

Package Leaflet: Information for the user

APO-go® Ampoules 10 mg/ml Solution for Injection or Infusion*

Apomorphine hydrochloride

* Abbreviated to APO-go Ampoules in the text

For use in adults

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What APO-go Ampoules is and what it is used for
2. What you need to know before you use APO-go Ampoules
3. How to use APO-go Ampoules
4. Possible side effects
5. How to store APO-go Ampoules
6. Contents of the pack and other information

1. What APO-go Ampoules is and what it is used for

APO-go Ampoules contains apomorphine solution for injection. It is injected into the area under the skin (subcutaneously). The active ingredient in APO-go Ampoules is apomorphine hydrochloride. There is 10 mg of apomorphine in each millilitre of solution.

Apomorphine hydrochloride belongs to a group of medicines known as dopamine agonists. APO-go Ampoules is used to treat Parkinson's disease. Apomorphine helps reduce the amount of time spent in an 'off' or immobile state in people who have previously been treated for Parkinson's disease with levodopa (another treatment for Parkinson's disease) and/or other dopamine agonists. Your doctor or nurse will help you to recognise the signs of when to use your medicine.

Despite the name, apomorphine does not contain morphine.

2. What you need to know before you use APO-go Ampoules

Before you use APO-go Ampoules, your doctor will obtain an ECG (electrocardiogram) and will ask for a list of all other medicines you take. This ECG will be repeated in the first days of your treatment and at any point if your doctor thinks this is needed. He or she will also ask you about other diseases you may have, in particular concerning your heart. Some of the questions and investigations may be repeated at each medical visit. If you experience symptoms which may come from the heart, e.g. palpitations, fainting, or near-fainting, you should report this to your doctor immediately. Also if you experience diarrhoea or start a new medication, this should be reported to your doctor.

Do not use APO-go Ampoules if:

- you are under 18 years of age
- you have breathing difficulties
- you have dementia or Alzheimer's disease
- you suffer from a mental illness with symptoms such as hallucinations, delusions, disordered thoughts, loss of contact with reality

- you have liver problems
- you have severe dyskinesia (involuntary movements) or severe dystonia (inability to move) despite taking levodopa
- you are allergic to apomorphine or any of the other ingredients of this medicine (listed in section 6)
- you or someone in your family are known to have an abnormality of electrocardiogram (ECG) called “long QT syndrome”.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using APO-go Ampoules if:

- you have kidney problems
- you have lung problems
- you have heart problems
- you have low blood pressure or feel faint and dizzy when you stand
- you are taking any medicines to treat high blood pressure
- you feel sick or suffer from being sick
- your Parkinson’s disease causes certain mental problems such as hallucinations and confusion
- you are elderly or frail.

Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or an increase in sexual thoughts or feelings. Your doctor may need to adjust or stop your dose.

Some patients develop addiction-like symptoms leading to craving for large doses of APO-go Ampoules and other medicines used to treat Parkinson’s disease.

If any of the above situations applies to you, please inform your doctor or nurse.

Children and adolescents

APO-go Ampoules should not be used in children and adolescents under 18 years of age.

Other medicines and APO-go Ampoules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Check with your doctor or pharmacist before taking your medicine if:

- you are using medicines that are known to affect the way your heart beats. This includes medicines used for heart rhythm problems (such as quinidine and amiodarone), for depression (including tricyclic antidepressants such as amitriptyline and imipramine) and for bacterial infections (‘macrolide’ antibiotics such as erythromycin, azithromycin and clarithromycin) and domperidone.

If you use this medicine with other medicines the effect of those medicines may be altered. This is especially true for:

- medicines such as clozapine to treat some mental disorders
- medicines to lower your blood pressure
- other medicines for Parkinson’s disease

Your doctor will tell you if you need to change the dose of your apomorphine or any of your other medicines.

If you are taking levodopa (another medicine for Parkinson’s disease) as well as apomorphine your doctor should check your blood regularly.

