

SHARED CARE

Drug: APOMORPHINE

Protocol number CV 02

Indication: **DISABLING MOTOR FLUCTUATIONS IN PARKINSON'S DISEASE**

General Guidance

This protocol sets out details for the shared care of patients taking **apomorphine** and should be read in conjunction with the General Guidelines for Shared Care (SC). Sharing of care requires communication between the specialist, GP and patient. The intention to share care should be explained to the patient by the Specialist initiating treatment. **The doctor who prescribes the medication legally assumes responsibility for the drug and the consequences of its use.** The prescriber has a duty to keep themselves informed about the medicines they prescribe, their appropriateness, effectiveness and cost. They should also keep up to date with the relevant guidance on the use of the medicines and on the management of the patient's condition.

Background

Disabling motor fluctuations are a common complication of idiopathic Parkinson's disease. Affected patients may develop unpleasant "off" period phenomena such as dystonia, depression, bladder dysfunction and swallowing difficulties. Apomorphine can reduce and sometimes reverse these disabling "off" period phenomena.

The rapid and reliable onset of action of apomorphine can be used to advantage when oral doses of levodopa become progressively less effective and less predictable. The aim of treatment is to optimise the delicate balance between an effective response and minimal side effects. The complex nature of apomorphine therapy necessitates that it should be initiated in specialist centres.

Apomorphine is a directly acting dopamine agonist with no opiate or addictive properties. Apomorphine is not used orally because it undergoes extensive first pass metabolism to an inactive metabolite. Treatment with apomorphine is usually administered either by intermittent subcutaneous injections or by continuous waking day subcutaneous infusion.

Following a single subcutaneous dose, apomorphine has an onset of action of between 5 to 15 minutes. The effect usually lasts for about one hour.

A. Consultant responsibilities

1. When treatment is **initiated** send Shared Care Request form with Shared Care Protocol to GP
2. Baseline and continued monitoring of clinical, haematological and biochemical parameters, including Coombs test.
3. Initiate therapy following full discussion with the patient of benefits and risks.
4. When a GP positive response to SC has been received and the patient has been stabilised send a letter to the GP "handing over" the Shared Care of the patient to the GP. The letter must specify which brand of apomorphine is to be prescribed (Apo-Go or Dacepton). Each brand of apomorphine needs to be administered via a specific device and are not interchangeable. If DACEPTON infusion is to be used the letter must state the number of D-Mine reservoirs to be supplied each month.
5. Respond to any request from GP to review the patient due to adverse effects of therapy.
6. Advise the GP on continuing or stopping apomorphine therapy following medical review of the patient and associated drug therapy.
7. Ensure that an ECG is done prior to domperidone treatment and domperidone is withdrawn within 2 weeks of commencing treatment. (please refer to adverse effects section)

8. Notify GP if patient is failing to attend for appropriate monitoring and advise GP on appropriate action.

B. General practitioner responsibilities

1. Within one week of request return the completed Shared Care request form to indicate whether or not willing to undertake Shared Care.
2. Prescribe apomorphine as part of the shared care agreement.
3. Monitor the general health of the patient.
4. Report adverse effects of therapy to the consultant and the Medicines and Health Care products Regulatory Agency (MHRA).
5. To act on advice provided by the Consultant if patient does not attend for appropriate monitoring.

C. Patient responsibilities

1. Consent to treatment with apomorphine.
2. Attend regular appointments with specialist centre and GP.
3. Report any side effects to the specialist or GP whilst taking apomorphine.

Dosage Regimen

The dose of apomorphine is carefully titrated on an individual basis and may range from a few milligrams daily by intermittent injections, up to 100 milligrams daily by continuous infusion.

Intermittent sub-cutaneous injections are used as a rescue from disabling off periods in conjunction with conventional oral therapy.

Intermittent sub-cutaneous injections may be suitable for patients who experience off periods of less than 60 minutes duration, occurring less than 10 times a day and for treating painful dystonia.

Patients whose overall control remains unsatisfactory using intermittent injections, or those patients who require more than 10 injections per day may be commenced on continuous sub-cutaneous infusion administered via a syringe driver.

Monitoring

Once stabilised on an effective dose, patients should be assessed regularly for adverse effects, changes in response and clinical condition.

Conduction of a Coomb's test and a full blood count - every 6-12 months by hospital team.

Regular monitoring will be carried out by the Parkinson's Specialist Nurse or District Nurse team. This will include checking patient's skin for nodule formation and the syringe driver.

Adverse Effects

Possible side effects can be divided into those derived from apomorphine's pharmacology and those attributable to the mode of administration ie. localised reactions.

Pharmacological side-effects

- Nausea and vomiting
- Dyskinesias during "on" periods
- Confusion

- Hallucinations
- Personality changes
- Sedation
- Euphoria
- Light-headedness
- Restlessness
- Postural instability
- Postural hypotension
- Tremors
- Haemolytic anaemia
- Eosinophilia

Apomorphine is a strong emetic and all patients should start domperidone at an initial dose of 10mg every 8 hours, three days prior to the apomorphine challenge. Domperidone will be withdrawn within 2 weeks of commencing treatment by the hospital team.

Drug induced dyskinesias during "on" periods can be severe and in a few patients may result in the cessation of therapy.

Transient mild confusion and visual hallucinations have occurred, most commonly in patients reporting previous levodopa induced neuropsychiatric complications. Should these continue to develop, attempts should be made to identify the contributing factor under the direct supervision of the hospital team.

On initiation of apomorphine therapy, patients are assessed in hospital or the out patient clinic for the possible development of postural hypotension. The use of apomorphine in conjunction with levodopa may cause Coomb's positive haemolytic anaemia. Patients are screened prior to apomorphine initiation and six monthly thereafter by the hospital team.

Localised reactions

- Nodule formation
- Ulceration

To minimise localised reactions patients are trained to rotate the site of injection and to massage the area post infusion for at least 30 seconds.

Storage and Stability

All Brands

Ampoules containing apomorphine should be stored at room temperature (at or below 25°C) and protected from direct sunlight. Do not use if the solution has turned green. Keep out of the reach and sight of children.

Apo-Go

Syringes filled with apomorphine should be stored in the fridge when not being carried for immediate use. No antimicrobial preservative is included in the formulation, so all drawn up syringes must be used within 24 hours. Unused solution should be discarded in the appropriate manner. If using pre-filled syringes, store in the outer carton.

Dacepton

Cartridges for use with pen devices

Cartridges must be discarded after a maximum of 15 days use

Solution for infusion

Once added to the infusion reservoir solutions should be used immediately and must not be used for more than 7 days

Contact Details

For further information contact Tracy Williams or Sandra Mahon (Parkinson's Disease Nurse Specialists) on 029 2031 3838

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