

EVER Pharma D-mine[®] Pen

Pen injector for Apomorphine 10 mg/ml

Instructions for Use

with Dacepton[®] 3 ml Cartridges

Apomorphine hydrochloride hemihydrate solution for injection



Subcutaneous Use



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INTENDED PURPOSE

The D-*mine*® Pen is a non-sterile, reusable medical device intended for the subcutaneous administration of Dacepton® (Apomorphine 10 mg/ml) from compatible cartridges. The D-*mine*® Pen is intended to be used for treatment of Parkinson's disease.

INTRODUCTION

These instructions for use contain instructions for using, storing and cleaning your EVER Pharma D-*mine*® Pen. Do not use the D-*mine*® Pen without having received introductions by your healthcare professional (physician or nurse). The carton contents includes 1 EVER Pharma D-*mine*® Pen, 1 Pen Case, 1 Instruction for Use. Note: Carton does not include pen needles or Dacepton® 3 ml cartridges. You should read the instructions in this manual completely and carefully even if you have used D-*mine*® Pen or other drug delivery systems before. Otherwise there is the risk of getting an incorrect dose. The Pen is a maintenance free reusable injector with an automatic spring driven delivery-system.

The D-*mine*® Pen is intended to be used by self-injecting adult patients (above the age of 18), healthcare professionals as well as third parties such as adult relatives and caregivers. Wash your hands before using the D-*mine*® Pen. Make sure you use the D-*mine*® Pen in a clean environment. You will need some disinfectant wipes, a sharps disposal container and one needle in its outer needle protective cap. Use a disinfectant wipe, clean the area of skin where you plan to inject the medicine and around

it. Never rub the injection site. Do not blow on the disinfected site to accelerate drying process. Inject into a site on the front of your waist (abdomen) or your outer thighs under the skin (subcutaneously) as shown by your healthcare professional. 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). Do not inject through clothing.



Compatible Pen cartridges and needles:

- Dacepton® 3 ml cartridges (Apomorphine 10 mg/ml) from EVER Neuro Pharma GmbH proved according to ISO EN 11608-3.
- BD Ultra-Fine™ needles 29 to 32 gauge (diameter 0.23 – 0.33 mm) and 4 - 12.7 mm length.
- Pen needles from other manufacturers can be used according to their stated compatibility details.

Remark:  Do not use needles or cartridges with passed expiry date.  The D-*mine*® Pen is intended for use only with Dacepton®. Do not use it with other drug cartridges. Your D-*mine*® Pen can deliver doses from 0.1 to 6.0 mg, in increments of 0.1 mg (corresponds to 10 µl per increment). The scale shows steps of 0.5 mg, the intermediate steps are marked with a dot. If you have any questions relating to your D-*mine*® Pen, our local service helpline will be happy to help at any time (see page 27). A healthcare professional must prescribe the dose selected for therapy with Dacepton® using the D-*mine*® Pen.

WARNINGS / IMPORTANT RISK INFORMATION

The following instructions must be observed to avoid incorrect medication, incorrect dosage, disease transmission or infection. Seek immediate medical attention if you have any health concern.

-  Read these **instructions for use** before using your D-*mine*® Pen. Follow the instructions for use of your D-*mine*® Pen, pen needle and your cartridge and use your D-*mine*® Pen only after consultation with your healthcare professional.
-  Contact your healthcare professional in case of adverse effects. Please refer to the package leaflet of the cartridge for more information on adverse effects.
-  Ensure **correct handling**
 - The D-*mine*® Pen is not designed to be used by patients that are blind or have visual impairments, which cannot be corrected by glasses or similar. In case of hearing or tactile impairment consult your healthcare professional.
 - Store your D-*mine*® Pen, pen needles, and cartridges out of reach of children or other people who are not familiar with the correct method of use. The D-*mine*® Pen, pen needles and Dacepton® cartridges contain small parts that might be swallowed.



