

Rare side effects (1 to 10 users in 10,000):

- 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.

Side effects with unknown frequency (frequency cannot be estimated from the available data):

- pathological gambling (failure to resist gambling impulses despite serious personal or family consequences)
- increased sex drive
- hypersexuality (altered sexual interest and behaviour of significant concern to the patient or to others)
- swelling of the legs, feet or fingers

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store APO-go PFS

Keep out of the reach and sight of children.

Do not use APO-go PFS after the expiry date which is stated on the label/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.

Do not use APO-go PFS 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What APO-go PFS contains

The active substance is apomorphine hydrochloride.

1ml contains 5mg apomorphine hydrochloride.

Each 10ml pre-filled syringe contains 50mg apomorphine hydrochloride.

The other ingredients are:

- Sodium metabisulphite (E223)
- Hydrochloric acid (37%)
- Water for Injections

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.

APO-go PFS is supplied in clear glass pre-filled syringes. Each pack contains 5 syringes in an outer cardboard carton.

Bundle packs of 25 (5x5) and bundle packs of 50 (10x5) are available in some territories.

Marketing Authorisation Holder and Manufacturer

Genus Pharmaceuticals
Park View House, 65 London Road,
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United Kingdom

Manufacturers

Catalent Belgium S.A	Britannia Pharmaceuticals Limited
Font Saint Landry 10	41-51 Brighton Road
B-1120 Brussels	Redhill
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Belgium	United Kingdom

This medicinal product is authorised in the Member states of the EEA under the following names:

Austria	APO-go 5 mg/ml Infusionslösung in einer Fertigspritze
Denmark	APO-go Pumpfill 5 mg/ml infusionsvæske, opløsning i fyldt injektionssprøjte
Germany	APO-go 5 mg/ml Infusionslösung in einer Fertigspritze
Greece	APO-go PFS 5mg/ml
Ireland	APO-go PFS 5mg/ml Solution for Infusion in Pre-filled Syringe
Sweden	APO-go Pumpfill 5 mg/ml infusionsvätska, lösning i förfylld spruta
The Netherlands	APO-go 5mg/ml oplossing voor infusie in een voorgevulde spuit
United Kingdom	APO-go PFS 5mg/ml Solution for Infusion in Pre-filled Syringe

This leaflet was last approved in

02/2010

APO-go® PFS 5mg/ml

Solution for Infusion in Pre-filled Syringe

apomorphine hydrochloride

For use in adults

Package Leaflet - Information for the User



Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What APO-go PFS is and what it is used for
2. Before you use APO-go PFS
3. How to use APO-go PFS
4. Possible side effects
5. How to store APO-go PFS
6. Further information

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

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.

2. Before you use APO-go PFS**Do not use APO-go PFS**

- if you are under 18 years of age
- if you have breathing difficulties or suffer from asthma
- if you have dementia or Alzheimer's disease
- if you suffer from confusion, hallucinations or any other similar problems
- if you have liver problems
- if you have severe dyskinesia (involuntary movements) or severe dystonia (inability to move) on account of the treatment with levodopa
- if you are allergic to apomorphine or any of the other ingredients of APO-go PFS (for other ingredients see section 6)
- if you or someone in your family are known to have an abnormality of electrocardiogram (ECG) called "long QT syndrome". Tell your doctor.

Take special care with APO-go PFS

- if you have kidney problems
- if you have lung problems
- if you have heart problems
- if you have low blood pressure or feel faint and dizzy when you stand
- if you are taking any medicines to treat high blood pressure
- if you feel sick or suffer from being sick
- if you have any mental disorders when APO-go PFS is started,
- if you are elderly or frail

- when driving or operating machinery since apomorphine may cause sleepiness including sudden sleep onset episodes (you must not drive or operate machinery if APO-go PFS makes you sleepy)
- your doctor should check your blood regularly when taking APO-go PFS with levodopa (another treatment for Parkinson's disease).

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

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.

Taking other medicines

If you take apomorphine in combination with other medicines (especially neuroleptics such as clozapine or medicines to reduce your blood pressure or other medicines for Parkinson's disease) the effect of your medicines may be altered. Your doctor will advise you if you need to adjust the dose of your apomorphine or any of your other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Using APO-go PFS with food and drink

Food and drink do not affect APO-go PFS.

Pregnancy and breast-feeding

APO-go PFS should not be used during pregnancy unless clearly necessary. Check with your doctor or nurse 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 APO-go PFS makes you sleepy.

Important information about some of the ingredients of APO-go PFS

Rarely sodium metabisulphite may cause a severe allergic reaction and difficulty breathing. This medicinal product contains less than 1 mmol (23mg) of sodium per 10ml, i.e. essentially sodium free.

3. How to use APO-go PFS

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

Do not use a syringe if the solution has turned green.

Always use APO-go PFS exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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.

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 1mg and 4mg 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 100mg. 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 should 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, APO-go PFS 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 side effects (more than 1 user in 10):

- 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.

Common side effects (1 to 10 users in 100):

- 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 side effects (1 to 10 users in 1,000):

- 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.
- 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.