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

This medicine is sold with a doctor's prescription only

Pramin Tablets

Active ingredient:
Each tablet contains: Metoclopramide hydrochloride (HCl) 10 mg
For a list of the other ingredients, please see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.
Read this entire leaflet carefully before using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for treating your condition. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is the medicine intended for?

The medicine is intended to prevent nausea and vomiting and to stimulate gastrointestinal motility. The medicine is given in specific conditions, as determined by the doctor.
Therapeutic group: Dopamine receptor antagonists.

2. Before using the medicine

Do not use the medicine if:

- Do not use if you are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (for a list of the other ingredients, please see section 6).
- Do not use if you suffer from conditions in which stimulating the gastrointestinal system may cause harm, e.g.: bleeding in the digestive system, narrowing, obstruction or perforation in the digestive system (e.g. in the intestine or stomach).
- Do not use if you suffer or there is a suspicion you suffer from pheochromocytoma.
- Do not use if you suffer from Parkinson's disease, convulsions or epilepsy.
- Do not use if you suffer or have suffered in the past from tardive dyskinesia, after taking certain medicines (e.g. neuroleptic medicines or medicines containing metoclopramide).
- Do not use if you are taking levodopa, or other dopaminergic medicine.
- Do not use if you suffer or have suffered in the past from methemoglobinemia or NADH cytochrome b5 deficiency (red blood cells syndromes).
- Do not use in children under one year of age – see also 'Use in children' below.

Special warnings regarding the use of this medicine:

- If you are sensitive to any type of food or medicine, inform the doctor before taking this medicine.

Before starting treatment with Pramin (and during treatment) tell your doctor:

- If you suffer or have suffered in the past from impaired function of the: heart (including heart rhythm disturbances), kidneys, liver.
- If you suffer or have suffered in the past from neurological problems.
- If you suffer or have suffered in the past from problems in the levels of salts in your blood (e.g.: potassium, sodium, magnesium).

If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition 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 mentions the active ingredients of the medicines. If you are unsure whether you are using any of these medicines, please consult with your doctor or pharmacist):

- Levodopa or dopaminergic medicines (dopamine agonists, used amongst other things to treat Parkinson's disease): do not use concomitantly with Pramin.
- Medicines that affect the central nervous system (e.g.: antianxiety medicines, sedatives, sleep-inducing medicines, certain antidepressants and medicines for treatment of mental illnesses, certain antihistamines against allergies, barbiturates, clonidine).
- Serotoninergic medicines such as antidepressants of the SSRIs group (such as fluoxetine, paroxetine).
- Opioid analgesics and anticholinergics or medicines with an anticholinergic activity (such as medicines against abdominal cramps) since they influence the motility of the digestive system.
- Neuroleptic medicines (for treatment of mental problems such as schizophrenia).
- Certain muscle relaxants e.g.: Mivacurium and suxamethonium.
- Medicines which affect the heartbeats.
- Digoxin, ciclosporine.
- Pramin can influence the absorption of a large number of other medicines. Confirm with your doctor whether the rest of the medicines you take do not contradict this medicine.

Use of this medicine and food:
In diabetic patients suffering from diabetic gastroparesis, the medicine should be used about half an hour before a meal.

Use of this medicine and alcohol consumption: Do not drink wine or alcoholic beverages during treatment with this medicine. Alcohol may increase the sedative effect of Pramin.

Pregnancy and breastfeeding:

- Do not use the medicine without consulting a doctor if you are pregnant, think you might be pregnant or planning a pregnancy.
- This medicine is not recommended for use if you are breastfeeding.

Driving and use of machinery: Use of this medicine may impair alertness and cause dizziness, involuntary muscle movements and other side effects that may affect vision and the ability to drive or operate machinery. If you feel these effects, do not drive or operate machinery. Either way, caution must be exercised when driving a vehicle, operating dangerous machinery and with any activity that requires alertness. As for children, they should be warned against riding a bicycle or playing near roads etc.

Use in children:

- The medicine is not intended for children who weigh less than 30 kg. In any case, the dosage will be determined by the doctor.
- Do not use in children under one year of age.

Use in the elderly and in patients with liver and/or kidney problems: a reduced dosage may be required. Elderly may be more sensitive to the side effects of the medicine.

Important information about some of the medicine's ingredients:
The tablets contain lactose. If you are sensitive to lactose, inform the doctor before taking this medicine (see section 6).