Ensure **correct application**

- Use your D-*mine*® Pen only as part of the treatment prescribed by your healthcare professional.
- Use the cartridges, dosage amounts and pen needles prescribed by your healthcare professional. Any changes must be made under the supervision of a healthcare professional.
- Before each injection, check that your D-*mine*® Pen contains the correct type of medication. Check that the cartridge is undamaged.
- Always refer to the instructions in the package leaflet of Dacepton® 3 ml cartridges (e.g. to visually check the solution).
- The pen needles, the D-*mine*® Pen, and cartridges are for use on one person only and must not be shared in order to prevent transmission of disease.
- Do not expose your D-*mine*® Pen to any extreme temperatures through direct exposure to sunlight or cold (e.g. do not store in a freezer compartment).
- Do not use the D-*mine*® Pen at a temperatures above 25°C. Failure to do this can reduce the life expectancy of your D-*mine*® Pen.
- Do not drop your D-*mine*® Pen and avoid knocking it against hard surfaces. Avoid immersing your D-*mine*® Pen in water. Generally handle it with care. Never use your D-*mine*® Pen if you have any doubts about its correct functioning.
- Never try to repair a damaged D-*mine*® Pen yourself. In case of a damaged or defective D-*mine*® Pen, please contact the Customer Services (see page 27).

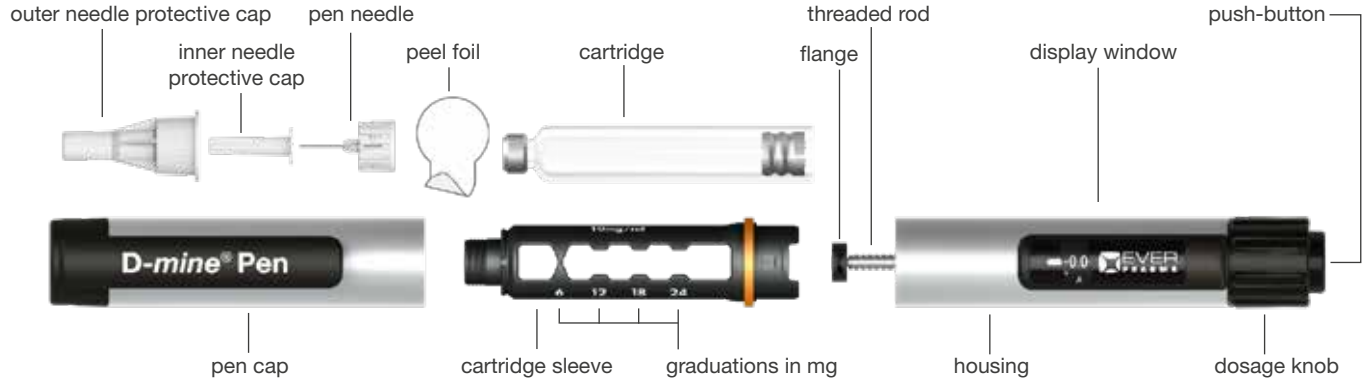


Ensure **correct delivery of medication**

- Before each injection, carry out a function check (Chapter “Priming / Function Check” step 1 – 4) to prevent incorrect dosage caused by air in the cartridge or a blocked pen needle. Use a new pen needle if the function check is not successful.
- Following each injection check to ensure there is no medication dripping from the pen needle or medication exuding from the injection site. Follow your healthcare professionals instructions regarding the handling of potential under-dosage. Seek medical attention if you have any health concern.
- In the event of interruption of injection by releasing the push-button, check on the display the amount of medicine not delivered. The remaining amount can be injected by pressing the push-button again.
- In the event of accidental medication injection seek immediate medical attention.

DESCRIPTION OF PARTS OF D-mine[®] PEN THERAPY

Note: The carton contents does not include pen needles or 3 ml cartridges.

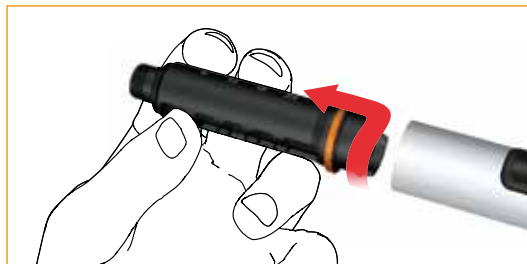


PEN PREPARATION / CHANGING CARTRIDGE

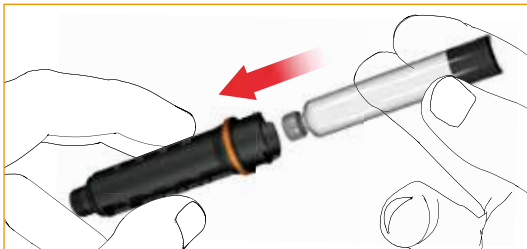
- 1 Remove the pen cap.



