

**PATIENT PACKAGE INSERT IN ACCORDANCE
WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

The medicine is dispensed with a doctor's prescription only

Kemadrin Tablets 5 mg

The active ingredient and its quantity:

Each tablet contains: Procyclidine Hydrochloride 5 mg
Inactive ingredients and allergens in the medicine: see sections 2 "Important information regarding some of the ingredients of the medicine" and 6 "Further Information" in the leaflet.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist. Kemadrin tablets are not intended for use in children.

This medicine has been prescribed as treatment for you. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine Kemadrin is intended for the treatment of all forms of Parkinson's disease: idiopathic (of unknown source), postencephalitic (after a viral inflammation of the brain) and arteriosclerotic (related to blood vessels).

Therapeutic group:

The active ingredient in Kemadrin is procyclidine, which belongs to the group of anticholinergic medicines that prevent the action of the substance acetylcholine in the body.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient procyclidine or to any of the other ingredients contained in the medicine (see section 6).
- You have problems passing urine (urinary retention).
- You suffer from a problem caused by excessive intraocular pressure called "closed angle glaucoma".
- You have stomach cramps and pains or constipation.

Do not take the medicine if any of the conditions listed above apply to you. If you are uncertain, discuss this with the doctor or pharmacist before starting use of Kemadrin.

Special warnings regarding use of the medicine

Before starting treatment with Kemadrin, tell the doctor if:

- You are elderly. You should adhere carefully to the dosage prescribed for you to avoid side effects.
- You suffer from a problem caused by excessive intraocular pressure called "narrow angle glaucoma" or if you are at increased risk for glaucoma.
- You have an obstructive bowel disease.
- You have an enlarged prostate gland.
- You have kidney or liver problems.

If you are uncertain whether any of the conditions listed above apply to you, discuss this with the doctor or pharmacist before starting use of Kemadrin.

Children

Kemadrin tablets are not intended for use in children.

Drug interactions

If you are taking, or have recently taken, other medicines including non-prescription medicines, nutritional supplements and herbal medicines, tell the doctor or pharmacist. This is because Kemadrin may affect the action of certain medicines and other medicines may affect the action of Kemadrin. In particular, inform the doctor or pharmacist if you are taking the following medicines:

- Medicines to treat mental disorders and mental illnesses (including Alzheimer's disease and dementia)
- Levodopa and amantadine to treat Parkinson's disease
- Disopyramide, quinidine and nitrate tablets (including tablets that dissolve under the tongue) to treat heart problems
- Cisapride, domperidone and metoclopramide to treat nausea and digestive problems
- Antihistamines to treat hay fever and allergies
- Nefopam to treat pain
- Ketoconazole to treat fungal infections
- Paroxetine

If you are uncertain whether any of the conditions listed above apply to you, discuss this with the doctor or pharmacist before starting use of Kemadrin.

Pregnancy and breastfeeding

If you are pregnant, may become pregnant or are breastfeeding, consult the doctor before taking the medicine.

Driving and operating machinery

During use of Kemadrin, you may experience blurred vision, dizziness, confusion or disorientation. If this happens to you, avoid driving and operating dangerous machinery and tools while using the medicine.

Important information regarding some of the ingredients of the medicine

Kemadrin contains lactose (a type of sugar). If you suffer from an intolerance to certain sugars, consult with the doctor before using the medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the medicine. The dosage and treatment regimen will be determined by the doctor only.

- Swallow the tablet with a glass of water.
- You can take Kemadrin at any time of the day, with or without food. Sometimes there is a reduced feeling of nausea if you take the medicine at a mealtime.
- The tablet can be halved or broken along the break-line to divide the dose into two equal halves.

For treatment of Parkinson's disease:

- The usual starting dosage is generally 2.5 mg, three times a day. This dosage can be increased every two or three days, by 2.5 mg to 5 mg a day, until an effect is achieved. The usual daily dosage is generally 3 to 6 tablets.
- The maximum dosage the doctor can prescribe for you is 12 tablets.
- Although the medicine is usually taken three times a day, the doctor may ask you to take a fourth dose before bedtime.

Elderly

If you are elderly, the dosage prescribed for you has to be carefully adhered to in order to avoid side effects.

Children

Kemadrin tablets are not intended for use in children.

- **Do not exceed the recommended dose.**
- **If you have accidentally taken a higher dose**

If you took an overdose or if a child or someone else has accidentally swallowed some medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

- **If you forget to take the medicine**
If you forgot to take this medicine at the designated time, do not take a double dose. Take the tablet as soon as you remember, and then continue taking the medicine as usual and consult the doctor.
- Adhere to the treatment as recommended by the doctor.
- **If you stop taking Kemadrin**
Even if there is an improvement in your health, do not stop treatment with the medicine without first consulting the doctor as the symptoms may recur.
- **Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**
- **If you have further questions regarding use of the medicine, consult the doctor or pharmacist.**

4. SIDE EFFECTS

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

The following side effects may occur during use of this medicine:

Common side effects (occur in 1-10 in 100 users)

- Problems passing urine (urinary retention)
- Blurred vision
- Dry mouth
- Constipation

Uncommon side effects (occur in 1-10 in 1,000 users)

- Nausea or vomiting
- Inflammation of the gums (gingivitis)
- Dizziness, nervousness, feeling confused, feeling disoriented, reduced concentration or memory, hearing unexpected noises or seeing unexpected things (hallucinations), anxiety, agitation (irritability)
- Skin rash

Rare side effects (occur in 1-10 in 10,000 users)

- "Psychotic disorder" that includes symptoms that occur simultaneously, such as: dizziness, confusion, reduced concentration or memory, disorientation, hearing unexpected noises or seeing unexpected things (hallucinations), anxiety, agitation (irritability)

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

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

In addition, you can report to Padagis via the following address: Padagis.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order 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.
- Store below 25°C.
- Can be used for 50 days after first opening, but not later than the expiry date.
- Do not dispose of medicines via wastewater or household waste. Ask the pharmacist how to dispose of medicines you no longer need. Taking these measures will help to protect the environment.

6. FURTHER INFORMATION

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

Lactose monohydrate, Sodium starch glycolate, Povidone K30 and Magnesium stearate.

What does the medicine look like and what are the contents of the package:

Kemadrin tablets are white, round and biconvex, with a break-line on one side and marked with KT above the line and 05 below the line, and a score-line on the other side. Kemadrin 5 mg comes in bottles containing 100 or 500 tablets.

Not all package sizes may be marketed.

- Registration holder and address: Padagis Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Manufacturer and address: Aspen Bad Oldesloe GmbH, Bad Oldesloe, Germany.
- Revised in May 2023 according to MOH guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 01827.20446