Quick set-up guide for Patients



D-mine[®] Pump







Introduction to the D-mine[®] Pump

The D-mine[®] Pump is a medical device for safe and reliable subcutaneous infusions of Apomine[®] Solution for Infusion (apomorphine hydrochloride hemihydrate 5 mg/mL in 20 mL vials) for the treatment of Parkinson's disease.

The infusion pump is connected to the body with an infusion set and the medicine will be delivered on a continuous level. This form of therapy is referred to as **Continuous Apomorphine Infusion Pump Therapy**.

Before starting administration, the medicine is transferred from the vial into the D-*mine*[®] Pump Reservoir. This process is automatically performed by the pump.

The quantity of Apomine[®] that is continuously delivered over the course of a day is referred to as **basal flow rate or basal rate**. The basal rate settings for a day are referred to as **basal profile** and are set up to your dose requirements.

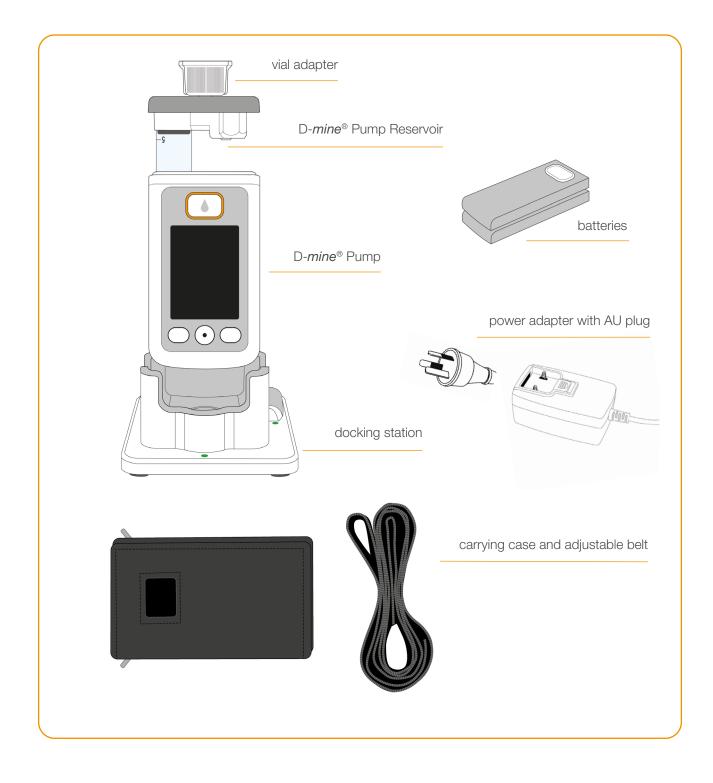
A **bolus** is an additionally required Apomine[®] dose released when pressing a specific **bolus button**. The bolus dose amount and quantity is likewise preset as appropriate for your specific requirements.

The basal profile and bolus settings are determined by a healthcare professional according to the instructions of a Parkinson's disease specialist.

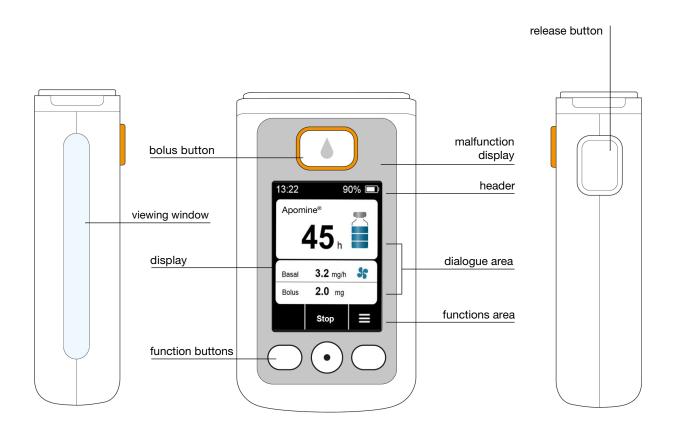
Before using the pump

- The pump must be preset by a healthcare professional to the dose prescribed and you should be trained according to the instructions for use of the pump system.
- The D-mine[®] Pump controls administration of the drug. It works only in conjunction with the D-mine[®] Pump Reservoir.
- The reservoir, the adapter, the infusion set and the vial with the drug are sterile in their packaging. Do not use these items if their packaging is damaged or missing.
- The reservoir, adapter and infusion set must not be reused.

The D-mine® Pump accessories



Operating elements



Screen

The pump is equipped with an illuminated colour screen which provides important information for your therapy.

The **header** displays general information, such as time and state of charge of the rechargeable battery. The device shows the progress when the pump is in operation.

