Parkinson's patients using APO-go® (apomorphine hydrochloride) therapies during the COVID-19 pandemic

Patients' Frequently Asked Questions – a tool for Healthcare Professionals

Prescription of APO-go® (apomorphine hydrochloride) products

1. Is there any possibility that supplies of APO-go® or infusion lines might run out?

Answer: *Britannia currently has no issues regarding the supply of APO-go® products. There is also a large stock of infusion lines that can be ordered by prescription through Britannia. This can be discussed with your pharmacy if you believe there are problems with supply.*

2. In addition to APO-go®, I am taking oral Parkinson's medication*. Do you know of any supply issues with oral Parkinson's treatments?

Answer: *Britannia is unable to answer this question and it is best that you ask your Parkinson's Disease (PD) Nurse Specialist/Consultant Neurologist or your local pharmacy.*

3. My pharmacist is struggling to process prescriptions on time. What should I do if I think I might run out of APO-go® or infusion lines?

Answer: *You should always make sure that you put in your order when you have a minimum of 10 days of your medicine left. This will help the pharmacy team have your prescription ready in plenty of time before you run out. You may also wish to discuss this with your APO-go® Nurse or PD Nurse Specialist if you have any concerns about getting supplies.*

4. Should I ask my Doctor to prescribe an extra quantity of APO-go® and infusion lines?

Answer: *Try not to ask for any extra medication as this can artificially disrupt the supply situation. There is no shortage of APO-go® therapies so there is no need to stockpile medication. Do however make sure you request your prescription in plenty of time, as discussed above (see question 3).*

5. What should I do if my pharmacist cannot obtain the infusion lines I normally use?

Answer: *You could discuss alternatives with your APO-go® Nurse or PD Nurse Specialist, but it is usually safe enough to use another type of infusion line in the short term. If you need any guidance on how to use a new line, please contact your local APO-go® Nurse or PD Specialist. Alternatively, call Britannia's dedicated Helpline on 0808 196 4242 and they can arrange for a Nurse Specialist to contact you.*

6. Who can I speak to if I am worried about prescriptions for my APO-go® items?

Answer: *If you are unable to speak with your local pharmacy, your local APO-go® Nurse might be able to liaise with your Doctor's surgery and/or local pharmacy on your behalf and can also check the status of prescriptions with Britannia Customer Services.*

*Such medications may include levodopa, dopamine agonists, monoamine oxidase type B [MAO-B] inhibitors, and catechol-O-methyltransferase [COMT] inhibitors

Job Code: UK-APOG0-2000013
Date of preparation: December 2020

7. **I live alone/with my partner, and government guidance is changing. We have no one to collect our medication, including APO-go® therapies, from the local pharmacy.**

   Answer: *Please contact your pharmacy and check if they can deliver your medication to your house. If not, please inform your APO-go® Nurse or PD Nurse Specialist so they can check and explore other options. For shielded patients who do not have a family member, friend, or carer to collect their prescriptions from the pharmacy, the pharmacy must:*

   a. *Provide advice to the patient on how to identify a local volunteer to collect the prescription from the pharmacy on their behalf and then deliver it. This could be locally-organised volunteer arrangements (e.g. organised by a local council) or volunteers from the NHS Volunteer Responders programme; or*

   b. *Where no volunteer is available, the pharmacy will deliver the medicine as part of their advanced service; or*

   c. *Where no volunteer is available, arrange for another pharmacy to deliver it on their behalf. The other pharmacy will be able to claim payment for the delivery under this advanced service; or*

   d. *Where no volunteer is available, arrange for the prescription to be dispensed and delivered by another pharmacy (by referring the patient to another pharmacy, including a distance-selling pharmacy).*

   e. *If a patient does not identify themselves as being shielded, but the prescription items make the pharmacy team think they are within that group of extremely vulnerable patients, they should ask the patient if they have been asked to self-isolate for 12 weeks via a letter from the NHS, their general practice or hospital consultant.*

APO-go® Infusion

1. **I am concerned that my Crono APO-go III Pump might be faulty. Who should I contact?**

   Answer: *You can call Britannia's dedicated Helpline on 0808 196 4242 who will help you identify and manage any technical problems with your Crono APO-Go Pump.*

2. **My Crono APO-Go III Pump is programmed to provide variable rates and is dependent on the clock being set correctly. Does the clock need to be adjusted?**

