

Package leaflet: Information for the user

APO-go® POD 5 mg/ml solution for infusion in cartridge apomorphine hydrochloride hemihydrate

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 possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

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

APO-go POD contains apomorphine hydrochloride hemihydrate (further referred to as ‘apomorphine’).

There is 5 mg apomorphine in each millilitre of solution.

Apomorphine 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, pharmacist or nurse will help you to recognise the signs of when to use your medicine. This medicine is for use in adults only.

Despite the name, apomorphine does not contain morphine.

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

Before you use APO-go POD, 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 POD 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 suffer from a mental disorder

- you have liver problems
- you have severe dyskinesia (involuntary movements) or severe dystonia (sustained or repetitive movements which can result in a fixed posture) during ‘on’ periods when treated with levodopa
- you are allergic to apomorphine or any of the other ingredients of this medicine (listed in section 6)
- you are taking anti-sickness medication from a certain class of drugs (5HT₃ antagonists) e.g. ondansetron, granisetron, dolasetron, palonosetron and alosetron

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using APO-go POD 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 POD is started
- you are elderly or frail
- you or someone in your family are known to have an abnormality of electrocardiogram (ECG) called ‘long QT syndrome’

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 POD and other medicines used to treat Parkinson’s disease.

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

Children and adolescents

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

Other medicines and APO-go POD

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

CHECK WITH YOUR DOCTOR, PHARMACIST OR NURSE BEFORE USING 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 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
- anti-sickness medicines such as ondansetron, granisetron, dolasetron, palonosetron and alosetron (APO-go POD should not be used if taking these medicines, refer to Section 2)
- anti-dopaminergic medicines such as haloperidol, chlorpromazine, promethazine, prochlorperazine, metoclopramide, levopromazine and droperidol

Your doctor will advise you if you need to adjust the dose of APO-go POD 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 POD with food and drink

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

Pregnancy and breast-feeding

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

It is not known whether apomorphine 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 using this medicine.

Driving and using machines

Do not drive if this medicine makes you sleepy.

Do not use any tools or machines if this medicine makes you sleepy.

APO-go POD contains sodium metabisulfite

APO-go POD contains sodium metabisulfite which may rarely cause severe allergic reactions and bronchospasm.

This medicine contains less than 1 mmol (23 mg) of sodium per 20 ml cartridge, that is to say essentially ‘sodium free’.

3. How to use APO-go POD

Before you use APO-go POD, your doctor will ensure that you tolerate this medicine and an anti-sickness medicine (domperidone) that you may need to use simultaneously.

Always use this medicine exactly as your doctor, pharmacist or nurse has told you.

Check with your doctor, pharmacist or nurse if you are not sure.

Do not use APO-go POD if:

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

Where to inject APO-go POD

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

APO-go POD has been designed for continuous infusion with a pump and CronoBell Sleeve. The pump you will receive will be either the Crono APO-go III Infusion Pump or the Crono PAR4 20 Infusion Pump.

How much to use

Both the amount of APO-go POD 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 be determined on your visit to the clinic. The average infusion dose per hour is between 4 mg and 6 mg apomorphine. Continuous infusion is usually given when you are awake and generally stopped before sleeping. The amount of apomorphine that you receive each day should not exceed 100 mg. Your doctor, pharmacist or nurse will decide which dose is best for you.

You may use a cartridge for up to 48 hours as long as a new infusion line and a different site for your infusion is used every 24 hours.

There is no need to dilute APO-go POD before use. In addition, do not mix it with other medicines.

Your doctor or nurse will show you how to set up and use APO-go POD, also refer to the end of this leaflet for instructions 'How to set up the infusion with APO-go POD'.

If you use more APO-go POD 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 POD 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 POD

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 POD

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.

