

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



For Subcutaneous Use



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INTRODUCTION

This manual contains instructions for using, storing and cleaning your EVER Pharma D-*mine*® Pen. 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 3 ml cartridges. You should read the instructions in this manual carefully even if you have used D-*mine*® Pen or other pen delivery systems before. The Pen is a maintenance-free and reusable injector with an automatic spring driven delivery-system. The D-*mine*® Pen fulfills the regulations of the EU directive on medical products and has been approved according to 93/42/EEC and harmonized standards and has been marked with a CE symbol (see page 30).

Indication: Pen injector for Dacepton® 3 ml cartridges (Apomorphine 10 mg/ml) solution for injection from EVER Neuro Pharma GmbH. The D-*mine*® Pen is intended to be used by self-injecting adult patients, health care professionals as well as third parties such as adult relatives and carers. Please refer to the package leaflet of the pharmaceutical product. Please wash your hands thoroughly before using the D-*mine*® Pen. You will need some surgical wipes and one needle in its protective cone. Using a surgical wipe, thoroughly clean around the area of skin where you plan to inject the medicine. 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 inflamed, infected or damaged. You must never inject yourself directly into a vein (intravenously) or muscle (intramuscularly).

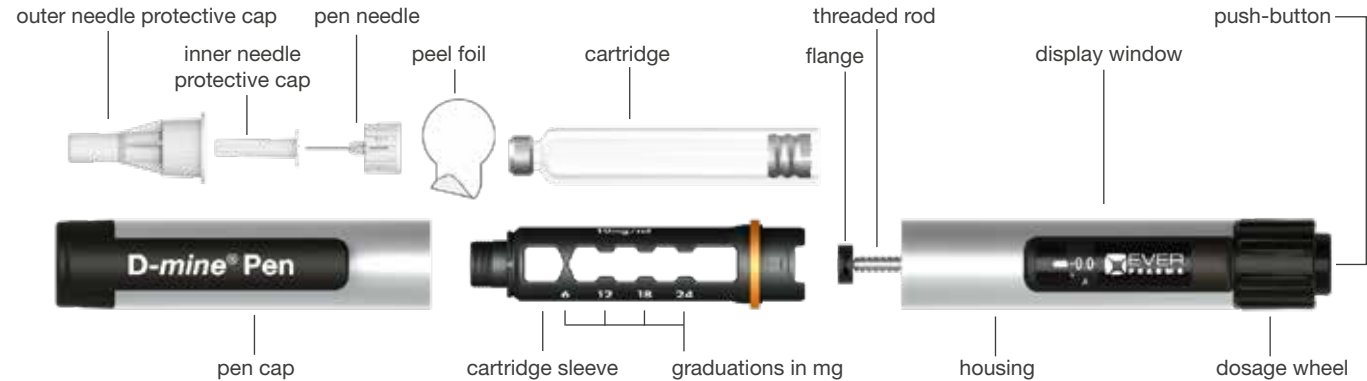
Compatible Pen cartridges and needles:

- Dacepton® 3 ml cartridges (Apomorphine 10 mg/ml) from EVER Neuro Pharma GmbH approved according to ISO EN 11608-1
- BD Micro-Fine Ultra™ needles 29 to 31 gauge (diameter 0.25 – 0.33 mm) and 5 - 12.7 mm length.
- Cartridges and Pen needles from other manufacturers can be used according to their stated compatibility details.

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). If you have any questions relating to your D-*mine*® Pen, please contact the support service, (see page 23).

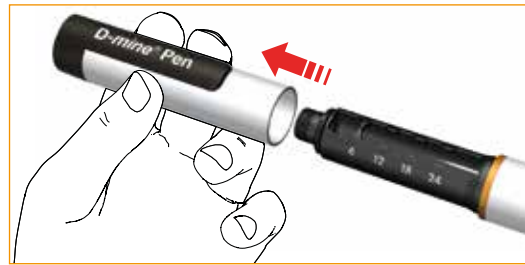
DESCRIPTION OF PARTS OF D-mine® PEN

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

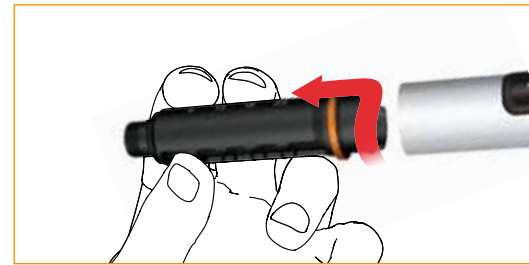


PEN PREPARATION / CHANGING CARTRIDGE

- 1 Remove the pen cap.



