

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

Dekinet

Tablets

Active ingredient:

Each tablet contains: Biperiden Hydrochloride (HCl) 2 mg.

For the list of the other ingredients, see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.

Read this entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is the medicine intended for?

This medicine is intended for relief of Parkinson's disease symptoms in all its forms.

Therapeutic group: the medicine belongs to the anticholinergic medicines group.

The medicine acts by relaxing muscles and controlling spasms.

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients the medicine contains (for the list of the other ingredients, see section 6).
- You suffer from narrow-angle glaucoma.
- You suffer from an irregular heartbeat or any other heart problems or illnesses that could lead to tachycardia.
- You have a narrowing of the stomach or bowels, intestinal obstruction, or any other bowel problems such as megacolon.
- You have a benign tumor of the prostate gland.

Special warnings regarding the use of this medicine:

Before (and during) treatment with Dekinet, tell your doctor if:

- You suffer from thyroid gland problems.
- You suffer from glaucoma - see 'Do not use the medicine if'.
- You belong to any of the following groups which might be more sensitive to the effects of the medicine and therefore you may need to be monitored more closely:
 - The elderly, particularly those who suffer or have suffered from a disease, injury or physical disorder that causes decrease in brain function.
 - If you have heart failure, rapid heartbeat (tachycardia) - see 'Do not use the medicine if'.
 - If you have a benign tumor of the prostate gland - see 'Do not use the medicine if'.
 - If you suffer from epilepsy, seizures.

Children and adolescents: this medicine is usually not intended for infants and children. The experience with use in children is limited. Consult your doctor.

Tests and follow-up:

- There are patients who may require closer monitoring while using this medicine. See the section 'Before (and during) treatment with Dekinet, tell your doctor if'.
- You should have your intraocular (in the eye) pressure values checked regularly by a specialist in this field.

Drug interactions:

If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list indicates the active ingredients in the medicines. If you are not sure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Any other medicine for the treatment of movement disorders (e.g., levodopa).
- Any other medicine for the treatment of Parkinson's disease.
- Any treatment for nerve disorders.
- Any medicine that treats muscle spasms/twitching including for the treatment of indigestion and abdominal pains, or medicines to treat nausea and vomiting (e.g., metoclopramide).
- Antihistamines (sometimes used to treat allergies such as hay fever and skin rashes).
- Quinidine (sometimes used to treat heart rate disturbances).
- Anti-cough & cold medicines.
- Anticholinergic medicines.
- Medicines affecting the central nervous system such as sedatives (calming medicines), sleeping pills, antidepressants, antipsychotic medicines.

Use of this medicine and food: it is recommended to take the medicine during a meal.

Use of the medicine and alcohol consumption: do not drink alcohol during the treatment period with this medicine.

Pregnancy and breastfeeding:

If you are pregnant, think you are pregnant, planning a pregnancy or if you are breastfeeding, consult your doctor before taking the medicine.

This medicine should only be used during pregnancy or during the breastfeeding period if your doctor decided that the use is considered essential.

Driving and use of machinery:

The use of this medicine may impair alertness and make you feel sleepy, particularly if you are taking other medicines such as those mentioned in the 'Drug interactions' section. Do not drive, operate machinery or perform activities that require alertness until you know how the medicine affects you.

Important information about some of the medicine's ingredients

Dekinet contains lactose. If you have intolerance to certain sugars, consult your doctor before taking this medicine.

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with the medicine.

The dosage and the manner of treatment will be determined by the doctor only.

The standard dosage is usually:

The dosage is according to the doctor's instructions only.

The initial dosage for treatment of Parkinson's disease is usually half a tablet twice a day. Your doctor will then gradually adjust to the most suitable dosage for you, to control the symptoms.

The dosage for treatment of extrapyramidal symptoms caused by medicines is usually one tablet, 1-3 times a day.

Use this medicine at set times as determined by your attending doctor.

Do not exceed the recommended dose.

The elderly: caution should be exercised. These patients may be more sensitive to the effects of the medicine.

Manner of use:

There is no information on crushing or chewing the tablets.

The tablet may be halved according to the marked score line.

Swallow the tablet with a little water.

It is recommended to take the medicine during a meal to prevent stomach irritation.

If you have accidentally taken a higher dosage: if you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

Overdose symptoms can include anticholinergic effects such as dilated pupils, dryness of mucous membranes, flushing, increase in heart rate, decrease in intestinal motility, urinary system problems, fever, excitation, confusion, clouding of consciousness, hallucinations. In severe cases of overdose cardiac and respiratory depression may occur.

If you forgot to take the medicine: if you forgot to take a dose of this medicine at the set time, take the next dose at its usual time. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor. Even if your state of health improves, do not stop the treatment with the medicine without consulting your doctor.

If you stop taking the medicine: do not stop taking the medicine just because you feel better. If you stop taking the medicine without your doctor's instruction, your condition may get worse. Discontinuation of the medicine should be carried out gradually as directed by your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Dekinet may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

Stop treatment and refer immediately to get urgent medical assistance if the following side effects appear:

- Hypersensitivity (allergic reactions, which may include breathing difficulties, swelling of the lips or face, rash, itching).
- Increased tendency to convulsions /seizures.
- Involuntary movement disorders.
- Impaired coordination of movement and speech disturbances.
- Increase in the pressure in the eye, named glaucoma (narrow-angle glaucoma). You should have your intraocular pressure values checked regularly by a specialist in this field.
- Slowing of the heart rate.
- Difficulty in emptying the urinary bladder, in particular in patients with an enlarged prostate gland (prostate adenoma).

Side effects may occur particularly at the beginning of the treatment and if the dosage is increased too quickly. In patients with disturbances in the brain, excitation is frequently seen. In these cases, it may be necessary to reduce the dosage.

Additional side effects:

Rare side effects (appear in 1-10 users out of 10,000):

- In high doses: excitement, agitation, fear, confusion, mental delusions (illusions and hallucinations), sleepiness.

- Influence on sleep phases.
- Fatigue, dizziness, memory disorders.
- Accelerated pulse (palpitations), tachycardia.
- Dry mouth (marked dryness of the mouth can be improved by frequently drinking small amounts of liquid or by chewing sugar-free chewing gum).
- Digestive system disorders.
- Nausea.
- Muscle twitching.
- Drowsiness.

Very rare side effects (appear in less than one user out of 10,000):

- Nervousness, unusually elevated mood (euphoria).
- Headache.
- Visual disturbances.
- Pupil dilatation with sensitivity to light.
- Constipation.
- Reduced sweating.
- Allergic skin rash.
- Difficulty in passing urine (urinary retention).

Side effects of unknown frequency (effects whose frequency has not yet been determined):

- Swelling or inflammation of the salivary glands.
- Decrease in blood pressure.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with your doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.il) which leads to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, should be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Storage conditions: store below 25 °C.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Corn starch, lactose, microcrystalline cellulose, calcium phosphate dibasic dihydrate, povidone 25, talc micronized, magnesium stearate.

Each tablet contains about 38 mg of lactose.

What does the medicine look like and what does the package contain?

Almost white tablet with a score line. D/2 is embossed on the tablet.

Manufacturer and registration holder: Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 0153224634

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