   Answer: *Yes, ideally the clock should be adjusted if possible. Our APO-go® Nurses are currently making contact with anyone who's Crono APO-Go III Pump is programmed in this way. It might be possible for the clock to be adjusted with guidance from our Nurses over the telephone but, if not, they will be able to discuss possible options to manage this.*

3. **A family member/carer usually sets up my Crono APO-Go III Pump for me – what should I do if they are unable to do this for any reason?**

   Answer: *It should be possible to request assistance from the District Nurse Team. This can be arranged by contacting your local Doctors' surgery. Alternatively, please contact your local APO-go® Nurse who will be able to contact the District Nurses and make a referral on your behalf. The APO-go® Nurse will also be able to provide any training and support if required by the District Nurses.*

4. **What should I do if I need to go into hospital?**

   Answer: *It is important to take the clinic letter from your last hospital appointment, which will include your medication and your pharmacy prescription form. The clinic letter will have details of the Consultant/PD Nurse Specialist who is looking after you.*

If you have a local APO-go® Nurse, please provide their contact details for the ward staff when you reach the hospital. This will enable the Doctors and Nurses to obtain any information, support, or advice regarding your APO-go® treatment during your stay in hospital.

You will need to take with you a few days' worth of your APO-go® items including:

- *APO-go® pre-filled syringes or pens*
- *Plastic Crono syringes*
- *Connectors*
- *Infusion lines*

If you have a copy of your Crono APO-Go III Pump settings, this will help the Doctors understand how to prescribe the APO-go® and avoid any gaps in your treatment.

5. **What if the hospital staff are unsure how to manage my APO-go® Infusion or APO- go® PEN?**

   Answer: *They can contact Britannia's dedicated Helpline on 0808 196 4242 or alternatively your APO-go® Nurse. Either will be able to provide guidance and support over the phone and also arrange to send written instructions to assist the staff who are managing your APO-go® therapy.*

   If the hospital you are admitted to has a PD Nurse Specialist on site, an internal referral can be made. The PD Nurse Specialist will have access to APO-go® guidance and support and can also provide training to Ward Nurses.

   If necessary, there is also the option of using a different type of infusion, which the Ward Nurses will be familiar with.

6. **During hospital admission my consultant decided that I could benefit from keeping the APO-go® infusion running overnight but at a lower rate. How can that be achieved?**

   Answer: *That can be organised. The PD Nurse/APO-go® Nurse can order a second Crono APO-Go III Pump for the night-time where they will set the infusion at the lower rate required.*
   However, if the volume is less than 20 ml for day and night the Crono APO-Go Pump can be adjusted to accommodate a day and a night setting. This means that no alternative Crono APO-Go Pump would be required.

Managing possible adverse effects of APO-go® therapy

1. **I started using APO-go® injection/infusion, and have developed redness and a skin reaction at the site of the injections. What can I do?**

   Answer: *You can contact your APO-go® Nurse or your PD Nurse Specialist by email or telephone, informing them of any skin issues. They can provide advice on skin management and may ask you to send them photos so they can monitor this and discuss with your Doctor, if needed.*

2. **I have developed dizziness when standing up. Could this be related to APO-go®?**

   Answer: *If the weather is warm, it is important that you drink plenty of water and potentially increase salt intake in your diet as well. If you are feeling dizzy, please contact your APO-go® Nurse by email or phone. She will check if you have a blood pressure monitoring machine at home and will ask you to measure your blood pressure when lying down, sitting, and standing, to see if your blood pressure drops when changing positions.*

If low blood pressure on sitting or standing is identified (so-called postural hypotension), a further assessment over the phone will be required.

If you do not have a home blood pressure monitoring machine, your PD Nurse Specialist will be able to discuss next steps with you and, if necessary, make arrangements for your blood pressure to be taken.

The PD Nurse Specialist will also need to determine what other PD medication you are taking as well as any blood pressure medication and will discuss this with your Doctor who will advise what needs to be done in relation to your APO-go® therapy.

3. **Over the last few days, I have developed visual hallucinations. What should I do?**

   Answer: *You can contact your APO-go® Nurse or PD Nurse Specialist if you are concerned about any new developments or symptoms. They will need to assess whether anything else has changed that could contribute to this kind of symptom occurring. They will want to know:*

   a. Are there any signs of infection, e.g. urinary or chest infection?

   b. Are you constipated?

   c. Are you dehydrated?

   d. Have you started taking any new medications prescribed by your GP?

   e. How bad are the visual hallucinations and how much they are affecting you?

   f. What other medication are you taking in addition to APO-go®?