APO-go Ampoules with food and drink

Food and drink do not affect the way this medicine will work.

Pregnancy and breast-feeding

APO-go Ampoules should not be used during pregnancy unless clearly necessary. Check with your doctor or pharmacist before using APO-go Ampoules if you are pregnant, think you may be pregnant or you are planning to become pregnant.

It is not known whether APO-go Ampoules is transferred to breast milk. Talk to your doctor if you are breast-feeding or intend to breast-feed. Your doctor will explain to you, whether you should continue/discontinue breast-feeding or continue/discontinue taking this medicine.

Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines

APO-go Ampoules can cause drowsiness and a strong desire to sleep. Do not drive or use any tools or machinery if this medicine affects you in this way.

This medicine can affect your ability to drive. Do not drive whilst taking this medicine until you know how this medicine affects you. It may be an offence to drive if your ability to drive safely is affected. There is further information for patients who are intending to drive in Great Britain – go to <https://www.gov.uk/drug-driving-law>

APO-go Ampoules contains sodium metabisulphite

APO-go Ampoules contains sodium metabisulphite which rarely can cause a severe allergic reaction with symptoms such as rash or itchy skin, difficulty breathing, puffiness of the eyelids, face or lips, swelling or redness of the tongue. If you experience these side effects, immediately go to the nearest hospital casualty department.

APO-go Ampoules contain less than 1 mmol (23 mg) of sodium per 10 ml, i.e. essentially sodium free.

3. How to use APO-go Ampoules

Before you use APO-go Ampoules, your doctor will ensure that you tolerate the medicine and an antiemetic medicine that you need to use simultaneously.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Domperidone should be taken at least 2 days before APO-go Ampoules is started to stop you feeling or being sick.

Do not use APO-go Ampoules if:

- the solution has turned green
- the solution is cloudy or you can see particles in it.

Where to inject your APO-go Ampoules

- inject your APO-go Ampoules into an area under the skin (subcutaneously) as shown by your doctor or nurse.
- **do not inject APO-go Ampoules into a vein.**

How much to use

The amount of APO-go Ampoules you should use and the number of injections required each day will depend upon your personal needs. Your doctor will discuss this with you and tell you how much of your medicine you should inject and how often. The amount that will work best for you will have been determined during your visit to the specialist clinic.

- The usual daily dose is between 3 mg and 30 mg
- You may need as much as 100 mg per day
- Typically, you will need between 1 and 10 injections each day
- Each injection should not be more than 10 mg.

If your symptoms are not controlled well enough with separate injections or if you find you are requiring more than 10 injections per day, you may require a continuous infusion of apomorphine. Your doctor or nurse will decide if you need this. For a continuous infusion:

- The usual dose is between 1 mg and 4 mg per hour
- Usually this is given to you when you are awake and stopped before you go to sleep
- A different site for each infusion should be used every 12 hours.

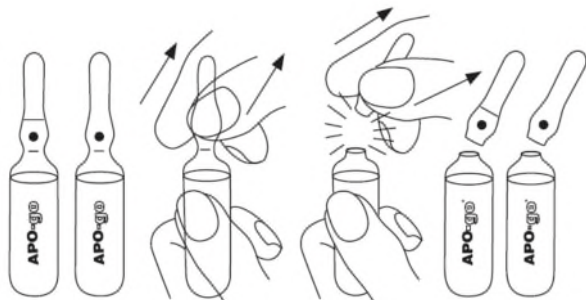
The choice of which minipump and/or syringe driver to use will be decided by your doctor. You should check with your doctor, pharmacist or nurse if you are not sure.

What you need to inject APO-go Ampoules

For an injection, you will need:

- one syringe and needle
- a bin called a “Sharps” bin to dispose safely of the used needles and glass containers. These are available from your doctor or pharmacist. Alternatively, use another suitable container such as an empty coffee jar.