If you experience an allergic reaction **stop** using APO-go POD 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

Tell your doctor if you think your medicine is making you feel unwell or if you get any of the following side effects:

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, 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 POD. Domperidone should be started at least 2 days before APO-go POD 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, pharmacist or nurse as soon as possible.
- feeling extremely sleepy
- confusion or hallucinations
- yawning
- feeling dizzy or light-headed
- feeling sleepy for a short period of time, especially when the medication is first started. This usually resolves over the first few weeks

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 and breakdown of tissue
- reduction in blood platelets, which increases the risk of bleeding or bruising
- feeling dizzy or light-headed when standing up from a sitting or lying position due to low blood pressure

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

- 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 arms, legs, feet or hands
- 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:

HPRA Pharmacovigilance

Website: www.hpra.ie

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

5. How to store APO-go POD

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 after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Once opened, APO-go POD should be used immediately.
Any unused solution should be discarded after 48 hours and a new cartridge used.

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

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 infusion line, CronoBell Sleeve and cartridge should be discarded in a 'Sharps' bin.

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 POD contains

- The active substance is apomorphine hydrochloride hemihydrate. 1 ml of APO-go POD solution contains 5 mg apomorphine hydrochloride hemihydrate. Each 20 ml cartridge contains 100 mg apomorphine hydrochloride hemihydrate.
- The other ingredients are:
 - sodium metabisulfite (E223)
 - hydrochloric acid, concentrated (for pH adjustment)
 - water for injections.

Refer to 'Section 2: APO-go POD contains sodium metabisulfite' regarding sodium metabisulfite.

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

APO-go POD is a solution for infusion in cartridge. The solution is clear and colourless.

Contents of the pack

APO-go POD is supplied in a clear glass siliconized cartridge with a chlorobutyl rubber stopper (with aluminium seal and purple flip-off cap) and a siliconized chlorobutyl rubber plunger.

Each pack contains 5 cartridges containing 20 ml solution in a cardboard tray, inside an outer cardboard carton.

The CronoBell Sleeve is supplied separately in blister packs containing 5 CronoBell Sleeves.

Single use Luer lock caps will be provided as required.

Where bundle packs are available, the 25 cartridge bundle packs consist of 5 packs, each containing 5 cartridges. The 50 cartridge bundle packs consist of 10 packs, each containing 5 cartridges.

Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

STADA Arzneimittel AG
Stadastraße 2-18
D-61118 Bad Vilbel
Germany

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

Austria:	APO-go 5 mg/ml Infusionslösung in einer Patrone
Denmark:	APO-go Pod
Germany:	APO-go 5 mg/ml Infusionslösung in einer Patrone
Greece:	APO-go POD 5 mg/ml Διάλυμα για έγχυση σε φουσίγγιο
Luxembourg:	APO-go POD 5 mg/ml solution pour perfusion en cartouche
Netherlands:	APO-go Pod 5 mg/ml oplossing voor infusie in een patroon
Norway:	Britaject
Portugal:	Apo-go 5 mg/ml solução para perfusão em cartucho
Romania:	APO-go 5 mg/ml soluție perfuzabilă în cartuș
Slovenia:	APO-go 5 mg/ml raztopina za infundiranje v vložku
Spain:	APO-go POD 5 mg/ml solución para perfusión en cartucho
Sweden:	APO-go för POD 5 mg/ml infusionsvätska, lösning i cylinderampull
United Kingdom (Northern Ireland):	APO-go POD 5 mg/ml solution for infusion in cartridge

This leaflet was last revised in May 2022

How to set up the infusion with APO-go POD

Wash and dry your hands before handling any infusion equipment.

Make sure you have a 'Sharps' bin and these items before you begin:

- 1 x Infusion line (for every 24 hours)
- 1 x CronoBell Sleeve
- 1 x Cartridge (containing the medicine)
- 1 x Pump (Crono APO-go III Infusion Pump or Crono PAR4 20 Infusion Pump) with collar attachment
- 1 x Tray

You may also be provided with:

- 1 x box of single use sterile Luer caps



Infusion line



CronoBell Sleeve



Cartridge



Luer cap



Crono APO-go III Infusion Pump with collar attachment

Or


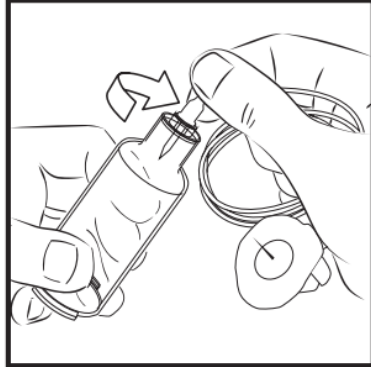
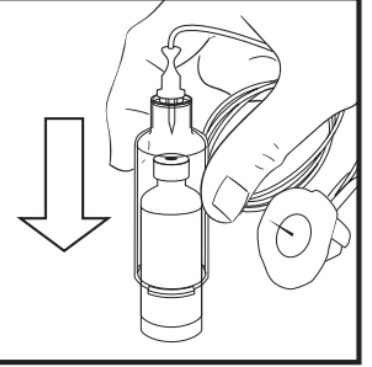

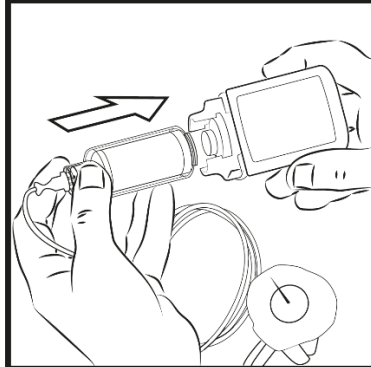
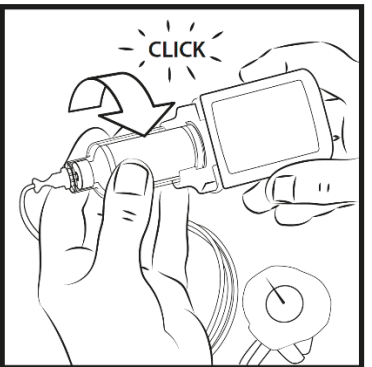
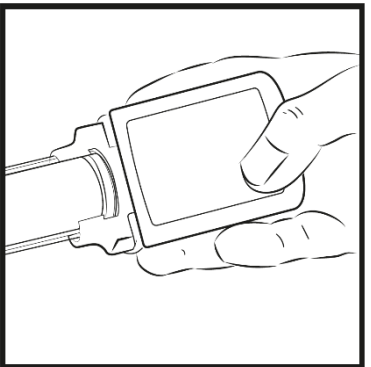


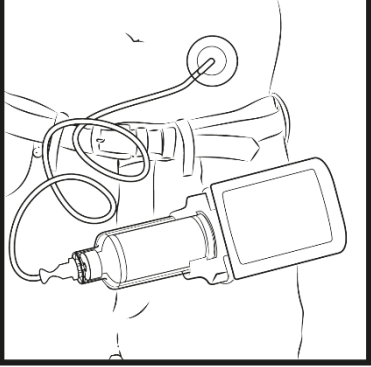
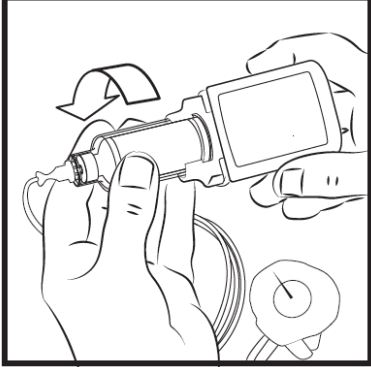
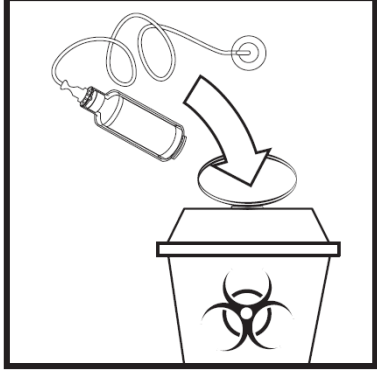
Crono PAR4 20 Infusion Pump with collar attachment

Please note that there are three different scenarios on how to use and change the cartridge and are shown in the steps below. Please follow the instructions below as directed by your healthcare professional.