   The advice given will be dependent on the answers you give to the above questions, which will then be discussed with your Consultant/GP to decide what action, if any, needs to be taken.

4. **Over the last few days my partner/carer says that I appear intermittently confused. What could be the cause for this?**

   Answer: *You can contact your APO-go® Nurse or PD Nurse Specialist if you are concerned about any new developments or symptoms. They will need to assess whether anything else has changed that could contribute to this kind of symptom occurring. They will want to know:*

   a. Are there any signs of infection, e.g. urinary or chest infection?

   b. Are you constipated?

   c. Are you dehydrated?

   d. Have you started taking any new medications prescribed by your GP?

   e. How bad is the confusion and what difficulties is it causing?

   f. What other medication are you taking in addition to APO-go®?

   The advice given will be dependent on the answers you give to the above questions and will then be discussed with your Consultant/GP to decide what action, if any, needs to be taken.

5. **I have developed swelling in my legs. What could be the cause for this?**

Answer: *This could be because you are less able to get out and about at the moment. However, if you send your APO-go® Nurse/PD Nurse Specialist a photo of your legs they will be able to assess you. To do this, they will also need to ask you a few questions to determine:*

a. What medication you are taking in addition to APO-go® (e.g. blood pressure tablets, diuretics/water tablets, steroids)

b. If it could be related to salt retention or cellulitis.

c. If you have any breathing difficulties, congestive heart failure or venous insufficiency.

The advice given will be dependent on the answers you give to the above questions and will then be discussed with your Consultant/GP to decide what action, if any, needs to be taken.

Important note: *Painless swelling of the feet and ankles is a common problem, especially among older people. However, an abnormal build-up of fluid in the ankles, feet, and legs can cause swelling. This fluid build-up and swelling is called oedema, and would require advice from a professional, so please contact your PD Team. Some tips that may help reduce swelling:*

1. *Put your legs on pillows to raise them up while lying down.*
2. *Exercise your legs by moving your feet and ankles whenever possible.*
3. Follow a low-salt diet, which may reduce fluid build-up and swelling.
4. *Wear support stockings that can be prescribed by your GP.*
5. *Avoid wearing tight socks around your ankles or below your knees, or tight shoes.*
6. *Avoid sitting on a chair all day if possible.*

6. **Over the last few days, I have developed abnormal movements, and I am not sure what they are?**

Answer: *Abnormal movements (dyskinesia) in people with Parkinson's can be related to PD medication. You can contact your APO-go® Nurse or PD Nurse Specialist if you are concerned about any new developments or symptoms. They may need to ask you a few questions, such as:*

a. When did these movements start?

b. What time of the day do they usually occur?

c. How long do they last?

d. What did you notice prior to these movements? Any triggers?

e. What makes them worse and what makes them better?

f. Are these movements painful?

g. How intrusive are these movements?

h. What medication are you taking in addition to APO-go®?

i. Do you have any signs of infection, e.g. urinary or chest infection?

j. Are you constipated?

The advice given will be dependent on the answers you give to the above questions and will then be discussed with your Consultant/GP to decide what action, if any, needs to be taken.

It may be useful to send your APO-go® Nurse or PD Nurse Specialist a short video to capture these abnormal movements, as it will allow the clinicians to get an idea of what these movements could possibly be.

General queries

1. **Will my APO-go® Nurse still be able to visit me if I need to discuss anything?**

   Answer: *Like NHS Nurses, Britannia's APO-go® Nurses are taking all necessary precautions to keep our patients as safe as possible. For this reason, home visits are being replaced with telephone or video calls (such as FaceTime) wherever possible. APO-go® Nurses will be able to discuss any concerns you might have and then request advice from your PD Nurse Specialist or Doctor, if necessary.*

   In some specific situations, a home visit might be necessary, but this will only be done following careful risk assessment and if the intervention cannot be managed over the telephone. APO-go® Nurses have been provided with protective equipment and will complete the risk assessment with you prior to their visit.

