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PACKAGE LEAFLET: INFORMATION FOR THE USER

Donepezil Krka 5 mg orodispersible tablets
Donepezil Krka 10 mg orodispersible tablets

Donepezil hydrochloride

You and your caregiver should read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

Donepezil belongs to a group of medicines called acetylcholinesterase inhibitors.

Donepezil Krka is used to treat the symptoms of dementia in people diagnosed as having mild to moderately severe Alzheimer's disease.

2. Before you take Donepezil Krka

Do not take Donepezil Krka
- if you are allergic (hypersensitive) to donepezil hydrochloride or to piperidine derivatives, or any of the other ingredients of Donepezil Krka.

Take special care with Donepezil Krka
Tell your doctor or pharmacist before starting to take Donepezil Krka if you have or have had:
- stomach or duodenal ulcers
- seizures (fits) or convulsions
- a heart problem (especially irregular or very slow heart beat)
- asthma or other long term lung disease
- liver problems or hepatitis
- difficulty passing urine or mild kidney disease.

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 Krka. This is because your medicine may affect the amount of anaesthetic needed.

Donepezil Krka 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 Krka.

Taking other medicines
Especially tell your doctor if you are taking any of the following types of medicines:
- 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,
- antibiotics e.g. erythromycin, rifampicin,
- anti-fungal medicine e.g. itraconazole or ketoconazole,
- anti-depressants e.g. fluoxetine,
- anticonvulsants e.g. phenytoin, carbamazepine,
- medication for a heart condition e.g. quinidine, beta-blockers (propanolol and atenolol),
- muscle relaxants e.g. succinylcholine,
- general anaesthetic,
- medicines obtained without a prescription e.g. herbal remedies.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Donepezil Krka with food and drink
Food will not influence the effect of Donepezil Krka.
Do not drink alcohol during treatment with Donepezil Krka because alcohol may reduce its effectiveness.

Pregnancy and breast-feeding
Do not take Donepezil Krka if you are pregnant.

Do not breast-feed while taking Donepezil Krka.

Ask your doctor or pharmacist for advice before taking any medicine.

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.

Important information about some of the ingredients of Donepezil Krka
- *Aspartame (E951):*
Contains a source of phenylalanine. May be harmful for people with phenylketonuria.
- *Glucose (dextrose), sucrose and sorbitol (E420):*
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

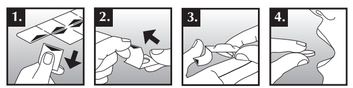
3. How to take Donepezil Krka

Always take Donepezil Krka exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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

Usually, you will start by taking 5 mg every night before you go to bed.
After one month, your doctor may tell you to take 10 mg every night before you go to bed.

Donepezil Krka orodispersible tablets are fragile. They should not be pushed through the foil in the blister pack as this will cause damage to the tablet. Do not handle the tablets with wet hands as the tablets may break up. Remove a tablet from the package as follows:
1. Hold the blister at the edges and separate one blister cell from the rest of the blister by gently tearing along the perforations around it.
2. Pull up the edge of the foil and peel the foil off completely.
3. Tip the tablet out onto your hand.
4. Put the tablet on the tongue as soon as it is removed from the packaging.



In a few seconds it begins disintegrating in the mouth and subsequently can be swallowed with or without water. The mouth should be empty before placing the tablet on the tongue.

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.

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

No dosage adjustment is required if you have kidney problems.

If you have liver problems, your dose may need to be adjusted to your needs by your doctor (see section 2 „Before you take Donepezil Krka").

Do not stop taking the tablets unless told to do so by your doctor.

You will need to see your doctor from time to time to review your treatment and assess your symptoms.

If you take more Donepezil Krka than you should
DO NOT take more than one tablet each day. Call your doctor immediately if you take more than you should. If you cannot contact your doctor, contact the local hospital Accident and Emergency department at once. Always take the tablets and the carton with you to the hospital so that the doctor knows what has been taken.

Symptoms of overdosing include 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 Krka
If you forget to take a tablet, just take one tablet the following day at the usual time.