Instructions for using the cartridge for one day



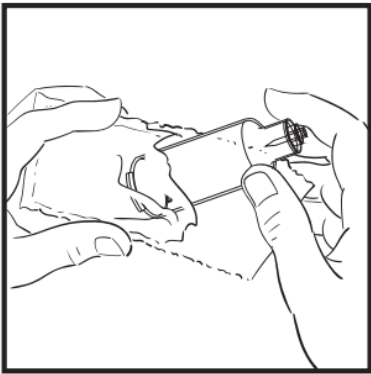
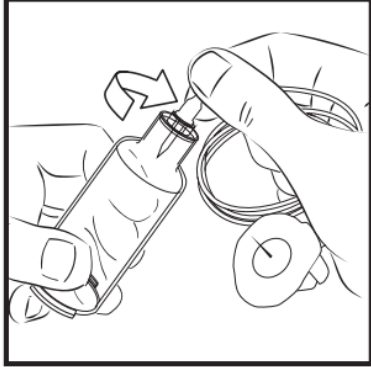
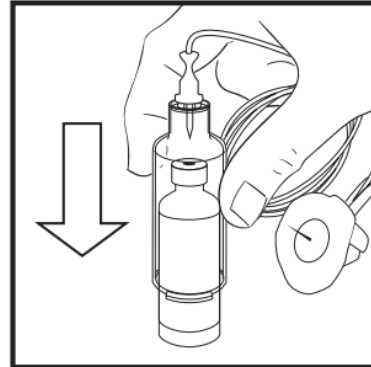

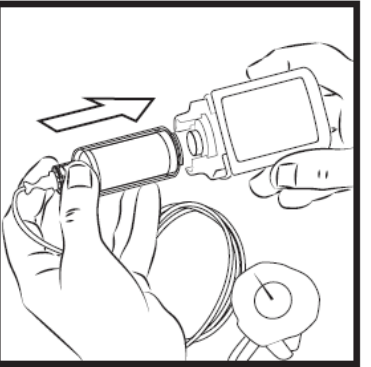
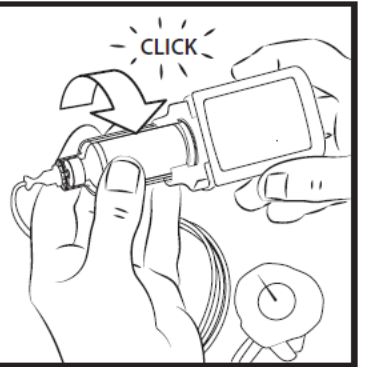
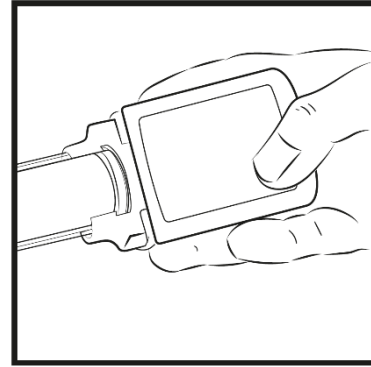
Please follow the steps below if using the cartridge for one day, without changing the cartridge during the day:

		
<p>1. Wash and dry your hands.</p>	<p>2 Remove the plastic cap from the cartridge and discard.</p>	<p>3. Remove the CronoBell Sleeve from its sterile packaging.</p>
		
<p>4. Connect the infusion line to the top of the CronoBell Sleeve and turn clockwise until tight.</p>	<p>5. Place the cartridge on a flat surface and push the CronoBell Sleeve firmly down onto the cartridge until the rubber bung in the top of the cartridge is pierced.</p>	<p>6. The CronoBell Sleeve (with cartridge and infusion line) is now ready to be connected to the pump.</p>
		

<p>7. Slide the CronoBell Sleeve (with cartridge inside) into the collar on the pump aligning the outer lip on the CronoBell Sleeve with the gap in the collar of the pump.</p>	<p>8. Once inserted, turn the CronoBell Sleeve (with cartridge inside) clockwise until it clicks into place.</p>	<p>9. If instructed by your healthcare professional, the infusion line can be primed. Insert the infusion line, as directed by your healthcare professional. Please refer to the APO-go Skin Management Guide.</p>
		