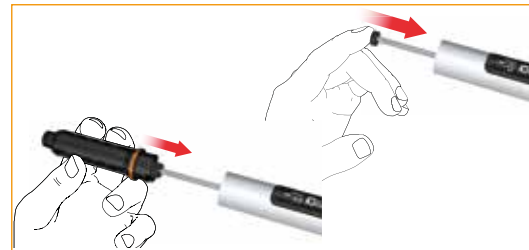
- 2 Remove the cartridge sleeve by twisting it clockwise. You will hear a click. Remove the empty cartridge if necessary.



- 3** Insert the new cartridge into the cartridge sleeve.



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



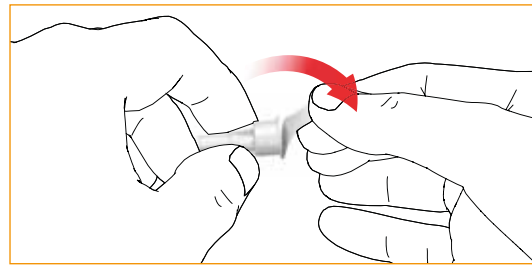
- 5** Push the cartridge sleeve into the housing and turn anti-clockwise to lock. You will hear a click.



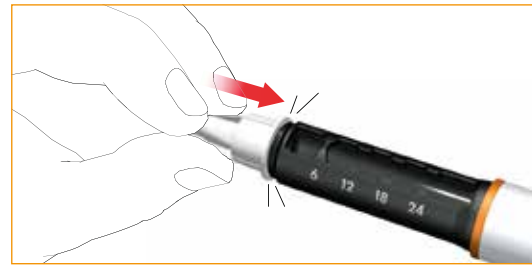
ATTACHMENT OF PEN NEEDLE

Follow the instructions for use of your pen needle.

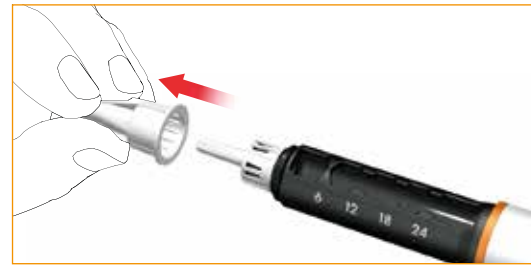
- 1 Pull off the peel foil.



- 2 Click on / twist on the pen needle to the cartridge sleeve. Check that the pen needle is attached correctly.



- 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 the inner needle protective cap.



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.

- 1 Dial the test dose forward by turning the dosage wheel. Check the dialed dose by looking vertically from above and not at an angle onto the display, so that the 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.

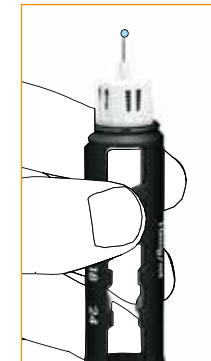


- 3 Press the push-button.



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

If no drops emerge, repeat steps 1 to 4. If after several function checks no drops emerge, change the pen needle and repeat the function check (steps 1 to 4). If still no drops emerge or if you have any concerns, please call Service Helpline mentioned on page 23.



SETTING THE DOSE



Dial the required dose

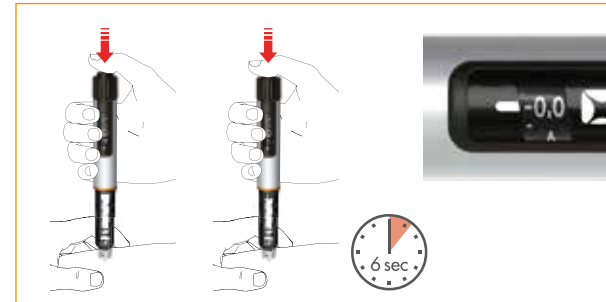
Dial the required dose by turning the dosage wheel clockwise. Correct the dose by turning in anti-clockwise direction. Check the dialed dose by looking vertically from above and not at an angle onto the display, so that the numbers are clearly identified.

