossed with 'RC25' on one side. Available in packs of 28 tablets.
- DONEPEZIL RBX 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 RBX 5 mg - 5 mg donepezil hydrochloride/tablet.
- DONEPEZIL RBX 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 RBX tablets do not contain gluten.

Sponsor

DONEPEZIL RBX is supplied in Australia by:

Ranbaxy Australia Pty Ltd.

Suite 4.02, Building D, Level 4
12 - 24 Talavera Road
North Ryde NSW 2113

Australian Registration Numbers

Donepezil hydrochloride 5 mg -
172751

Donepezil hydrochloride 10 mg -
172754

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