<p>10. Once the infusion line needle is inserted into the body, the pump can be switched on and the infusion started.</p> <p>At the end of the infusion stop the pump and detach the infusion line from the body/patient.</p> <p>The infusion is generally stopped before sleeping.</p>	<p>11. Ensure the pusher of the pump is fully retracted, once this is done the CronoBell Sleeve (with cartridge inside) and the infusion line can be turned and detached.</p>	<p>12. Dispose of the CronoBell Sleeve (with cartridge inside) and the infusion line in a sharps bin.</p>

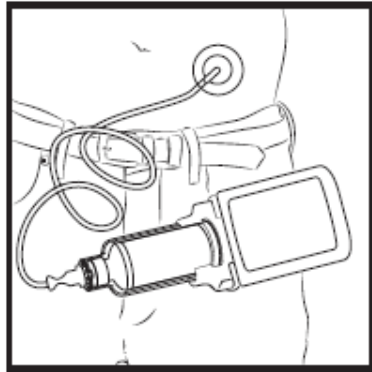
Instructions for using the same cartridge over 2 days

Please use the following steps if using the cartridge up to a maximum of 48 hours:

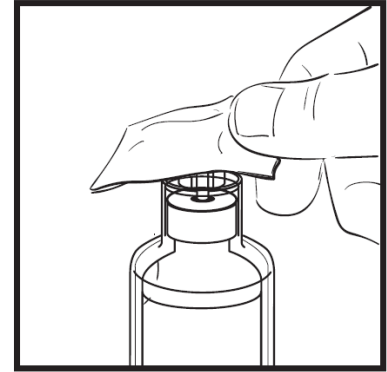
		
<p>1. Wash and dry your hands.</p>	<p>2 Remove the plastic cap from the cartridge and discard.</p>	<p>3. Remove the CronoBell Sleeve from its sterile packaging.</p>
		
<p>4. Connect the infusion line to the top of the CronoBell Sleeve and turn clockwise until tight.</p>	<p>5. Place the cartridge on a flat surface and push the CronoBell Sleeve firmly down onto the cartridge until the rubber bung in the top of the cartridge is pierced.</p>	<p>6. The CronoBell Sleeve (with cartridge and infusion line) is now ready to be connected to the pump.</p>
		
<p>7. Slide the CronoBell Sleeve (with cartridge inside) into the collar on the pump aligning the outer lip on the CronoBell</p>	<p>8. Once inserted, turn the CronoBell Sleeve (with cartridge inside) clockwise until it clicks into place.</p>	<p>9. If instructed by your healthcare professional, the infusion line can be primed. Insert the infusion line, as directed by your healthcare</p>

Sleeve with the gap in the collar of the pump.

professional. Please refer to the APO-go Skin Management Guide.



How to put the pump with cartridge and CronoBell sleeve away for the night (steps 11-13)



10. Once the infusion line needle is inserted into the body, the pump can be switched on and the infusion started.

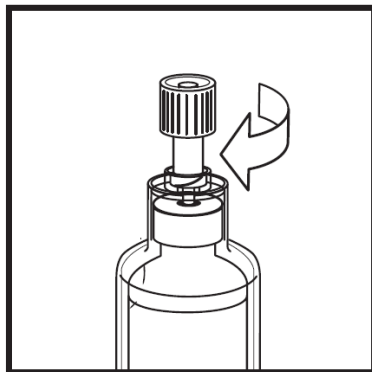
At the end of the infusion stop the pump.

The infusion is generally stopped before sleeping.

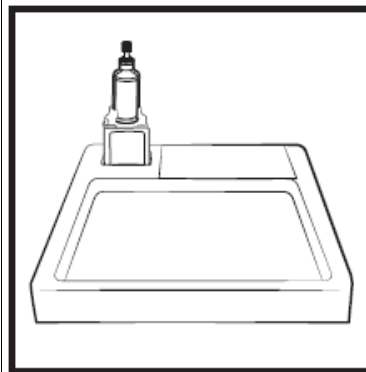
11. Wash and dry your hands as in step 1 and detach the infusion line from the body/patient.