Note: Each “-” marking on the dose dialer represents 0.1 mg of medicine. You will hear a click for each increment you dial. Do not rely on counting these clicks to measure the correct dose. The mg are displayed in increments of 0.5 mg steps.

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 wheel cannot be turned any further in a clockwise direction.

INJECTION

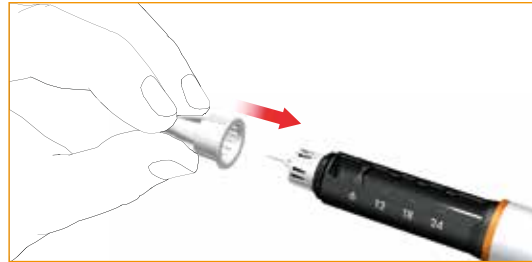


Note: You can interrupt the injection by releasing the push-button. The remaining amount of medicine not delivered can be seen on the display and can be injected by pressing the push-button again.

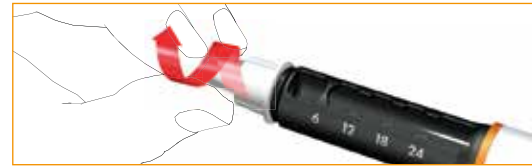
- 1** Please refer to the package leaflet of the pharmaceutical product and use the injection technique as recommended by your physician and/or health care professional. Press the push-button in fully for injection. Hold the push-button fully down during medication discharge.
- 2** After the medication has been completely discharged, wait for 6 seconds and then pull out the pen needle slowly. You may either 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

- 1 Carefully attach the outer needle protective cap on the pen needle.



- 2 Twist off the pen needle by turning the outer shield anti-clockwise and dispose it correctly, according to the advice of your physician and/or health care professional. Professional health care personnel should follow the specific directions for health care personnel including, without limitation, directions regarding recapping and disposal. To obtain the specific directions, please consult a physician.



Optional:

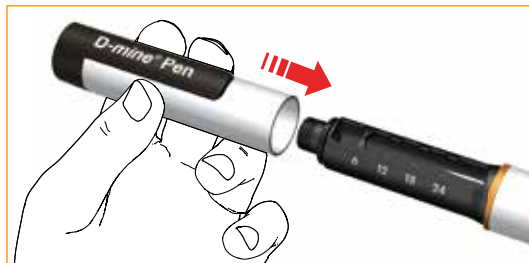
Place the outer pen needle shield in the appropriate left notch of your carrying case. The opening of the needle shield should be pointing up. Carefully insert the needle (attached to the pen) into the opening of the shield. Without holding onto the shield, push down firmly and turn counter-clockwise 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 click and a noticeable resistance will be provided.

Dose Dialing

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

Injection

The medication discharge of your D-mine® Pen is perceptible. An audible click is provided during the discharge and stops after the dialed amount of medication has been discharged 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 wheel cannot be turned any further in a clockwise direction.

- Do not try to force the dosage wheel 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

Do not use the *D-mine*® Pen if it is damaged or if you have any doubts about its correct functioning.

Once the cartridge has been inserted, it can remain in your *D-mine*® Pen. Please follow the storage instructions provided by the manufacturer of your medication.

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

A new needle must be used for each injection.

Please follow local regulations in your country concerning the handling of potentially infectious materials.

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.

Use and store your *D-mine*® Pen at a temperature between 5 and 35°C. Failure to observe 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 and moisture.

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.

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

CODIPHA

Nahas Building, 1st floor

4 St-Maron Str. / Georges Haddad Av.

Postal Code: 2028 5806 SAIFI

BEIRUT – LEBANON


Email: mary.bousaleh@codipha.net or info@codipha.net


P.O. Box: 11-3063

Phone number: +961.01.985 571 and +961.01.983 247

WARNINGS / IMPORTANT RISK INFORMATION

If the following instructions are not followed, there is a risk of incorrect medication, incorrect dosage, disease transmission or infection. Seek immediate medical attention if you have any health concern.