How to open APO-go Ampoules



- Locate the **spot** positioned directly above the short score mark on the thin part of the neck. This score is the breaking point of the ampoule.
- Hold the bottom of the ampoule in one hand
- **Cover the spot with your thumb** and use your forefinger to grasp the neck of the ampoule as shown in the diagram.
- Apply pressure with your thumb covering the spot in a **backward** direction.
- Carefully dispose of the top of the ampoule in a “Sharps” bin.

Once opened APO-go Ampoules should be used immediately.

Injecting APO-go Ampoules

- Place the needle firmly on the end of the syringe
- Withdraw the volume you require for your dose as advised by your doctor or nurse
- You may need to dilute APO-go Ampoules before use. Your doctor or nurse will have told you if you need to do this and how to do it
- Inject your medicine as shown by your doctor or nurse into an area under the skin (subcutaneously)
- Discard used syringes, needles and ampoules in a “Sharps” bin (available from your doctor or pharmacist) or other suitable container, such as an empty coffee jar
- Take care not to splash any of the solution onto yourself or the carpet as it may stain green.

If you have any further questions about the use of this medicine, ask your doctor or nurse.

If you use more APO-go Ampoules than you should

- Tell your doctor or contact your nearest hospital emergency department immediately
- You may experience a slow heart rate, excessive sickness, excessive sleepiness and/or difficulty breathing. You may also feel faint or dizzy particularly when you stand up, due to low blood pressure. Lying down and raising your feet may help you to feel better.

If you forget to use APO-go Ampoules

Take it when you next require it. Do not take a double dose to make up for a forgotten dose.

If you stop using APO-go Ampoules

Do not stop using APO-go Ampoules without first talking with your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience an allergic reaction, **stop** taking APO-go Ampoules and contact a doctor or your nearest hospital emergency department **immediately**. The signs of an allergic reaction may include:

- rash
- breathing difficulties
- swelling of the face, lips, throat or tongue.

APO-go Ampoules may sometimes cause the following:

Very common: may affect more than 1 in 10 people

- lumps under the skin at the site of injection which are sore, troublesome and may be red and itchy. In order to avoid getting these lumps, it is advisable to change the site of injection every time you insert the needle.
- hallucinations (seeing, hearing or feeling things that are not there).

Common: may affect up to 1 in 10 people

- feeling sick or being sick, particularly when starting APO-go Ampoules. If you are taking domperidone and still feel sick, or if you are not taking domperidone and you feel sick, tell your doctor or nurse as soon as possible.
- feeling tired or extremely sleepy
- confusion or hallucinations
- yawning
- feeling dizzy or light-headed when standing up.

Uncommon: may affect up to 1 in 100 people

- increased involuntary movements or increased shakiness during 'on' periods
- haemolytic anaemia, an abnormal breakdown of red blood cells in the blood vessels or elsewhere in the body. This is an uncommon side effect that can occur in patients also taking levodopa.
- suddenly falling asleep
- rashes
- breathing difficulties
- injection site ulceration
- reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness
- reduction in blood platelets, which increases the risk of bleeding or bruising.

Rare: may affect up to 1 in 1,000 people

- an allergic reaction
- eosinophilia, an abnormally high amount of white blood cells in the blood or in body tissues.

Not known: frequency cannot be estimated from the available data

- swelling of the legs, feet or fingers.
- inability to resist the impulse, drive or temptation to perform an action that could be harmful to you or others, which may include:
 - strong impulse to gamble excessively despite serious personal or family consequences
 - altered or increased sexual interest and behaviour of significant concern to you or to others, for example, an increased sexual drive
 - uncontrollable excessive shopping or spending
 - binge eating (eating large amounts of food in a short time period) or compulsive eating (eating more food than normal and more than is needed to satisfy your hunger).
- fainting
- aggression, agitation
- headache.

Tell your doctor if you experience any of these behaviours; she or he will discuss ways of managing or reducing the symptoms.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side affects you can help provide more information on the safety of this medicine.

