Package Leaflet: Information for the user

APO-go® PFS 5 mg/ml Solution for Infusion in Pre-filled Syringe*
Apomorphine hydrochloride
* *Abbreviated to* APO-go PFS *in the text*
50 mg/10 ml

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 PFS is and what it is used for

APO-go PFS contains apomorphine hydrochloride. Apomorphine hydrochloride belongs to a group of medicines known as dopamine agonists which are used to treat Parkinson's disease. It helps to 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 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 PFS

Before you use APO-go PFS 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 PFS if:
- you are under 18 years of age
- you have breathing difficulties or suffer from asthma
- you have dementia or Alzheimer's disease
- you suffer from confusion, hallucinations or any other similar problems
- you have liver problems
- you have severe dyskinesia (involuntary movements) or severe dystonia (inability to move) on account of the treatment with 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”.
- you are taking ondansetron (medicine to treat nausea and vomiting)

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using APO-go PFS 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
- you have any mental disorders when APO-go PFS is started
- 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 PFS 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 PFS should not be used in children and adolescents under 18 years of age.

Other medicines and APO-go PFS
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.
- you are taking ondansetron (medicine to treat nausea and vomiting), as this may result in severe drop in blood pressure and loss of consciousness.

If you use this medicine in combination with other medicines the effect of your 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 advise you if you need to adjust 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 PFS with food and drink
Food and drink do not affect the way this medicine will work.

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

It is not known whether APO-go PFS 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
Do not drive if APO-go PFS makes you sleepy. Do not use any tools or machines if this medicine makes you sleepy.

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

3. How to use APO-go PFS

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

The infusion is given subcutaneously (i.e. into the area under the skin).

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

Do not use APO-go PFS if:
- the solution has turned green.
- APO-go PFS has been designed for continuous infusion with a syringe driver. It is not to be used for intermittent injection. Your doctor will decide which minipump and/or syringe-driver and which dosage settings you should use.

How much to use
Both the amount of APO-go PFS that you should use and the total amount of time you should receive your medicine 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 administer. The amount that will work best will have been determined on your visit to the specialist clinic. The average infusion dose per hour is between 1 mg and 4 mg apomorphine hydrochloride. Continuous infusion is usually given when you are awake and generally stopped before sleeping. The amount of apomorphine hydrochloride that you

receive each day should not exceed 100 mg. Your doctor or nurse will decide which dose is best for you.

A different site for your infusion should be used every 12 hours.

This medicine must not be administered into a vein.

There is no need to dilute APO-go PFS before use. In addition, it should not be mixed with other medicines.

If you use more APO-go PFS than you should
- Tell your doctor or contact your nearest hospital emergency department immediately
- It is important to administer the correct dose of APO-go PFS and not to use more than the amount recommended by your doctor. Higher doses may cause 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 to treat low blood pressure.

If you forget to use APO-go PFS
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 PFS
Contact your doctor **before** stopping treatment and discuss whether this is appropriate or not.

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. Tell your doctor if you think your medicine is making you feel unwell or if you get any of 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 PFS. Domperidone should be started at least 2 days before APO-go PFS to stop you feeling or being sick. If you are taking domperidone and still feel sick, or if you are not taking domperidone and have sickness, 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 such as:
    - difficulty breathing or tightness of the chest
    - puffiness of the eyelids, face or lips
    - swelling or redness of the tongue.
- 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 PFS

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.

Keep the pre-filled syringe in the outer carton in order to protect from light.

Do not store above 25°C.

Once opened APO-go PFS should be used immediately and any remaining solution discarded.

Single use only.

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

Withdraw contents immediately after opening. Take care not to splash any of the solution onto yourself, or the carpet as it may stain green. At the end of use the glass pre-filled syringe should be discarded in a "Sharps" bin as well as any used plastic syringes and the adaptor.

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 PFS contains

- The active substance is apomorphine hydrochloride. 1 ml solution contains 5 mg apomorphine hydrochloride. Each 10 ml pre filled syringe contains 50 mg apomorphine hydrochloride.
- The other ingredients are:
  - sodium metabisulphite (E223)
  - hydrochloric acid, concentrated
  - water for injections

Refer to 'Section 2: Apo-go PFS contains sodium metabisulphite' regarding sodium metabisulphite.

What APO-go PFS looks like and contents of the pack
APO-go PFS is a solution for infusion, pre-filled syringe. The solution is clear and colourless.

Contents of the pack

APO-go PFS is supplied in clear glass pre-filled syringes.

Each pack contains 5 syringes containing 10 ml solution, in an outer cardboard carton.

Bundle packs of 25 (5 x 5) and bundle packs of 50 (10 x 5) are available in some territories.

Not all pack sizes may be marketed

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OR

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UK

Distributor in Ireland
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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 5 mg/ml Infusionslösung in einer Fertigspritze
Bulgaria	АПО-го® ПНС 5 mg/ml Инфузионен разтвор в предварително напълнена спринцовка
Cyprus	APO-go® PFS 5 mg/ml Διάλυμα για Έγχυση σε Προγεμισμένη Σύριγγα
Denmark	APO-go Pumpfill 5 mg/ml infusionsvæske, opløsning i fyldt injektionssprøjte
Greece	APO-go PFS 5 mg/ml Διάλυμα για Έγχυση σε Προγεμισμένη Σύριγγα
Ireland, United Kingdom (Northern Ireland), Malta	APO-go PFS 5 mg/ml Solution for Infusion in Pre-filled Syringe
Netherlands	APO-go 5 mg/ml oplossing voor infusie in een voorgevulde spuit
Norway	Britaject 5 mg/ml infusjonsvæske, oppløsning i ferdigfylt sprøyte
Portugal	Apo-go 5 mg/ml Solução para perfusão em seringa pré-cheia

Romania	APO-go 5 mg/ml soluție perfuzabilă în seringă preumplută unidoză
Slovenia	APO-go 5 mg/ml raztopina za infundiranje v napolnjeni injekcijski brizgi
Spain	APO-go PFS 5 mg/ml Solución para Perfusión en Jeringa Precargada
Sweden	APO-go Pumpfill 5 mg/ml infusionsvätska, lösning i förfylld spruta

This leaflet was last revised in December 2023.

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

Versioning table

Version	Variation	Date of approval	RA representative
	IE/H/0658/003/IA/117		Andrew Briggs