In the **two dialogue areas**, the most important information on operation and control of the pump is displayed.

The **function button section** at the lower edge shows the respective meaning of the function buttons.

Bolus button

The bolus button enables fast delivery of a bolus.

Function buttons

Three function buttons are provided for operating the pump. These are located below the screen. The meaning of the three function buttons changes, depending on what commands are required for operating the selected function.

Release button

The reservoir is inserted into the pump and snaps into place audibly. The reservoir can be unlocked and removed by pressing the release button at the right side of the pump.

Always use the buttons to make your selection – do not press the screen.

Setting up the D-mine® Pump

Before starting the infusion, the reservoir must be filled with the Apomine[®] Solution for Infusion.

I. CHECK SETTINGS

On the main screen, the following information has to be checked:

- the time is set correctly
- there is no error display
- the indicated dose settings are correct
- the delivery of the medicine is stopped (the dialogue area of the display is greyed out)

II. GET THE MATERIALS READY

- a new vial of Apomine®
- a new D-mine® Pump Reservoir
- the docking station to place the pump upright
- a new infusion set
- swabs, disinfectant or similar and a patch

III. CONNECTING AND FILLING THE RESERVOIR

1. Prepare the D-mine® Pump Reservoir

Wash hands thoroughly before touching sterile parts.

Never use a reservoir that has damaged packaging. The reservoir will no longer be sterile and may be dirty.

Remove the reservoir from its sterile packaging.



2. Attach the reservoir to the pump

Plug the reservoir into the opening of the pump as shown. The reservoir should engage with an audible click.



The pump recognises that a reservoir has been inserted. If the reservoir is new, it must first be filled with medicine.

3. Prepare the vial

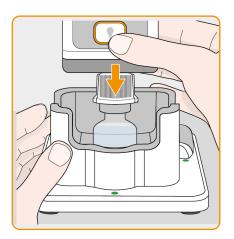
Take the new vial from its packaging and remove only the orange cap. Then wipe the grey stopper of the vial with a sterile swab.

Place the vial in the holder provided in the docking station.



4. Fix the pump with the reservoir and adapter onto the vial

Fix the entire pump with reservoir and attached adapter onto the vial, vertically from above, as shown. The adapter will snap onto the vial with an audible click.



5. Start filling

Place the pump upright into the docking station. The pump must be kept upright at all times during filling.

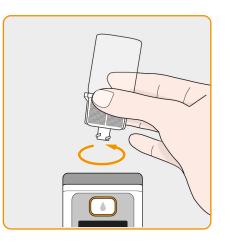


Press voto start the filling process. The unit will pump the medicine from the vial into the reservoir.

6. Remove and discard the vial

The pump notifies you when the reservoir is full. Make sure that this is the case and then press \checkmark .

Grip the vial on the adapter and twist to the left to remove both from the reservoir.



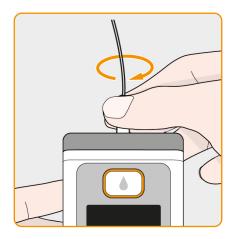
Dispose according to the vial's instructions. To continue to connect an infusion set, press Yes



IV. PRIMING AND STARTING THE INFUSION

1. Connecting the infusion set

Remove a new infusion set from its packaging and connect it with the reservoir of the pump. Make sure that the connection is well tightened.



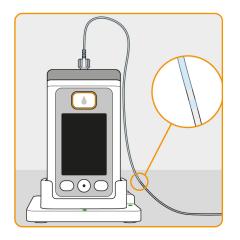
2. Place the pump with the infusion set into the docking station

The pump must remain upright during the priming of the infusion set.

3. Start the priming procedure

Press Yes. The unit will pump the drug from the reservoir into the infusion set.

It will take a few seconds until the liquid is visible in the infusion set.



Stop priming just before the fluid reaches the needle.

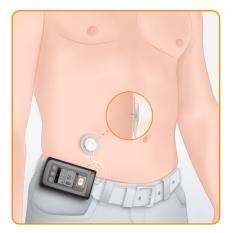
4. Prepare the puncture site

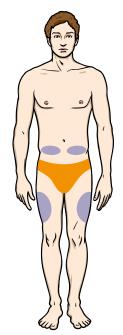
The following areas are suitable to place the infusion set subcutaneously:

- waist around the lower abdomen
- outer thighs
- or as advised by a healthcare professional

Use a disinfectant pad or solution to disinfect the puncture site. Then:

- take a fold of skin and puncture it with the needle of the catheter
- press the adhesive foil of the catheter onto the skin
- remove the grip of the catheter (depending on catheter type) to support the tube of the catheter, loop it 1–3 times and attach it with an adhesive tape on the skin





5. Starting or stopping drug delivery

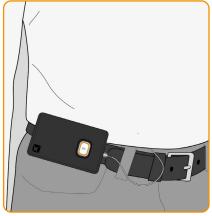
To start the infusion, press Start and hold until the audible sound is heard and then release. A propeller symbol should now be seen on the screen

To stop the infusion, press Stop and hold. The propeller symbol should no longer be showing.