5. How to Store APO-go Ampoules

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in original carton to protect from light.

Once opened, APO-go Ampoules should be used immediately.

Do not use this medicine if the solution has turned green. It should only be used if the solution is clear and colourless and free of visible particles.

Used syringes, needles and ampoules should be discarded in a “Sharps” bin or other suitable container, such as an empty coffee jar. When your “Sharps” bin or container is full, please give it to your doctor or pharmacist for safe disposal.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other Information

What APO-go Ampoules contains

- The active substance is apomorphine hydrochloride. Each millilitre of APO-go Ampoules contains 10 mg of apomorphine hydrochloride.
- The other ingredients are:
 - sodium metabisulphite (E223)
 - hydrochloric acid, concentrated (or sodium hydroxide)
 - water for injections

APO-go Ampoules is available in either 2 ml ampoules containing 20 mg of apomorphine hydrochloride or 5 ml ampoules containing 50 mg of apomorphine hydrochloride.

Refer to 'Section 2: APO-go Ampoules contains sodium metabisulphite' regarding sodium metabisulphite.

What APO-go Ampoules looks like and contents of the pack

APO-go Ampoules is a solution for injection or infusion. The solution is clear and colourless.

Contents of the pack

Glass ampoules containing 2 ml Solution for Injection or Infusion, in packs of 5 ampoules.
Glass ampoules containing 5 ml Solution for Injection or Infusion, in packs of 5 ampoules.
The ampoules are contained in a plastic tray within a cardboard carton.

Each ampoule is partially scored with a coloured spot positioned directly above the short score mark. This score mark indicates the breaking point of the ampoule.

Bundle packs of 25 and 50 ampoules are available in some territories.

- The 25 ampoule bundle pack consists of 5 packs each containing 5 ampoules.
- The 50 ampoule bundle pack consists of 10 packs each containing 5 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder for UK

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Email: bplwebmaster@britannia-pharm.com

Marketing Authorisation Holder for Ireland

STADA Arzneimittel AG
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61118 Bad Vilbel
Germany

Manufacturer

STADA Arzneimittel AG
Stadastraße 2 – 18
61118 Bad Vilbel
Germany

Distributor in UK

Britannia Pharmaceuticals Ltd.
200 Longwater Avenue, Green Park,
Reading, Berkshire, RG2 6GP, UK

Distributor in Ireland

Clonmel Healthcare Ltd.
Waterford Road, Clonmel,
County Tipperary, Ireland

This medicine is authorised in the Member States of the EEA and in the United Kingdom (Northern Ireland) under the following names:

Austria, Germany:	APO-go® Ampullen 10 mg/ml Injektions-/Infusionslösung
Belgium:	APO-GO-AMP 10 mg/ml oplossing voor injectie of infusie
Estonia:	APO-go 10 MG/ML, süste-või infusioonilahus
Ireland, United Kingdom (Northern Ireland):	APO-go Ampoules 10 mg/ml Solution for Injection or Infusion
Lithuania:	Britaject 10 mg/ml injekcinis/infuzinis tirpalas
Luxembourg:	APO-go \ Ampoules 10 mg/ml Solution Injectable/ pour Perfusion
Netherlands:	APO-go Ampullen 10 mg/ml oplossing voor injectie of infusie
Portugal:	Apo-go 10 mg/ml Solução injectável ou para perfusão
Romania:	APO-go 10 mg/ml soluție injectabilă/perfuzabilă
Slovenia:	APO-go 10 mg/ml raztopina za injiciranje ali infundiranje v ampuli
Spain:	APO-go 10 mg/ml Solución Inyectable o para Perfusión en Ampollas
Sweden:	APO-go 10 mg/ml injektionsvätska, lösning

This leaflet was last revised in December 2021.

If this leaflet is difficult to see or read and you would like it in a different format, please contact Britannia Pharmaceuticals Ltd.