Package Leaflet: Information for the user

APO-go® PEN 10 mg/ml Solution for Injection *
Apomorphine hydrochloride
* *Abbreviated to* APO-go Pen *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 Pen is and what it is used for

APO-go Pen contains apomorphine solution for injection. It is injected into the area under the skin (subcutaneously). The active ingredient in APO-go Pen 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 Pen is used to treat Parkinson's disease. Apomorphine helps to reduce the amount of time spent in an "off" or immobile state in people who have been previously treated for Parkinson's disease with levodopa 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 Pen

Before you use APO-go Pen, 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 Pen 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 Pen if:
- you have kidney problems
- you have lung problems
- you have heart problems
- you have low blood pressure or feel faint or 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 Pen and other medicines used to treat Parkinson’s disease.

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

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

Other medicines and APO-go Pen
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 particularly true for:
- medicines such as clozapine to treat 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 Pen with food and drink
Food and drink do not affect the way this medicine will work.

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

It is not known whether APO-go Pen 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 taking any medicine.

Driving and using machines
APO-go Pen 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 Pen contains sodium bisulphite
APO-go Pen contains sodium bisulphite 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 Pen contains less than 1 mmol (23 mg) of sodium per 10 ml, i.e. essentially sodium free.

3. How to use APO-go Pen

Before you use APO-go Pen, 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 Pen is started to stop you feeling or being sick.

Do not use APO-go Pen if:
- the solution has turned green
- the solution is cloudy or you can see particles in it.

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

How much to use
The amount of APO-go Pen you should use and how often to use it will depend upon your personal needs. Your doctor will discuss this with you and tell you how much of your medicine to use. The amount that will work best for you will have been determined on 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 per day
- Each single injection should not be more than 10 mg.

Before using APO-go Pen, study the diagram below and your Pen to familiarise yourself with your medicine.

Instructions for Use

1) Dosage dial

7) Arrow showing the dosage selected

8) Numbers indicating the dose per injection (1-10 mg)

9) Graduations (*in mg*) on the cartridge showing total amount of apomorphine in the Pen

4) Membrane

10) Needle*

6) Needle protector*

3) Outer sleeve of Pen

2) Needle in sealed unit* containing
10) needle
6) needle protector
5) protective cone

*This pack does NOT contain needles for use with your Pen.
Use pen needles not more than 12.7 mm (½") in length and not finer than 30G. Pen needles recommended for use with insulin pens are compatible with APO-go Pen.

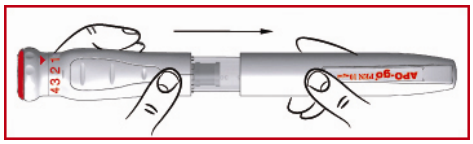
How to use your APO-go Pen

Read these instructions carefully
IMPORTANT: Do not pull the red capped dosage dial (see 1) before you have set the dosage (see 'Selecting the correct dose').

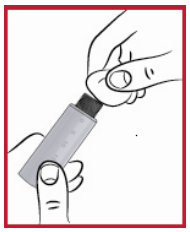
Attaching the needle

(a) Before using APO-go Pen you will need some surgical wipes and one needle in its protective cone (**see 2**).

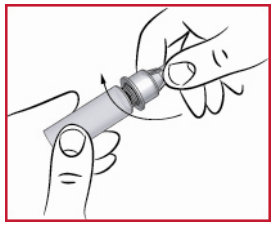
(b) Take the Pen out of its box and remove the outer sleeve (**see 3**).

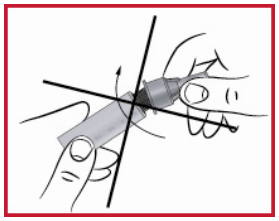


(c) Wipe the membrane of the Pen (**see 4**) with a surgical wipe.



(d) Peel off the paper from the needle cone (**see 2**).