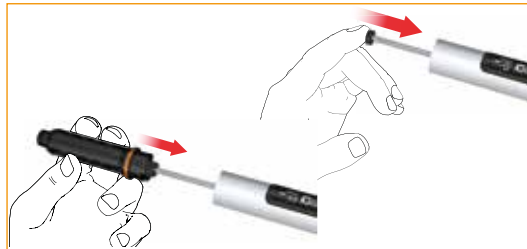
- 2  Perform a visual check of your D-mine® Pen. Turn the cartridge sleeve to unlock it and remove it from the pen housing. Remove the empty cartridge if necessary.



- 3**  Perform a visual check of your cartridge and its content and check the expiry date before each injection. To perform the visual check please refer to the package leaflet of the cartridge. Insert the new cartridge into the cartridge sleeve.



- 4** Push the threaded rod back completely. This is best performed using your fingertip (alternatively you can also use the cartridge sleeve with the inserted cartridge).



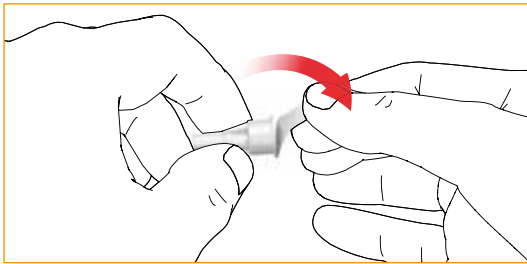
- 5** Push the cartridge sleeve as shown in the picture to lock it onto the pen housing. You will recognise it locks on the pen housing.



ATTACHMENT OF PEN NEEDLE

Follow the instructions for use of your pen needle.

- 1 Pull off the peel foil.



- 2 Click on / twist on the pen needle to the cartridge sleeve. Make sure that the pen needle is attached correctly and sits firmly on the cartridge.



- 3** Remove the outer needle protective cap.
Keep the outer needle protective cap to safely
remove and dispose of the pen needle after use.



- 4** Remove and dispose of the inner needle protective cap.



PRIMING / FUNCTION CHECK

The priming and function check shall ensure that any remaining air in the cartridge is removed and that no blockage is present in the needle. Priming is recommended before every injection.

- 1 Dial the priming dose (drop symbol) by turning the dosage knob. Check the dialed dose in the display window by looking vertically from above and not at an angle onto the display window, so that the drop symbol “δ” is clearly displayed.



- 2 For the function check, hold the D-mine® Pen pointing upwards and gently tap the cartridge sleeve, so that the air can rise to the top.



Never hold the pen with exposed needle tip towards your face or other persons. In the event that Dacepton® comes into contact with the skin or eyes, you must immediately rinse the affected area with water for 15 minutes. If signs of irritation persist following this initial action, it is strongly recommended to seek medical advice from your healthcare provider without delay.

- 3** Press the push-button.



- 4** A few drops of medicine will emerge from the pen needle tip.

If no drops emerge, repeat steps 1 to 3. If after several function checks no drops emerge, change the pen needle and repeat the function check (steps 1 to 3). If still no drops emerge or if you have any concerns, please call Customer Services mentioned on page 27.



SETTING THE DOSE



Dial the required dose

Dial the required dose by turning the dosage knob clockwise. Correct the dose by turning counterclockwise, if required. 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: Each “-” marking on the display window represents 0.1 mg of medicine. You will recognise each increment you dial by turning the dosage knob. Do not rely on counting these increments to measure the correct dose.

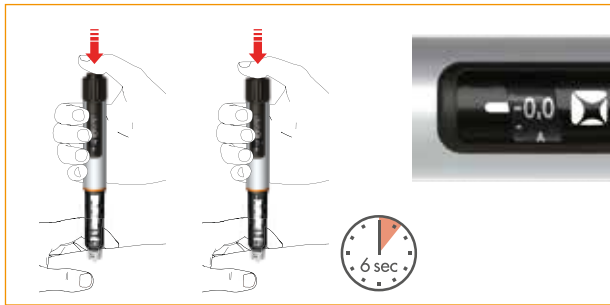


Safety stop

The medication dose that can be set on the D-mine[®] Pen is limited to the amount remaining in the cartridge. If the amount of medicine left in the cartridge is no longer sufficient for the desired dose, the dosage knob cannot be turned any further in a clockwise direction (see page 23, section safety stop).

INJECTION

Inject into an injection site on the front of your waist (abdomen) or your outer thighs under the skin (subcutaneously) as shown by your healthcare professional.