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.
The dosage and the manner of treatment will be determined by the doctor only.
Use this medicine at set intervals as determined by the attending doctor.

This medicine is usually not recommended for prolonged use (more than 3 months).
The dosage will be determined by the doctor only. The medicine is usually taken up to 3 times daily. Make sure that between doses there is an interval of no less than six hours (even in case of vomiting the dose).
The duration of treatment with the medicine is usually limited to 5 days. In diabetic patients suffering from diabetic gastroparesis the duration of the treatment is usually limited to 3 months.
Do not exceed the recommended dose.

Directions for use:
Swallow the tablet with water.
There is no information regarding crushing or chewing the tablets. The tablet may be halved according to the scored line.
Tests and follow up: the doctor may recommend certain blood tests.
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 hospital emergency room and bring the package of the medicine with you. Symptoms of overdose may include: involuntary movements (extrapyramidal disorders), drowsiness, decreased level of consciousness, confusion, hallucinations, heart problems.

If you forgot to take the medicine at the set time, take the dose as soon as you remember, but never take two doses together! In any case, make sure that there is an interval of no less than six hours between doses.
Even if your state of health improves, do not stop the treatment with this medicine without consulting 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 any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side effects
Like any medicine, the use of Pramin may cause side effects in some users. If the side effects persist or they are bothersome or get worse, consult your doctor. Do not be alarmed upon reading the list of side effects, you may not suffer from any of them.
Stop the treatment and refer to a doctor immediately, if the following side effects occur:
- Involuntary movements of the face (e.g. eyes, lips, tongue), neck or any other body part (these effects may occur especially at the beginning of the treatment, even after one dose and especially when using high dosage).
- High fever, high blood pressure, convulsions, sweating, increased production of saliva. These symptoms may be part of a neuroleptic malignant syndrome.
- Itching, rash, swelling of the face, lips or throat, breathing difficulties. These symptoms may indicate an allergic reaction that might be severe.
- Methemoglobinemia (which may also be manifested by change of skin color).

Additional side effects including frequencies:
Very common side effects (appear in more than one user out of ten): Sleepiness/ drowsiness.
Common side effects (appear in 1-10 users out of 100): Depression, uncontrollable movements such as tics, tremor, twitching movements or muscle contractions (including stiffness), symptoms similar to Parkinson's disease, restlessness, decrease in blood pressure, diarrhea, weakness.

Uncommon side effects (appear in 1-10 users out of 1,000): Movement impairments and impairments in muscles tone, increased prolactin levels (which may cause milk production in men and in non-breastfeeding women), disruptions in menstrual cycle (including absence of menstruation), hallucinations, decreased level of consciousness, slow heartbeat, hypersensitivity (allergy).
Rare side effects (appear in 1-10 users out of 10,000): Confusion, convulsions.
Side effects of unknown frequency (effects whose frequency has not yet been determined): Methemoglobinemia or sulfhemoglobinemia (which may also be manifested by change of skin color), abnormal enlargement of the breasts, involuntary muscle spasms and movement impairment during prolonged use and/or after stopping prolonged use (tardive dyskinesia), neuroleptic malignant syndrome, changes in heart rate (which can be seen on an ECG), cardiac arrest, severe allergic reaction (anaphylactic reaction), shock (severe decrease in blood pressure), fainting, transient increase in blood pressure, very high blood pressure.

Side effects and drug interactions in children and infants: Parents must inform the attending doctor of any side effect, as well as any additional medicine being given to the child. See above for detailed side effects and drug interactions.

In any case you experience side effects that are not mentioned in this leaflet or if there is a change in your general feeling, consult the doctor immediately!

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 you to an online form for reporting side effects, or by entering the link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) stated 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 tablets also contain:**
  Cellulose microcrystalline, lactose, corn starch, silicone dioxide colloidal, magnesium stearate, ponceau lake.

Each tablet contains about 75 mg lactose.

What does the medicine look like and what does the package contain?
Package of 30 pink, round tablets with a scored line, imprinted with 'RAFA'.

Registration holder: Rafa laboratories Ltd., P.O.Box 405, Jerusalem 9100301.
Medicine registration number in the National Medicines Registry of the Ministry of Health:
0514924302

This leaflet was checked and approved by the Ministry of Health in April 2017.

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