Place the pump standing upwards on the tray with the cartridge/sleeve still attached. Detach the infusion line from the pump and dispose of in the sharps bin.

Wipe any spillage with the alcohol wipe.



12. Screw the sterile Luer cap onto the CronoBell Sleeve (leaving cartridge inside).

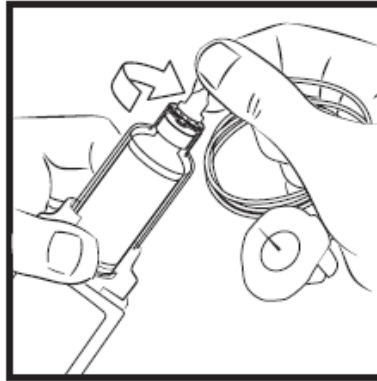


13. Place the tray with the infusion pump in a safe place. Store below 30°C and do not refrigerate. Keep out of reach from children.

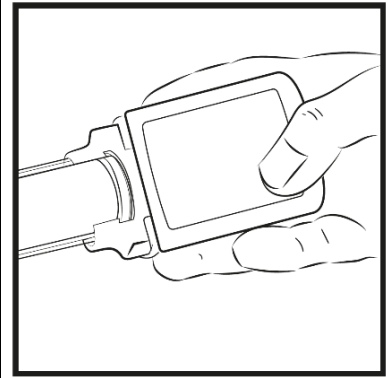
How to start the infusion the following morning (steps 14-17)



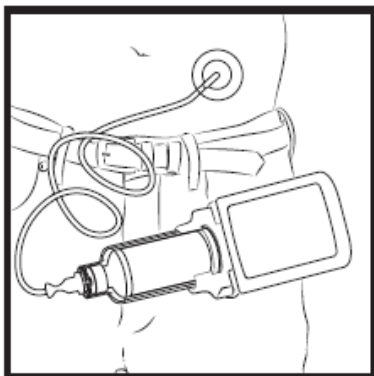
14. The following day, wash and dry your hands.



15. Unscrew the Luer cap and dispose of in the bin. Clean the top of the CronoBell Sleeve with an alcohol wipe. Immediately, take a new infusion line and connect to the top of the CronoBell Sleeve (with cartridge still inside) by turning clockwise until tight.

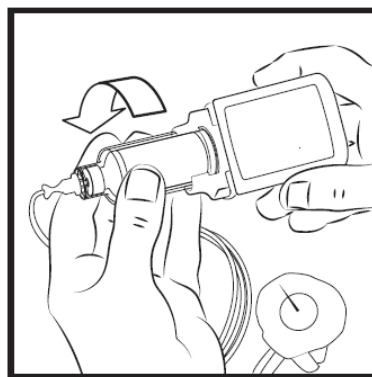


16. If instructed by your healthcare professional, the infusion line can be primed. Insert the infusion line, as directed by your healthcare professional. Please refer to the APO-go Skin Management Guide.

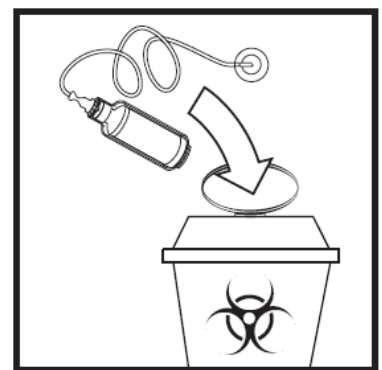


17. Once the infusion line needle is inserted into the body, the pump can be switched on and the infusion restarted.

At the end of the infusion stop the pump and detach the infusion line from the body/patient.





