PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Dopicar

Tablets

Composition

Each tablet contains:
Levodopa 250 mg
Carbidopa 25 mg
For information about inactive ingredients see section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.
This medicine is not intended for children under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?

Dopicar is intended for the relief of Parkinson's disease symptoms.

Therapeutic group

Parkinson's disease is a long-term illness where:
- You become slow and unsteady
- There is a feeling of muscle stiffness
- You may develop tremor

If not treated, Parkinson's disease can make it hard for you to continue with your normal daily activities.
Dopicar contains two different medicines called: levodopa and carbidopa.
- Levodopa is converted in the brain into a substance called "dopamine". The dopamine helps to improve your Parkinson's disease symptoms.
- Carbidopa belongs to a group of medicines called dopa-decarboxylase enzyme inhibitors. Carbidopa helps levodopa to work more effectively by slowing the speed at which levodopa is broken down in your body.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:
- You are sensitive (allergic) to the active ingredients (carbidopa or levodopa) or to any of the other ingredients this medicine contains (see section 6 – "Additional information").
- You are suffering or have suffered in the past from skin cancer or you have abnormal moles which have not been examined by a doctor.
- You are taking certain medicines called "MAOIs" (from the monoamine oxidase inhibitors group) that are used to treat depression. These medicines should be discontinued at least two weeks before starting to use Dopicar (see also the section "Drug interactions").
- You have a condition called "narrow-angle glaucoma" which may cause a sudden increase in intraocular pressure.
- You have a severe mental disorder.
- You are pregnant, might become pregnant, or are breastfeeding.

Do not take Dopicar if any of these apply to you. If you are not sure, consult the doctor or pharmacist before taking Dopicar.

Special warnings regarding the use of the medicine

Before commencing treatment with Dopicar, inform the doctor if:
- You have suffered in the past from spasms (convulsions).
- You have had an ulcer in the digestive system (called "duodenal ulcer" or "peptic ulcer") or have vomited blood.
- You have had a heart attack, heart arrhythmias, blood circulation problems or breathing problems.
- You have had kidney problems, liver problems or hormonal problems.
- You have had depression or other mental problems.
- You have a condition called "chronic open-angle glaucoma" which may cause an increase in intraocular pressure. You will need to have regular intraocular pressure tests.
- You sometimes have sudden sleep attacks or you sometimes feel very sleepy.
- You are due to have surgery.

If you are not sure if any of these apply to you, consult the doctor or pharmacist before taking Dopicar.
Inform the doctor if you or your family/caregiver notices that you are developing an urge or desire to behave in ways that are unusual for you, or you are unable to resist the urge, desire or temptation to carry out certain activities that may harm you or others. These behaviors are called "impulse control disorders" and may include addiction to gambling, excessive eating, excessive spending, an unusually high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to re-evaluate your treatments.

Children and adolescents

Dopicar is not intended for use in children under 18 years of age.

Tests and follow-up

This medicine may affect certain laboratory tests of blood or urine samples, that the doctor will ask to perform. Please remind the doctor if you are taking Dopicar and are expected to have any tests.

Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. This is because Dopicar may affect the way other medicines work and other medicines may also affect the way Dopicar works. Especially if you are taking:
- Medicines for Parkinson's disease containing levodopa:
  - If they are "slow release", wait 24 hours after taking the last dose before starting Dopicar.
  - If they are "regular release", wait 12 hours after taking the last dose before starting Dopicar.
  - Tell the doctor or pharmacist even if you have only taken these medicines in the past.

  Medicines for Parkinson's disease which do not contain levodopa will usually be continued. However, your dosage may need to be changed.
- Medicines for the treatment of mental problems (including depression), medicines for tuberculosis, medicines for hypertension, medicines for muscle spasms, medicines for the treatment of epilepsy, or other diseases associated with involuntary movements. Your dosage may need to be changed.
- Medicines to treat low iron levels. Your dosage may need to be changed.
- Medicines called MAOIs (monoamine oxidase inhibitors, see also the section "Do not use this medicine if").
- Anticholinergic medicines (such as orphenadrine, trihexyphenidyl, benzatropine and procyclidine). Your dosage may need to be changed.
- Phenytoin – used to treat spasms (convulsions).
- Papaverine.

If you are not sure if any of these apply to you, consult the doctor or pharmacist before taking this medicine.

Use of the medicine and food

Try to avoid taking the tablets with a heavy meal. If your diet contains too much protein (meat, eggs, milk, cheese), Dopicar may not work properly.

Pregnancy and breastfeeding

Do not use Dopicar if you are pregnant, might become pregnant or are breastfeeding.
Levodopa (one of the ingredients in Dopicar) passes into breast milk.
If you are pregnant or breastfeeding, consult the doctor or pharmacist before taking any medicine.

Driving and operating machinery

- Dopicar affects different people in different ways. Some people have side effects which affect the ability to drive or operate tools or machinery (see section 4 – "Side effects"). Do not drive or operate tools or machinery if you experience these effects.
- This medicine may also make you sleepy or cause "sudden sleep attacks". If this happens to you, do not drive or operate tools or machinery. Your doctor will tell you if you can return to driving if these attacks stop.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

Dosage

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

Do not exceed the recommended dose.