2. **What will happen if my APO-go® pen/infusion dose needs adjusting?**

   Answer: *It may be necessary for your dose to be increased or decreased, after a discussion with your Doctor. It may be that this can be managed over the phone, but if not, a visit will be organised which will be carefully risk assessed beforehand. In some cases, APO-go® Nurses have been successful in teaching patients and carers how to adjust the dose during a video call, but this will need to be assessed on an individual basis.*

3. **I was due to commence APO-go® therapy, but this has been postponed. When is this likely to go ahead now?**

   Answer: *Britannia is sorry for the delay in starting your treatment due to the restrictions in place in response to the COVID-19 pandemic. Your APO-go® Nurse/PD Nurse Specialist will be staying in touch with your Parkinson's care team regarding the current hospital policy. It is difficult to plan ahead due to the current situation as it is uncertain how long the restrictions may last. If you have any concerns, please contact either your APO-go® Nurse or PD Nurse Specialist who will be able to update you.*

4. **I have been receiving APO-go® treatment for a while and over the last few weeks I have noticed an increased level of resting tremor and dyskinesia. What could be the reason for this?**

   Answer: *This is a stressful time for everyone, in particular those over 70 years of age and those with conditions such as PD. Inevitably, experiencing extra stress and anxiety may result in worsening of your PD symptoms, such as increased levels of your resting tremor and dyskinesia. If you are concerned you can contact your APO-go® Nurse or PD Nurse Specialist who will ask you some questions to determine whether worsened PD symptoms are related to other factors or due to this stressful and worrying time (other causes may include infection, constipation, compliance with medication, or injection technique with APO-go®). If necessary, the Nurse can then speak to your Consultant/GP to determine if anything needs to be done to alleviate your symptoms.*

APO-go® Apomorphine hydrochloride. PRESCRIBING INFORMATION.

Consult Summary of Product Characteristics before prescribing.

Indications Treatment of motor fluctuations ("on-off" phenomena) in patients with Parkinson's disease which are not sufficiently controlled by oral anti-Parkinson medication.

Dosage and Administration Apomorphine hydrochloride is administered subcutaneously either as an intermittent bolus injection or by continuous subcutaneousinfusion.Apomorphineshouldbeinitiatedinthecontrolledenvironmentofaspecialistclinic.Thepatientshouldbesupervisedbyaphysician experienced in the treatment of Parkinson's disease (e.g. neurologist). The patient's treatment with levodopa, with or without dopamine agonists, should be optimised before starting APO-go treatment. The appropriate dose for each patient is established by incremental dosing schedules. For bolus injection it is suggested to start with 1 mg of apomorphine (0.1 ml) during a hypokinetic or 'off' period. If no response or an inadequate response is obtained after 30 minutes, a second dose of 2 mg is injected and the patient is observed for a further 30 minutes. The dosage may be increased by incremental injections with at least a forty minute interval between succeeding injections, until a satisfactory motor response is obtained. Patients who have shown a good 'on' period response during the initiation stage of apomorphine therapy, but whose overall control remains unsatisfactory using intermittent injections, or who require many and frequent injections (more than 10 per day), may be commenced on or transferred to continuous subcutaneous infusion by minipump and/or syringe driver. Continuous infusion is started at a rate of 1 mg apomorphine HCl (0.1 ml) per hour then increased according to the individual response. Increases in the infusion rate should not exceed 0.5 mg per hour at intervals of not less than 4 hours. Hourly infusion rates may range between 1 mg and 4 mg (0.1 ml and 0.4 ml), equivalent to 0.015 - 0.06 mg/kg/hour. Infusions should run for waking hours only. Patients treated with apomorphine will usually need to start domperidone at least two days prior to initiation of therapy. The domperidone dose should be titrated to the lowest effective dose and discontinued as soon as possible. Before the decision to initiate domperidone and apomorphine treatment, risk factors for QT interval prolongation in the individual patient should be carefully assessed to ensure that the benefit outweighs the risk. The optimal dosage of apomorphine HCl has to be determined on an individual patient basis; individual bolus injections should not exceed 10mg and the total daily dose should not exceed 100mg. Do not use if the solution has turned green. The solution should be inspected visually prior to use. Only clear, colourless and particle free solution should be used. Apomorphine must not be used via the intravenous route.

Contraindications Children and adolescents (up to 18 years of age). Known hypersensitivity to apomorphine or any excipients of the medicinal product. Respiratory depression, dementia, psychotic disease or hepatic insufficiency. Intermittent apomorphine HCl treatment is not suitable for patients who have an "on" response to levodopa which is marred by severe dyskinesia or dystonia.

Pregnancy and lactation Apomorphine should not be used in pregnancy unless clearly necessary. Breastfeeding: It is not known whether apomorphine is excreted in breast milk. A decision on whether to continue/discontinue breastfeeding or to continue/discontinue therapy with APO-go should be made taking into account the benefit of breast-feeding to the child and the benefit of APO-go to the woman.

