PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

APO-GO®
Ampoules
For injection or subcutaneous infusion

Composition
Each ml contains:
Apomorphine Hydrochloride 10 mg

For a list of the inactive ingredients in the preparation, see section 6 – "Further Information".

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.

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

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of Parkinson's disease.
Apomorphine helps to reduce the duration of attacks of immobility (a state in which the patient loses mobility and is unable to perform routine daily activities) in Parkinson's patients for whom treatment with oral preparations **for Parkinson's disease** is insufficient.

Therapeutic group:
Dopamine agonist.

2. BEFORE USING THE MEDICINE

Do not use the medicine:
- If there is a known sensitivity to any of its ingredients, to sulphite or bisulphite.
- If you suffer from breathing problems, dementia, Alzheimer's disease, hallucinations, delusions, illusions, loss of contact with reality, a psychotic disease or liver problems.
- If you are under the age of 18.
- If you had a severe reaction of involuntary movements (dyskinesia) or muscle tension disorder (dystonia) despite treatment with levodopa (to treat Parkinson's).
- If you or one of your family members has a known ECG phenomenon called "long QT syndrome".
- If you are taking ondansetron (for the treatment of nausea and vomiting).

Special warnings regarding use of the medicine
Before starting treatment with APO-go ampoules, you must bring the attending doctor your ECG tests and a list of the other medicines that you are taking. You will be requested to repeat the ECG test in the first few days of treatment as well as whenever the doctor thinks it is necessary. You must inform the doctor immediately of any other ailments, especially those related to the heart, such as palpitations, fainting or near fainting. Inform the doctor if you have diarrhea or commenced treatment with a new medicine.

Before starting treatment, inform the doctor if you suffer, or have suffered in the past, from any medical problem or if there is a family history, including:
If you suffer, or have suffered in the past, from dysfunction of the respiratory system (e.g., pulmonary diseases), the heart, the liver, the kidney, the nervous system, propensity toward nausea and vomiting, low blood pressure (feeling faint or dizzy upon standing), if you are taking medicines to lower high blood pressure, if the Parkinson's disease causes mental problems such as hallucinations and confusion, if you are elderly or frail, or if you are breast-feeding.
If you are sensitive to any food or medicine, inform the doctor before taking the medicine.

Additional warnings
Tell the doctor if you experience, or if your caregiver notices, the development of uncontrollable urges or desires or temptation to carry out unusual activities that may harm yourself or others. These actions are called impulse-control disorders and may include a range of behaviors such as addictive gambling, excessive eating, exaggerated spending, increased sex drive or an increase in sexual thoughts or feelings. The doctor will consider adjusting the dosage or stopping treatment.
Some patients develop addiction-like symptoms that lead to craving for high dosages of APO-go ampoules and other medicines used to treat Parkinson's disease.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or the pharmacist if you are taking:
- medicines for high or low blood pressure
- medicines to regulate heart rhythm (e.g., quinidine or amiodarone)
- neuroleptic medicines (e.g., clozapine)
- antidepressants including tricyclic antidepressants (e.g., amitriptyline, imipramine)
- antibiotics of the macrolide group (e.g., erythromycin, azithromycin, clarithromycin)
- domperidone (medicine for the stomach)
- other medicines for treatment of Parkinson's. If you are taking this medicine concomitantly with levodopa (for treatment of Parkinson's), perform blood tests regularly
- ondansetron (medicine for the treatment of nausea and vomiting), which may cause a severe drop in blood pressurre and loss of consciousness.

Use of this medicine together with food and drink
Food and drink do not influence the effect of the medicine.

Pregnancy
Do not use the medicine if you are pregnant, except in circumstances when use of the medicine is essential, only after consultation with the doctor.
If you are pregnant, planning to become pregnant or think that you are pregnant, consult the doctor before using the medicine.

Breast-feeding
It is unknown whether the medicine passes into breast milk, and therefore, you should consult with the doctor if you are breast-feeding or are planning to breast-feed. The doctor will advise you whether to stop treatment with the medicine or to stop breast-feeding.