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Navodila prepognjena na sredini z vidno prvo stranjo (naslovom); pharma kodi, ki izhajata iz sredine navodila, morata biti vidni!

[redacted] - *PMS-433U-KRKA*

KRKA
Emb. mat.: NA. Donepezil Krka odt IE
Izdelal: A. Bradač
Datum: 26.02.2013

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NA. Donepezil Krka odt IE druga stran

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Do not take a double dose to make up for a forgotten tablet. Inform your doctor if you have forgotten to take Donepezil Krka for several days. He or she will tell you how to start taking it again.

If you stop taking Donepezil Krka

Do not stop taking the tablets unless told to do so by your doctor. If you stop taking Donepezil Krka, 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, Donepezil Krka can cause side effects, although not everybody gets them.

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

- fever with muscle stiffness, sweating or a lowered level of consciousness (a disorder called "Neuroleptic Malignant Syndrome") (affects less than 1 user in 10,000)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 (affects 1 to 10 users in 10,000)
- stomach or duodenal ulcers. The symptoms of ulcers are stomach pain and discomfort (indigestion) felt between the navel and the breast bone (affects 1 to 10 users in 1,000)
- bleeding in the stomach or intestines. This may cause you to pass black tar like stools or visible blood from the rectum (affects 1 to 10 users in 1,000)
- seizures (fits) or convulsions (affects 1 to 10 users in 1,000)

Side effects are classified into the following groups in order of frequency:

Very common:	Affects more than 1 user in 10
Common:	Affects 1 to 10 users in 100
Uncommon:	Affects 1 to 10 users in 1,000
Rare:	Affects 1 to 10 users in 10,000
Very rare:	Affects less than 1 user in 10,000
Not known:	Frequency cannot be estimated from available data

Very common:
- diarrhoea
- nausea (feeling sick)
- headaches

Common:
- common cold
- loss of appetite
- hallucinations (seeing or hearing things that are not really there)
- agitation
- aggressive behaviour
- fainting
- dizziness
- difficulty in sleeping (insomnia)
- vomiting (being sick)
- stomach feeling uncomfortable
- skin rash
- itching
- muscle cramp
- passing urine uncontrollably
- tiredness
- pain
- accidents (patients may be more prone to falls and accidental injury)

Uncommon:
- slow heart beat
- slight increase in serum concentration of a certain muscle enzyme (creatine kinase)

Rare:
- stiffness, shaking or uncontrollable movement especially of the face and tongue but also of the limbs (extrapyramidal symptoms)
- disorders of the electrical conduction system of the heart (sino-atrial block, atrioventricular block)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Donepezil Krka

Keep out of the reach and sight of children.

Do not use Donepezil Krka after the expiry date which is stated on the packaging after EXP. The expiry date refers to the last day of that month.

Store in the original blister in order to protect from moisture. This medicinal product does not require any special temperature storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Donepezil Krka contains

- The active substance is donepezil hydrochloride.
  Donepezil Krka 5 mg: Each orodispersible tablet contains donepezil hydrochloride monohydrate equivalent to 5 mg donepezil hydrochloride.
  Donepezil Krka 10 mg: Each orodispersible tablet contains donepezil hydrochloride monohydrate equivalent to 10 mg donepezil hydrochloride.
- The other ingredients are mannitol (E421), microcrystalline cellulose, low-substituted hydroxypropylcellulose, maltodextrine, dextrose, sucrose, gum arabic, sorbitol (E420), banana flavouring, aspartame (E951), calcium silicate and magnesium stearate.

What Donepezil Krka looks like and contents of the pack

Tablets are white round orodispersible tablets, bevel-edged.

Tablets are available in boxes of 10, 28, 30, 50, 56, 60, 84, 90, 98 and 100 orodispersible tablets in blisters.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

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

Name of the Member State	Name of the medicinal product
Czech Republic, France, Ireland	Donepezil Krka
United Kingdom	Donepezil hydrochloride
Italy	Yasnoro
Spain	Yasnal
Greece	Niritos

This leaflet was last approved in

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