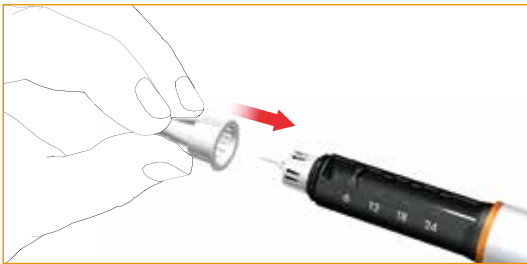
Note: You can interrupt the injection by releasing the push-button. The remaining amount of medicine not delivered can be seen on the display and can be injected by pressing the push-button again.

- 1 Please refer to the package leaflet of Dacepton® and use the injection technique as recommended by your healthcare professional. Press the push-button in fully for injection. Hold the push-button fully down during medication discharge. Do not tilt the pen during injection, to prevent needle breaking. Broken needles can get stuck in the skin. Immediately consult your healthcare professional if a broken needle is stuck in the skin.
- 2 Press and hold down the push button until the dose indication has returned to the start position, wait for 6 seconds and then pull out the pen needle slowly. You may either keep the push-button pressed or release it during the 6 seconds.
- 3 Check that the display is at the “0.0” position to confirm full dose delivery.

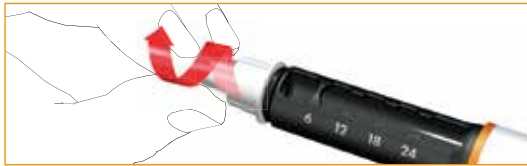
REMOVAL OF PEN NEEDLE AFTER EACH INJECTION

 Pen needle is for single use only. Every injection requires a new needle.

- 1 Carefully attach the outer needle protective cap on the pen needle. Do not use the inner needle cover.



- 2  Twist off the pen needle by turning the outer shield clockwise and dispose of it correctly, according to the advice of your healthcare professional (sharps disposal container). Professional healthcare personnel should follow the specific directions regarding recapping and disposal. To access the specific directions, please consult your healthcare professional.



Optional:

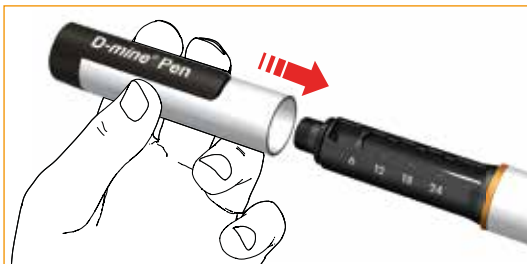
Place the outer pen needle shield in the appropriate left notch of your carrying case. The opening of the needle shield should be pointing up. Carefully insert the needle (attached to the pen) into the opening of the shield. Without holding onto the shield, push down firmly and turn counterclockwise to twist off the pen needle.

Note: The larger notch located on the right-hand side of the carrying case fits to needles used by healthcare professionals.



ATTACHMENT OF PEN CAP

Attach the pen cap securely after each use.



ADDITIONAL INFORMATION

Audible and tactile indications

Your *D-mine*[®] Pen features the following audible and/or tactile indications:

Remove/Lock Cartridge Sleeve

When removing or locking the cartridge sleeve an audible signal and a noticeable resistance will be provided.

Dose Dialing

During dose dialing and dose correction your *D-mine*[®] Pen provides an audible signal and a noticeable resistance for each dialed step.

Injection

The medication discharge of your *D-mine*[®] Pen is perceptible. You will recognise the release of the medication after pressing the push button. The release stops after the dialed amount of medication has been delivered completely.

Safety stop

 The dose that can be set on the D-*mine*® Pen is limited to the amount remaining in the cartridge. If the amount of medicine left in the cartridge is no longer sufficient for the desired dose, the dosage knob cannot be turned any further in a clockwise direction.

- Do not try to force the dosage knob to turn further.
- Note the remaining dose that can be dispensed and inject.
- Change the cartridge and pen needle, and carry out function checks (Chapter “Priming / Function Check” step 1 – 4).
- Dial and inject the outstanding dose.

General

Once the cartridge has been inserted, it can remain in your *D-mine*[®] Pen. Please follow the storage instructions of the drug given in the package leaflet of the cartridges.

When changing the cartridge you should ensure that a new cartridge is inserted into the cartridge sleeve. Partially used cartridges shall not be inserted into the cartridge sleeve.

