INTRODUCTION

This brochure contains instructions for using the EVER Pharma D-mine® Pen injector and disposables. It is not intended to replace the instructions for use of the pen.

Your D-mine® Pen can deliver doses from 0.5 to 6.0 mg, in increments of 0.5 mg (corresponds to 50 μl per increment). It is designed to be used with Dacepton® 3 ml cartridges (Apomorphine 10 mg/ml) from EVER Pharma GmbH (please refer to the package leaflet of the pharmaceutical product) and appropriate pen needles. Compatible pen needles:

- BD Micro-Fine Ultra™ needles 29 to 31 gauge (diameter 0.25 – 0.33 mm) and 5 - 12.7 mm length.
- Pen needles from other manufacturers can be used according to their stated compatibility details.

Please refer to the package leaflet of the pharmaceutical product. Before using the D-mine® Pen wash your hands. You will need some surgical wipes and one needle in its protective cone. Use a surgical wipe, clean the area of skin where you plan to inject the medicine and around it. Inject into an injection site on the front of your waist (abdomen) or your outer thighs under the skin (subcutaneously) as shown by your doctor or nurse. Change your injection site each time you use the D-mine® Pen. Do not inject into an area of skin that is sore, red, infected or damaged. You must never inject yourself directly into a vein (intravenously) or muscle (intramuscularly).
DESCRIPTION OF PARTS OF D-mine® PEN THERAPY

Please refer to the instructions of use of your D-mine® Pen for complete information. If you have any questions relating to your D-mine® Pen, our local service helpline will be happy to help at any time.

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ATTACHMENT OF PEN NEEDLE

Follow the instructions for use of your pen needle.

1. **Pull off the peel foil.**
   Click on / twist on the pen needle to the cartridge sleeve. Check that the pen needle is attached correctly.

2. **Remove the outer and inner needle protective cap.**
   Keep the outer needle protective cap to safely remove and dispose of the pen needle after use.
FUNCTION CHECK AND DOSE DIALING

Priming/Function Check
The function check ensures that any remaining air in the cartridge is removed and that no blockage is present in the needle. Priming is recommended before every use, including cartridge change and attachment of pen needles.

Dial the required dose by turning the dosage wheel clockwise. Correct the dose by turning anti-clockwise. Check the dialed dose by looking vertically from above and not at an angle onto the display, so that the numbers are clearly identified.
**Note:** You can interrupt the injection by releasing the push-button. The remaining amount of medicine not delivered can be seen on the display and can be injected by pressing the push-button again.

1. **Use the injection technique as recommended** by your physician and/or health care professional. Press the push-button in fully for injection. Hold the push-button pressed down during medication discharge.

2. **After the medication has been completely discharged, wait for 6 seconds** and then pull out the pen needle slowly. You may either hold the push-button pressed or release it during the 6 seconds.

3. **Check** if the display is at the “0.0” position for full dose delivery.

4. **Place the Outer Pen Needle Shield in the notch** located in your carrying case to dispose the needle correctly.
**POSOLOGY AND METHOD OF ADMINISTRATION**

- Apomorphine hydrochloride hemihydrate should be given with caution to patients with renal, pulmonary or cardiovascular disease. Patients selected for treatment with Dacepton 10 mg/ml solution for injection should be informed of the risks of their "off" symptoms and be capable of identifying themselves or others with a responsible carer able to give assistance 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 start of domperidone treatment patients should be informed of the risk of extrapyramidal symptoms and report any change in their usual actions. They should also report clinical changes that could lead to hypokalaemia, such as gastroenteritis or the initiation of new Medicinal Products. They should be encouraged to report any change in their usual eating habits and be informed of the risk of sudden sleep onset episodes. General practitioners should be informed of the risk of sudden sleep onset episodes, and the potential for sudden sleep episodes to put themselves or others at risk of serious injury or death until such recurrent episodes and somnolence have resolved.

- The patient should be instructed to report possible cardiac symptoms including palpitations, syncope, or near-syncope. They should also report clinical changes that could lead to hypokalaemia, such as gastroenteritis or the initiation of new Medicinal Products. They should be encouraged to report any change in their usual eating habits and be informed of the risk of sudden sleep onset episodes. General practitioners should be informed of the risk of sudden sleep onset episodes, and the potential for sudden sleep episodes to put themselves or others at risk of serious injury or death until such recurrent episodes and somnolence have resolved.

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