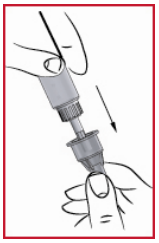




(e) It is important to bring the needle to the Pen in a straight line, as shown above. This will attach the needle securely. If the needle is presented at an angle it may cause the Pen to leak.

(f) Screw the cone (**see 2**) clockwise onto the membrane until it is tight. This securely attaches the needle.

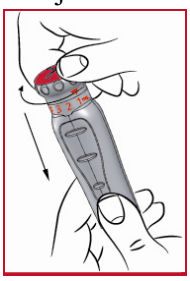
(g) Remove the protective cone (**see 5**), but do not throw it away. Do not remove the needle protector (**see 6**) at this stage.



(h) Replace the Pen's outer sleeve (**see 3**).

Selecting the correct dose

(i) Press the red capped dosage dial (**see 1**) and whilst holding it down, turn the dial clockwise until the arrow points to the dose your doctor chose for you (**see 7** & **8**). Release the downward pressure on the red capped dial. The dose is now set and you do not need to redial for subsequent injections.

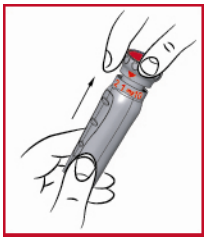


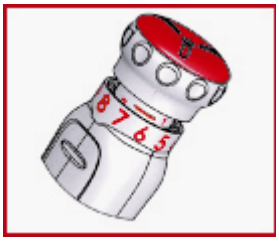
Important: If you pass your prescribed dose while turning the dial, just continue pressing and turning in the same direction until the arrow points to the dose your doctor chose for you.
Never pull and turn the red capped dosage dial at the same time.

If your dose is 1 mg, start by emptying a 1 mg dose onto a paper tissue and discarding it. This is called 'priming' and is important because it ensures you get a full dose the first time you use your Pen. Then, set the dose you require for injection and inject it in the usual way (**see "Injecting"**). If the first dose required is more than 1 mg, you do not need to prime the Pen.

Injecting

(j) Once you have set the dose, gently pull out the red capped dosage dial as far as it will go. Check the red scale on the plunger (**see 9**) and inject only if the line that is just visible matches the intended dose.

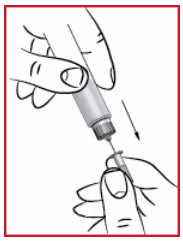




(k) Using a surgical wipe, clean the area of skin where you plan to inject the medicine and around it.

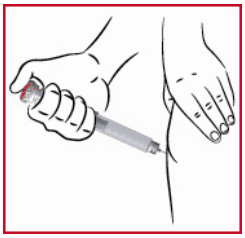
(l) Remove the Pen's outer sleeve (**see 3**).

(m) Remove the needle protector (**see 6**).

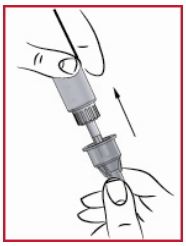


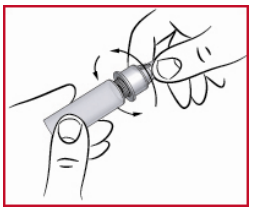
(n) Insert the needle (**see 10**) into the skin as shown by your doctor.

(o) To inject, press the red capped dosage dial (**see 1**) down as far as it will go, using your thumb if possible. Once the red capped dosage dial is fully depressed, count to three before withdrawing the needle.



(p) Replace the protective cone (**see 5**) onto the used needle and push gently into place. Once secure, turn the needle anti-clockwise to unscrew it. Keep the needle in its protective cone and discard it in a safe place, such as a "Sharps" bin or an empty coffee jar.



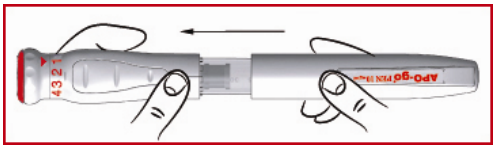


Preparing for the next injection

(q) Remove the outer sleeve of the Pen and check there is enough apomorphine left in the cartridge for your next injection. If there is, put a new needle in place in the same way as before.