 Read this **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 physician and/or health care professional.

 Ensure **correct handling by the intended user**

- The D-*mine*® Pen must not be used by blind or visually impaired patients without the help of someone who has been trained accordingly. In case of hearing or tactile impairment consult your physician.
- Store your D-*mine*® Pen, the pen needles as well as the cartridges so that they are out of reach of children or other people who are not familiar with the correct method of use.



Ensure **correct application**

- Use your D-*mine*® Pen only as part of the treatment prescribed by your physician and/or health care professional.
- Use the cartridges, dosage amounts and pen needles prescribed by your physician and/or health care professional. Any changes must be made under the supervision of a physician and/or health care professional.
- Before each injection, check that your D-*mine*® Pen contains the correct type of medication. Check that the cartridge is undamaged and that the medication corresponds to the details on the product leaflet.
- The pen needles and the cartridge must be used by only one person, 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. in a freezer compartment).
- Use and store your D-*mine*® Pen at a temperature between 5 and 35°C.
- 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 Support Service (see page 23).



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 priming is not successful.
- Check after each injection according to your physician’s and/or health care professional’s instructions whether medication drips from the pen needle or D-*mine*® Pen, or exudes from the injection site. If the medication drips from the pen needle or D-*mine*® Pen, or exudes from the injection site, follow your physician’s and/or health care professional’s 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.

CONFIRMED LIFE SPAN

The continued dosing accuracy and requirements according to EN ISO 11608-1 have been verified for the amount of injections and cartridge exchanges as defined hereinafter in the table below from the date of first use:

Daily dose [mg]	Injections/day [#]	Dose/injection [mg]	Life span [months]
3	3	1	36
6	3	2	36
9	3	3	36
12	3	4	36
15	3	5	36
16	4	4	30
20	4	5	30
24	4	6	30
25	5	5	24
30	5	6	24

Daily dose [mg]	Injections/day [#]	Dose/injection [mg]	Life span [months]
30	6	5	18
36	6	6	18
35	7	5	12
42	7	6	12
40	8	5	12
48	8	6	12
45	9	5	12
54	9	6	12
50	10	5	12
60	10	6	12

WARRANTY

EVER Neuro Pharma 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 10mg/ml) from EVER Neuro Pharma GmbH according to EN ISO 11608-1 and may be used only with these cartridges. EVER Neuro Pharma GmbH is not liable for any damage caused by the use of non-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 those recommended by EVER Neuro Pharma GmbH.

DISPOSAL

Your *D-mine*® Pen can be disposed of according to the instructions by the local authorities or with your household waste. Your *D-mine*® Pen does not contain substances harmful to the environment.

LABELLING AND SYMBOLS

The *D-mine*® Pen fulfills the regulations of the EU directive on medical products, 93/42/EEC.

Technical Data			
Length:	170 mm	Scale:	0.5 mg
Diameter:	17 mm	Resolution of injection volume:	0.5 mg
Weight:	40 g	Max. dose/injection:	6 mg
Filling Volume:	3 ml	Storage conditions:	5 – 35°
Display:	mg	Operating conditions:	5 – 35°



Manufacturer's name and address



Protect from heat and sunlight



Warning: important safety information in instructions for use



Date of manufacture



Protect from moisture



Batch number



Item number



Read instructions for use



Marking for conformity with the European Medical Device Directive and number of the notified body

MANUFACTURER / DISTRIBUTOR



Manufacturer:

EVER Neuro Pharma GmbH
Oberburgau 3
4866 Unterach, Austria



Distributor:

CODIPHA

Nahas Building, 1st floor
4 St-Maroun Str. / Georges Haddad Av.
Postal Code: 2028 5806 SAIFI

BEIRUT – LEBANON

Email: mary.bousaleh@codipha.net or info@codipha.net

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Revision: 08/2020

D-mine_IFUPen_64370_LB_V01