Use in children
This medicine is not intended for use in patients under 18 years of age (see also section 2).

Driving and use of machines
Use of this medicine may impair alertness (may cause increased drowsiness), and therefore, caution must be exercised when driving a car, operating dangerous machinery, and when engaging in any activity which requires alertness.

Important information about some of the ingredients of the medicine
The medicine contains sodium metabisulphite, which may cause hypersensitivity reactions such as a rash or skin itchiness, breathing difficulties, swelling of the eyelids, face or lips, swelling or reddening of the tongue. If you experience these effects, refer immediately to your nearest hospital emergency room.

3. HOW SHOULD YOU USE THIS MEDICINE?

For injection or subcutaneous infusion.
Before using APO-go ampoules, the attending doctor will make sure that you can receive this medicine, as well as anti-nausea medicine, that you need to take simultaneously.
Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are unsure.
The dosage and treatment regimen will be determined by the doctor only.
Take the medicine exactly as prescribed. The doctor will adjust the dosage suitable for you on an individual basis.
If you are unsure in regards to the timing or the method of injection, you should consult the attending doctor.
Domperidone should be taken at least 2 days before starting treatment with APO-go, so that you will not suffer from nausea and vomiting.

Do not use APO-go ampoules if:
- the solution has turned green.
- the solution has become cloudy and particles can be seen in it.

Where to inject APO-go ampoules
Inject the ampoules subcutaneously as the doctor or nurse instructed you.
There are five suitable areas for injection: The front part of the abdomen, the front part of the thighs and the outer part of the upper arms. Read the APO-go ampoules injection instructions.
Do not inject APO-go into a vein.

Usual dosage:
The amount of APO-go ampoules that should be used and the number of daily injections will be determined according to your personal needs. During your visit to the specialist clinic, the doctor will discuss this with you and determine the amount and frequency of injection of the medicine that are best suited to your condition.
- The usual daily dosage is 3 mg - 30 mg.
- You may need a dosage of up to 100 mg per day.
- Generally, you will need between 1 to 10 injections per day.
- Do not use a dose exceeding 10 mg for each injection.

If the symptoms are not controlled by use of the aforementioned injections, or if you need more than 10 injections a day, it may be necessary to administrate a continuous infusion of apomorphine. This issue is at the doctor's or nurse's discretion.
In the event of continuous infusion:
The usual dosage is 1 mg to 4 mg over one hour.
The infusion is usually given during waking hours and stopped when you go to sleep.
The infusion site should be changed every 12 hours.
The doctor will determine the type of syringe suitable for your use. In case of doubt, consult the doctor, nurse or pharmacist.
Do not exceed the recommended dose.

Tests and follow-up
If you are taking this medicine concomitantly with levodopa, blood tests should be performed.

If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to the doctor or to a hospital emergency room and bring the package of the medicine.
If you took an overdose, you may experience a slow heartbeat, extreme states of illness, sleep and/or breathing difficulties. You may feel faint or dizzy after standing up - due to a drop in blood pressure. Lie down and raise your legs in order to feel better.

If you forgot to take the medicine
If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the regular time and consult the doctor.

Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without first consulting the doctor or pharmacist.

How can you contribute to the success of the treatment?
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 the preparation 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.
If you experience an allergic reaction, stop using APO-go ampoules and immediately refer to the doctor or to the nearest hospital emergency room. The signs of the allergic reaction:
- Rash.
- Breathing difficulties.
- Swelling of the face, lips, throat or tongue.

Very common side effects (affect more than 1 in 10 patients):
- Lumps under the skin at the site of injection, which are sore, troublesome, are red and cause irritation. In order to avoid getting these lumps, it is recommended to alternate the injection site each time that you inject.
- Hallucinations (seeing, hearing or feelings things that do not exist).

Common side effects (affect less than 1 in 10 patients):
- Nausea and vomiting, particularly at the beginning of treatment with APO-go ampoules. If you are taking domperidone and still feel sick, or if you are not taking domperidone and are suffering from nausea, tell the doctor or nurse as soon as possible.
- Feeling tired or a strong need to sleep.
- Confusion or hallucinations.
- Yawning.
- Dizziness or lightheadedness after standing up.

