

Dacepton 5 mg/ml solution for infusion & Dacepton® 10mg/ml solution for injection in cartridge

Apomorphine hydrochloride

PRESCRIBING INFORMATION

Consult Summary of Product Characteristics before prescribing.

Uses 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 Patients selected for treatment with Dacepton 5 mg/ml solution for infusion should be able to recognise the onset of their “off” symptoms and be capable of injecting themselves or else have a responsible carer able to inject for them when required. 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. Apomorphine should be initiated in the controlled environment of a specialist clinic. The patient should be supervised by a physician 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 treatment. Dacepton 5 mg/ml is presented in a prediluted vial and is intended for prolonged subcutaneous infusion only. Hourly infusion rates range between 1 mg and 4 mg (0.2 ml and 0.8 ml), equivalent to 0.014 - 0.06 mg/kg/hour and in almost all cases should run for waking hours only. The total daily dose of apomorphine hydrochloride should not exceed 100 mg.

The daily dose of Dacepton® 10mg/ml solution for injection in cartridge varies widely between patients, typically within the range of 3-30 mg, given as 1-10 injections and maximum 12 separate injections per day. The total daily dose of apomorphine hydrochloride hemihydrate should not exceed 100 mg and that individual bolus injections should not exceed 10 mg. The D-mine Pen that is required for the application of Dacepton solution for injection in cartridge is not suitable for patients needing above 6 mg/bolus. The D-mine device differs from other devices available on the market, patients and carers should be adequately trained for its use. 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.

Special Warnings and Precautions Contraindicated in children and adolescents under 18 years of age. Caution is recommended when initiating therapy in the elderly because of the risk of postural hypotension. Administer with caution to patients with renal, pulmonary or cardiovascular disease and those prone to nausea and vomiting. Because of the risk of hypotension care should be taken in administering apomorphine to patients taking vasoactive medicinal products. An ECG should be performed prior to treatment, during treatment initiation and as clinically indicated thereafter. In some patients neuropsychiatric

disturbances may be precipitated. Apomorphine may be associated with somnolence and episodes of sudden deep sleep and patients must be warned when operating machinery or driving. Patients should be regularly monitored for the onset of impulse control disorders. The concomitant use of apomorphine with ondansetron is contraindicated. **Side Effects** *Very common* Hallucinations, injection site reactions particularly with continued use, these may include subcutaneous nodules, induration, erythema, tenderness and panniculitis. Various other local reactions (such as irritation, itching, bruising and pain) may also occur. Local induration and nodules (usually asymptomatic) often develop at subcutaneous site of injection, leading to areas of erythema, tenderness, induration and panniculitis. *Common* Neuropsychiatric disturbances (including transient mild confusion and visual hallucinations), transient sedation that usually resolves with continued treatment, apomorphine is associated with somnolence, dizziness/light-headedness, yawning, nausea and vomiting particularly during initiation of treatment if domperidone is omitted. *Prescribers should consult the Summary of Product Characteristics in relation to the treatment of overdose and for details of other side effects*

Presentation and Basic NHS Cost.

The 20 ml vial contains 100 mg apomorphine hydrochloride hemihydrate each 1 ml contains 5 mg apomorphine hydrochloride basic NHS cost for 5-pack of 20ml Vials £145.00.

The Dacepton cartridges contain 3ml apomorphine hydrochloride 10mg/ml as follows: basic NHS cost per 5-pack of cartridges £123.00. NHS cost per pen £100.

Marketing Authorisation Numbers:

Dacepton 5 mg/ml solution for infusion PL 40369/0003

Dacepton® 10mg/ml solution for injection in cartridge PL 40369/0007

Legal Category POM

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For further information please contact: EVER Neuro Pharma GmbH, Oberburgau 3, 4866 Unterach, Austria

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Medical Information on 0800 254 0174 or info.uk@everpharma.com

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