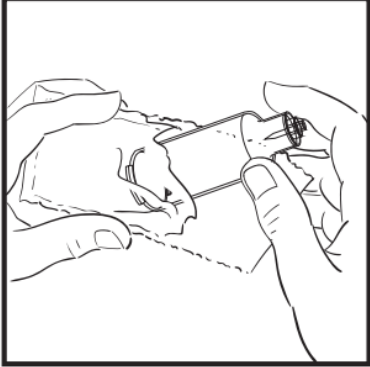
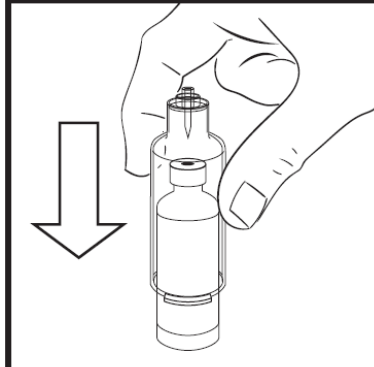
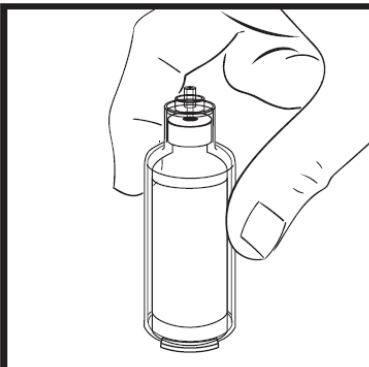
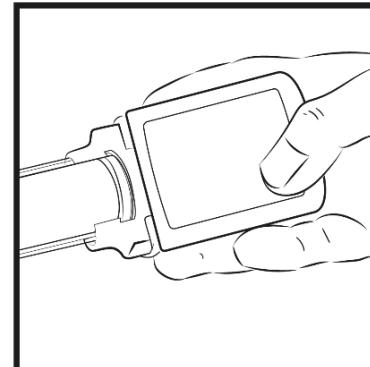
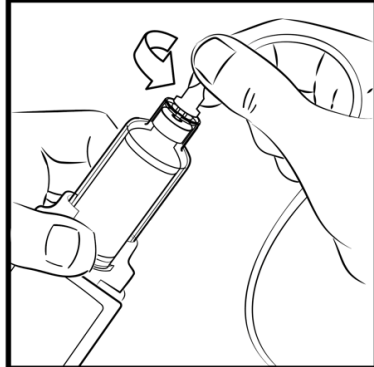
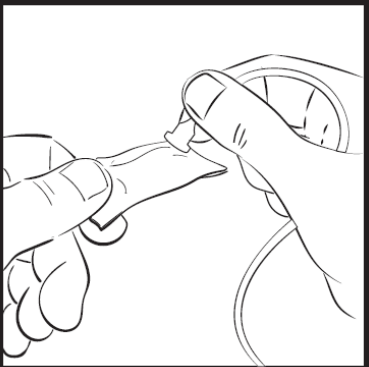
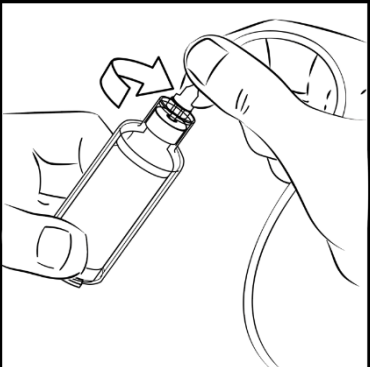
18. Ensure the pusher of the pump is fully retracted, once this is done the CronoBell Sleeve (with cartridge inside) and the infusion line can be turned and detached.