Ability to drive and operate machinery Apomorphine has minor or moderate influence on the ability to drive and use machines. Patients being treated with apomorphine and presenting with somnolence and/or sudden sleep episodes must be informed to refrain from driving or engaging in activities (e.g. operating machines) where impaired alertness may put them or others at risk of serious injury or death until such recurrent episodes and somnolence have resolved.

Interactions Patients should be monitored during initiation with apomorphine therapy particularly when used with other medications that have a narrow therapeutic window. There is potential for interaction with neuroleptic and antihypertensive agents and cardiac active medicinal products. It is recommended to avoid the administration of apomorphine with other drugs known to prolong the QT interval.

Precautions Use with caution in patients with renal, pulmonary or cardiovascular disease, or who are prone to nausea or vomiting. Apomorphine may produce hypotension, exercise care in patients with cardiac disease or who are taking vasoactive drugs. Neuropsychiatric disturbances may be exacerbated by apomorphine. Apomorphine has been associated with somnolence and episodes of sudden sleep onset (see advice on driving above). Haematology tests should be undertaken at regular intervals as haemolytic anaemia and thrombocytopenia have been reported. Monitor patients for the development of impulse control disorders. Dose reduction/tapered discontinuation should be considered if such symptoms develop. Dopamine dysregulation Syndrome (DDS) is an addictive disorder resulting in excessive use of the product seen in some patients treated with apomorphine; patients and caregivers should be warned of the potential risk of developing DDS. Apomorphine may have the potential for QT prolongation, exercise caution when treating patients at risk for torsades de pointes arrhythmia. Risk factors for use with domperidone include serious underlying heart conditions such as congestive cardiac failure, severe hepatic impairment or significant electrolyte disturbance. An ECG should be performed prior to treatment with domperidone, during the treatment initiation phase and as clinically indicated thereafter to monitor prolongation of QT interval. Patients should report possible cardiac symptoms; palpitations, syncope, or near-syncope and clinical changes that could lead to hypokalaemia, e.g. gastroenteritis or initiation of diuretic therapy. At each medical visit, risk factors should be revisited. Apomorphine has been associated with local subcutaneous effects that can be sometimes reduced by rotation of injection sites in order to avoid nodularity and induration. Contains sodium metabisulphite which may rarely cause severe allergic reactions and bronchospasm.

Side Effects: Very common: Hallucinations and injection site reactions. Common: Neuropsychiatric disturbances, somnolence, transient sedation, dizziness, yawning, nausea and vomiting. Rarely, injection site necrosis and ulceration have been reported. Severe drug-induced dyskinesias during "on" periods may require discontinuation. Postural hypotension is usually transient and infrequent. Positive Coombs' tests, haemolytic anaemia and thrombocytopenia have been reported. Eosinophilia occurs rarely. Dopamine agonists, including apomorphine, may cause impulse control disorders such as pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating or compulsive eating. Rarely, allergic reactions (including anaphylaxis and bronchospasm) due to sodium metabisulphite. Symptoms of overdose like excessive emesis, respiratory depression, hypotension and bradycardia may be treated empirically.

Prescribers should consult the Summary of Product Characteristics in relation to other adverse reactions.

Presentation and Basic NHS Cost APO-go pens (disposable multiple dosage injector system) contain apomorphine hydrochloride 10mg/ml, as follows: 30mg in 3ml – basic NHS cost £123.91 per carton of 5 pens. APO-go Pre-filled syringes contain apomorphine hydrochloride 5mg/ml, as follows: 50mg in 10ml – basic NHS cost £73.11 per carton of 5 syringes. APO-go ampoules contain apomorphine hydrochloride 10mg/ml as follows: 50mg in 5ml – basic NHS cost £73.11 per carton of 5 ampoules.

Marketing Authorisation Numbers:
APO-go® Ampoules: PL 04483/0072
APO-go® Pen: PL 04483/0073
APO-go® Pre Filled Syringes: PL 04483/0074

Legal Category POM

SmPC Revision Date January 2020

API Revision date April 2020

Marketing Authorisation Holder in the UK Britannia Pharmaceuticals, 200 Longwater Avenue, Green Park, Reading, Berkshire, RG2 6GP

Full prescribing information and further information is available from Britannia Pharmaceuticals at Britannia@medinformation.co.uk or 01483 920 763.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Britannia Pharmaceuticals Ltd at dso@britannia-pharm.com or 01483 920 763.

Version Number: APG.PI.V28

Job Code: UK-APOG0-2000013
Date of preparation: December 2020