Method of use

- Take the medicine by mouth.
- Although the medicine can have an effect after one day, it may take up to seven days for the medicine to work.
- Take the tablets at regular time intervals according to the treating doctor's instructions.
- Do not change the times at which you take your tablets, or any other medicine for Parkinson's disease, without prior consultation with the doctor.
- Try to avoid taking the tablets with a heavy meal.
- The tablets can be halved at the score line.
- There is no information regarding pulverization and chewing.
- Swallow the tablet with a glass of water.
- The medicine should be taken shortly before the meal.

If you have accidentally taken a higher dosage of Dopicar

If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take Dopicar

If you forgot to take this medicine at the required time, do not take a double dose to compensate for a forgotten dose.
Follow the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop taking Dopicar

Do not stop taking the medicine and do not change the dosage without prior consultation with the doctor. When treatment is stopped, the following effects may occur: muscle stiffness, high fever and mental changes.
Maximal improvement as a result of the treatment may not be felt until a few weeks after the beginning of treatment.

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

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Dopicar may cause side effects in some users.
Do not be alarmed when reading the list of side effects, you may not experience any of them.

Stop using Dopicar and refer to a doctor immediately if you notice any of the following side effects:
- An allergic reaction, the signs may include hives, itching, rash, swelling of the face, lips, tongue or throat. This may cause difficulty breathing or swallowing
- Chest pain
- Irregular heartbeat or palpitations
- Dizziness when standing up quickly
- Intestinal bleeding that may appear as blood in the stool or as dark stool (bleeding from the digestive system)
- Blood problems, the signs may include pallor, tiredness, fever, sore throat or mild bruising and longer-than-usual bleeding after injury
- Muscle stiffness, high fever
- Mental changes including delusions, hallucinations and depression
- Spasms (convulsions)

The most common side effects are:
- Abnormal movements such as twitching or spasms (which may or may not be like your Parkinson's disease symptoms)
- Nausea
- Urinary tract infections (very common side effects)

Additional side effects:
- Fainting, anorexia, high blood pressure
- Inflammation of the veins, vomiting, diarrhea, changes in color of urine, sweat or saliva
- "On-off" phenomenon, characteristic of some people with long-standing Parkinson's disease. The phenomenon is characterized by unpredictable changes from a state of mobility – "on", to a sudden inability to move – "off". The transition from "off" to "on" can occur just as suddenly
- Dizziness, sleepiness (including excessive drowsiness or episodes of suddenly falling asleep), prickling and tingling sensation
- Unusual dreams, confusion, feeling agitated, shortness of breath, hair loss

You may experience the following side effects:
- A craving for large doses of Dopicar, in excess of what is required to control motor symptoms, known as "dopamine dysregulation syndrome". Some patients experience severe involuntary movements (dyskinesia), mood swings or other side effects after taking large doses of the medicine
- Inability to resist the urge to carry out activities that may be harmful, including:
  - Strong urge to gamble excessively despite serious personal or family consequences
  - Altered or increased sexual interest and behavior, which cause discomfort to you or others, for example, an increased sexual drive
  - Excessive shopping or uncontrollable spending
  - Binge eating (eating large amounts of food in short time periods) or compulsive eating (eating more food than usual and more than is needed to satisfy your hunger)

Refer to the doctor if you experience any of these behaviors, your doctor will discuss with you ways of managing or reducing the symptoms.

Side effects that have been reported with medicines containing levodopa

These effects may occur when taking Dopicar.

Nervous system:
- Loss of control over the voluntary movements of everyday life
- Numbness, increased hand tremor, muscle spasms, muscle cramps, abnormal movements of the jaw muscles that cause difficulty opening the mouth
- Sleeping difficulties, feeling anxious or uplifted, falling over and abnormal walking patterns
- Headache

Eyes:
- Drooping of the eyelids and dilated pupils
- Changes in vision, abnormal movements of the eye

Digestive system:
- Digestive difficulties, dry mouth, bitter taste
- Swelling of the salivary glands, difficulty swallowing, teeth grinding
- Hiccups, abdominal pain or distress, constipation, flatulence
- Burning sensation of the tongue

Sexual:
- Abnormal and persistent erection

Urinary:
- Difficulty passing urine or incontinence (inability to control urine flow)

Skin:
- Changes in patches of pigmented skin, including irregular or irritated moles or moles in which you have noticed changes (melanoma)

General:
- Weight gain or loss, limb swelling
- Flushing, hot flashes, increased sweating
- Feeling weak, faint or tired
- Hoarseness, general malaise
- Increase in energy or activity, abnormal breathing patterns

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

It will help if you write down what you felt, when it started and how long it lasted.

Reporting side effects

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

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dry place below 25°C.**
- **The medicine can be used for up to 60 days after first opening the bottle, but no later than the medicine's expiry date.**
- Do not discard medicines via wastewater or the trash. Ask your pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. ADDITIONAL INFORMATION

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

Microcrystalline cellulose, pregelatinized starch, starch, magnesium stearate, FD&C Blue No.2.

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

A round, blue tablet, slightly spotted with white, debossed with the word "TEVA" on one side and quadrisected on the other side.
The package contains 30 tablets.

Name and address of marketing authorization holder and manufacturer:

TEVA ISRAEL LTD,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in December 2023 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:

040.96.22970