You must use a new needle with each injection because the needles

- are sterile packed and must not be reused in order to avoid infections
- can be blunted after use and if reused cause painful injection

Please follow local regulations in your country concerning the handling of potentially infectious materials. Do not use the *D-mine*[®] Pen if it is damaged or if you have any doubts about its correct functioning.

STORAGE AND CARE

Please store and handle your needles and cartridges according to the respective instructions for use.

After each use, securely attach the pen cap. Always keep your *D-mine*® Pen in the carrying case, without a pen needle attached.

You can store or transport your *D-mine*® Pen without inserted cartridge at a temperature between 5° and 35°C. If a cartridge is inserted please make sure not to use, transport or store it above 25°C. Failure to do this can reduce the life expectancy of your *D-mine*® Pen.

Even though your *D-mine*® Pen is robust, it can be damaged. Please handle your *D-mine*® Pen with care. Protect it from water, dust, moisture, direct sunlight, and extreme hot or cold temperatures. Do not use your *D-mine*® Pen, cartridge or pen needle if it looks damaged. Do not try to repair your pen or cartridge.

Do not use the D-*mine*® Pen until after the “FIRST USE BEFORE” date printed on the box.

Record the date the D-*mine*® Pen was first used here:

____ / ____ / ____.

Do not use the D-*mine*® Pen for more than 2 years after first use.

A damp cloth is sufficient to clean your D-*mine*® Pen. Please do not use alcohol, other solvents or cleaning agents.

Never immerse your D-*mine*® Pen in water, as this could damage the pen. The device must be protected from excessive contamination by dirt and water.

If you have any questions or problems relating to your D-*mine*® Pen, Customer Service will be available at the following local support number:

EVER Pharma UK Ltd.
Bloxham Mill, Barford Road
Bloxham, Oxfordshire
OX15 4FF
United Kingdom



Phone: 0800 254 0175
E-Mail: info.uk@everpharma.com

WARRANTY

The manufacturer guarantees the proper functioning of the pen for two years when used according to instructions for use. The warranty is limited to replacement of the pen.

Your *D-mine*[®] Pen has been developed for use with Dacepton[®] 3 ml cartridges (Apomorphine 10 mg/ml) from EVER Neuro Pharma GmbH and shall be used only with these cartridges. EVER Neuro Pharma GmbH is not liable for any damage caused by the use of not compatible cartridges. The warranty does not cover damage as a result of improper or careless use, handling or cleaning, and does not apply in the event of use contrary to the instructions for use and in the event that the pen has been used with a medical device or accessories or consumables other than specified in these instructions for use.

DISPOSAL

Your D-mine® Pen can be disposed of with your household waste or according to the instructions by the local authorities.

Your D-mine® Pen does not contain substances harmful to the environment.

 Needles and used cartridges must be disposed of separately and safely according to your local regulations. Dispose of the used needle in a sharps disposal container. Do not dispose of the used needle in the household waste.

LABELLING AND SYMBOLS

The D-mine® Pen fulfills the regulations of the EU for medical devices.

Technical Data			
Length:	171,5 mm	Scale:	0,5 mg
Diameter:	18 mm	Resolution of injection volume:	0,1 mg
Weight:	42 g	Max.dose/injection:	6 mg
Filling Volume:	3 ml	Storage conditions (without cartridge):	5°C – 35°C
Display:	mg	Operating conditions (with inserted cartridge):	not above 25°C



Manufacturer's name and address



Date of manufacture



Unique device identifier



Batch code



Consult instructions for use



Medical device



0123 Marking for conformity with the Regulation (EU) 2017/745, followed by the number of the notified body



0168 Marking for conformity with the UK MDR 2002, followed by the number of the notified body



Single patient multiple use



Caution



Catalogue number



Keep away from sunlight



Keep dry



UK Responsible Person



Distributor



Importer



Not suitable for children under 3 years of age

MANUFACTURER / DISTRIBUTOR

**Manufacturer:**

Ypsomed AG
Brunnmattstrasse 6
3401 Burgdorf, Switzerland



Ypsomed Ltd.
1 Park Court, Riccall Road
Escrick
North Yorkshire YO19 6ED, United Kingdom

**Distributor:**

EVER Pharma UK Ltd.
Bloxham Mill, Barford Road
Bloxham, Oxfordshire
OX15 4FF, United Kingdom



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