(r) If there is not enough apomorphine left for another injection, prepare another Pen.

(s) Finally, replace the outer sleeve of your Pen.



If you use more APO-go Pen 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 will help you feel better.

If you forget to use APO-go Pen

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 Pen

Do not stop using APO-go Pen 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 Pen 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 Pen 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 Pen. 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

Malta

ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store APO-go Pen

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

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

Do not store above 25°C. Keep the container in the outer carton to protect from light. Store at the same conditions after opening and between withdrawals.

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.

When you start using a new APO-go Pen, it can be used for up to 48 hours. Do not re-use your APO-go Pen after this time. Use a new Pen.

To dispose of your Pens safely, always remove the needle from the Pen before discarding it 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. If the Pen is completely empty you may dispose of it in your household waste.

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 Pen contains

- The active substance is apomorphine hydrochloride. Each millilitre of APO-go Pen contains 10 mg of apomorphine hydrochloride. Each APO-go Pen contains 3 ml of solution for injection.
- The other ingredients are:
  - sodium bisulphite (E222)
  - hydrochloric acid (37%)
  - water for injections.

Refer to 'Section 2: APO-go Pen contains sodium bisulphite' regarding sodium bisulphite.

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

APO-go Pen is a disposable multiple dose Pen injector system with a clear glass cartridge containing the apomorphine solution for injection. The solution is clear, practically colourless, odourless and free from visible particles.

Contents of the pack

Packs contain 1, 5 or 10 pens in a moulded plastic tray in an outer cardboard carton.

APO-go Pen is available in packs containing 1, 5 or 10 pens and in multipacks comprising 5 cartons, each containing 5 pens.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder for UK
Britannia Pharmaceuticals Ltd.
200 Longwater Avenue
Green Park
Reading, Berkshire
RG2 6GP
UK
Tel: +44 1189 209500
Email: bplwebmaster@britannia-pharm.com

Marketing Authorisation Holder for Ireland and Malta
STADA Arzneimittel AG
Stadastraße 2-18
61118 Bad Vilbel
Germany

Manufacturer(s)

Laboratoire Aguettant
1 Rue Alexander Fleming
Lyon, 69007
France

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 PEN 10 mg/ml Injektionslösung
Belgium:	APO-GO®-PEN 10 mg/ml oplossing voor injectie
Bulgaria:	АПО-го® ПИСАЛКА 10 mg/ml Инжекционен разтвор
Cyprus:	APO-go Συσκευή τύπου πένας 10 mg/ml Ενέσιμο Διάλυμα
Czech Republic:	BRITAJECT PEN
Denmark:	APO-go PEN 10 mg/ml injektionsvæske, opløsning
Estonia:	APO-go, 10 mg/ml süstelahus pen-süstlis
Finland:	Apogo PEN 10 mg/ml injektioneste, liuos
Greece:	APO-go Συσκευή τύπου πένας 10 mg/ml Ενέσιμο Διάλυμα

Ireland, Malta, United Kingdom (Northern Ireland):	APO-go Pen 10 mg/ml Solution for Injection
Latvia:	APO-go PEN 10 mg/ml šķīdums injekcijām
Lithuania:	Britaject 10 mg/ml injekcinis tirpalas
Luxembourg:	APO-go® PEN 10 mg/ml Solution Injectable
Netherlands:	APO-go PEN, oplossing voor injectie 10 mg/ml
Norway:	Britaject 10 mg/ml injeksjonsvæske, oppløsning i ferdigfylt penn
Portugal:	Apo-go Pen 10 mg/ml Solução injetável
Romania:	APO-go 10 mg/ml soluţie injectabilă în pen multidoză
Slovenia:	APO-go 10 mg/ml raztopina za injiciranje v peresniku
Spain:	APO-go PEN 10 mg/ml Solución inyectable
Sweden:	APO-go PEN 10 mg/ml injektionsvätska, lösning

This leaflet was last revised in 02/2022

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