Uncommon side effects (affect less than 1 in 100 patients):
- Increased involuntary movements or tremors during 'on' periods.
- Hemolytic anemia (abnormal breakdown of red blood cells in the blood vessels or elsewhere in the body - this is an uncommon side effect that occurs in patients taking levodopa as an additional preparation).
- Suddenly falling asleep.
- Skin rash.
- Breathing difficulties.
- Injection site ulceration.
- Decrease in red blood cells, which causes the skin to become yellow and causes weakness or breathlessness.
- Decrease in blood platelets, which increases the risk of bleeding or bruising.

Rare side effects (affect less than 1 in 1,000 patients):
- Allergic reaction.
- Abnormal increase in white blood cells in the blood or in body tissues (eosinophilia).

Side effects occurring in an unknown number of patients:
- Swelling of the legs, feet or fingers.
- Inability to resist stimuli, urge or temptation to perform an action that may be harmful to you or others, including:
  - Strong compulsive gambling urge (despite serious personal or family consequences).
  - Altered or increased sexual interest, a behavioral pattern that causes concern to you or to others, such as an increased sex drive.
  - Uncontrollable tendency to shop or spend money.
  - Binge eating (eating large amounts in a short time period) or compulsive eating (eating an amount beyond normal needs and beyond feeling satiated).
  - Fainting.
  - Aggressiveness, agitation.
  - Headache.

  Tell the doctor if you notice any of the above behaviors; the doctor will consider ways to overcome these effects or reduce the symptoms.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in this leaflet, consult with the doctor immediately.

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

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 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 expiration date (Expiry date) appearing on the package. The expiration date refers to the last day of that month.
Store at a temperature below 25ºC.
Store in the original package in order to protect from light.
Do not use if the solution has changed colors to green. Use the solution only if it is clear and transparent.
Use immediately after opening; dispose of remaining unused contents.
Dispose of used syringes, needles and injections into a waste-bin or device or into an appropriate container. When the container is full, bring it to the doctor or pharmacist who will see to safely disposing of the waste.
Do not discard medicines in the sewage or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help preserve the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
Sodium metabisulphite, hydrochloric acid, sodium hydroxide, nitrogen, water for injection.
Each 1 ml of solution contains 0.023 mg sodium.
This medicine contains sodium metabisulphite, which may cause rare allergic reactions (see section 2).

What the medicine looks like and the contents of the package
APO-go ampoules contain a solution intended for injection or infusion. The solution is clear and colorless.
Glass ampoule containing 2 ml of solution for injection or infusion, in packs of five ampoules.
Glass ampoule containing 5 ml of solution for injection or infusion, in packs of five ampoules.
The ampoules are packed in a plastic tray placed inside an outer carton box.
There are two types of ampoules:
An ampoule marked with a colored dot (half a break line).
An ampoule marked with a ring around the narrowest part of the neck of the ampoule (complete break line).

License Holder
Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020

Manufacturer and address
Britannia Pharmaceuticals Ltd.,
England.

The leaflet was revised in March 2024 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 128.26.30682.00

HOW TO INJECT APO-go

Injection preparation
1. Wash your hands.
2. Prepare a clean surface.
3. Prepare the syringes as you were taught. Release the air bubbles in the syringe carefully, to ensure that the correct dose of apomorphine is ready for injection.
4. Replace the needle protector carefully to prevent self-injury, damage or contamination of the needle.

Notes
- Full syringes can be kept in the refrigerator for up to 24 hours. After this time, they should be disposed into a container approved for the collection of sharps.
- Apomorphine causes green stains resistant to most cleaning agents.

How to inject
1. Wash your hands.
2. Remove the needle cover from the syringe.
3. Be careful not to bend the needle.
4. Gently press the skin with your hand and insert the needle.
5. Inject apomorphine into the skin gently and slowly as you have been taught.

Where to inject
There are five areas in the body: the front part of the abdomen, the front part of the thighs and the outer part of the upper arms.