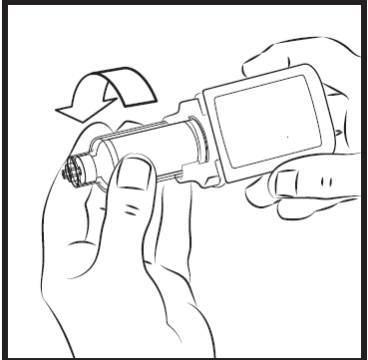
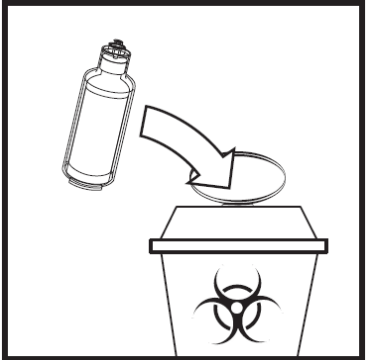
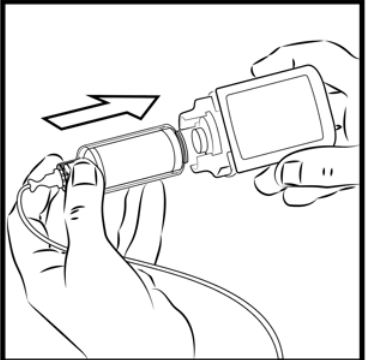
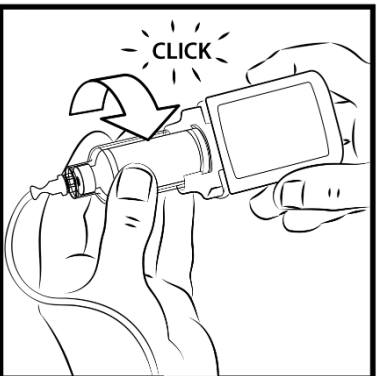
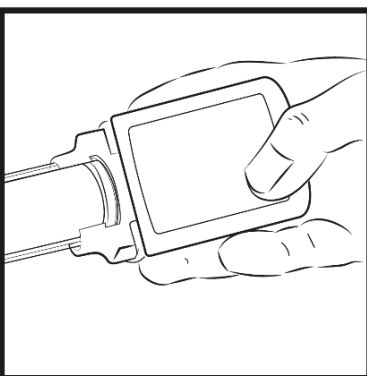


19. Dispose of the CronoBell Sleeve (with cartridge inside) and the infusion line in a sharps bin.

Instructions for changing the cartridge during the day

If you are using the cartridge for more than one day, it may be necessary to use a new cartridge when the old one finishes. Please use the following steps when changing the cartridge during the day:

		
<p>1. Wash and dry your hands.</p>	<p>2. Remove the plastic cap from the new cartridge and discard.</p>	<p>3. Remove the CronoBell Sleeve from its sterile packaging.</p>
		
<p>4. Place the cartridge on a flat surface and push the CronoBell Sleeve firmly down onto the cartridge until the rubber bung in the top of the cartridge is pierced.</p>	<p>5. The CronoBell Sleeve (with cartridge) is now ready to be connected to the pump. Wipe any spillage with the alcohol wipe.</p>	<p>6. Stop the infusion.</p>
		

<p>7. Detach the infusion line from the used CronoBell sleeve (with cartridge inside), leaving the infusion line in the skin.</p>	<p>8. Wipe the end of the infusion line with a new alcohol wipe. In order to prevent contamination, do not touch the end of the infusion line except to wipe it.</p>	<p>9. Connect the infusion line to the new CronoBell Sleeve (with cartridge inside).</p>
		
<p>10. Ensure the pusher of the pump is fully retracted, once this is done the used CronoBell Sleeve (with cartridge inside) can be turned and detached.</p>	<p>11. Dispose of the used CronoBell Sleeve (with cartridge inside) in a sharps bin.</p>	<p>12. Slide the new CronoBell Sleeve (with cartridge inside) into the collar on the pump aligning the outer lip on the CronoBell Sleeve with the gap in the collar of the pump.</p>
		
<p>13. Once inserted, turn the CronoBell Sleeve (with cartridge inside) clockwise until it clicks into place.</p>	<p>14. The pump can be switched on and the infusion started.</p>	

Note: Different infusion lines require different insertion techniques. The choice of needle will be determined by the doctor.

User guides for the pump and CronoBell Sleeve are provided for the healthcare professional, refer to your healthcare professional for details on how to set up APO-go POD for continuous infusion and additional dosing (referred to as a boost or bolus dose).

There are differences in the dosing pump of this product and other apomorphine products on the market. Therefore if you switch from or to a different product, re-training under the supervision of a healthcare professional is required.