6. How to wear the pump

Put the pump into the carrying case. The pump can be worn with the adjustable strap around the neck, over the shoulder or on the waist.





7. Taking off and recharging the pump

Remove the infusion set from the body. Then disconnect it from the reservoir and dispose of it.

Place the pump in the docking station. The device switches on the screen and confirms with a notice that the rechargeable battery in the pump is being recharged.



V. DEVICE SETTINGS

1. The basal and the bolus rate

The basal rate is the quantity of Apomine[®] that is continuously delivered over the course of a day.

A bolus is an additional dose of Apomine[®] released when the specific bolus button is pressed.

The basal rate and the bolus dose amount is determined and preset by your healthcare professional according to your specialist's instructions.

Your healthcare professional will be able to fill in the following table with the basal rates they have set for you.

Basal rate for basal time 1	Start	End	Basal rate
	h	h	mg/h
Basal rate for basal time 2	Start	End	Basal rate
	h	h	mg/h
Basal rate for basal time 3	Start	End	Basal rate
	h	h	mg/h
Basal rate for basal time 4	Start	End	Basal rate
	h	h	mg/h
Basal rate for basal time 5	Start	End	Basal rate
	h	h	mg/h

2. Delivering a bolus

A separate button above the screen is provided for delivering a bolus. The device displays a corresponding message in the text section of the screen.



The pump indicates completion with a notice on the screen and the 'bolus dose completed' signal tone.

The bolus function is disabled:

- if too little time has elapsed since the last bolus
- if the limited number of boluses has already been exceeded
- if the amount of apomorphine available is no longer sufficient for a bolus

In these cases, the pump displays the lock symbol next to the bolus quantity.

VI. CLEANING AND STORAGE

When cleaning the D-mine[®] Pump:

- stop medicine delivery, and take off the pump as described in the section 'Taking off and recharging the pump'
- wipe the pump with a moist cloth, with the reservoir attached
- if cleaning the connection of the pump to the reservoir, take care to ensure that no pressure is put on the flexible coupling located there
- preferably use water or a mild cleaning agent
- do not use medical cleaning wipes or alcoholic liquids
- never use aggressive cleaning agents such as acetone or acids

Store the D-mine[®] Pump and its accessories under normal indoor climate conditions.

VII. SYMBOLS AND WARNINGS



Reservoir Filling level 100%



Reservoir Filling level 75%



Reservoir Filling level 50%



Reservoir is filling Filling level 25%



Reservoir (not during filling) Filling level 25%



Alarm Reservoir empty

No reservoir or reservoir is filling Filling level 0%



4

b

Alarm Rechargeable battery empty

Rechargeable battery

Rechargeable battery

Rechargeable battery

is being charged

Warning

almost empty

ΟK



Alarm

Notice



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Warning Message



Unlock buttons



Bolus currently disabled



Ongoing delivery

VIII. SPECIFICATIONS

Dimensions (with reservoir, without adapter)	Length	114.3	mm
	Width	61.4	mm
	Thickness	29.9	mm
Weight	Pump	140	g
weight	Reservoir empty	22	g
Temperature	In operation	+5 to +40	°C
	Storage	-25 to +70	°C
Air humidity	In operation	15 to 93	% rel.
	Storage	up to 93	% rel.
Atmospheric pressure	In operation	70 to 106	kPa (mbar)
Autosphene pressure	Storage	n/a	kPa (mbar)
Power supply	Rechargeable battery	Lithium polymer 3.7 650 2.4	V mAh Wh
Service life of a	Typical operating time with one charge	7	days
rechargable battery	Number of charging cycles	300	cycles
History	View	3 800	days entries per day
	Export	up to 12,500	entries

Any other questions?



A national team of mobile, registered nurses with training in Parkinson's disease.

ANSSER provides phone-based and face-to-face nursing support services both in the community and in aged care facilities.

To organise treatment support for issues such as pump use, contact ANSSER on 1800 APOMINE (1800 276 646).

If you have questions about using Apomine[®] Solution for Infusion, or experience any side effects, please talk to your doctor or nurse. Additional information about Apomine[®] Solution for Infusion is also available in the Consumer Medicine Information which you can access from your doctor or pharmacist.

NOTE: The 1800 276 646 phone service is available every Monday to Friday (except public holidays), from 9am to 5pm Australian Eastern Standard Time (AEST). Each nurse will have a specific roster which may be subject to change. If you require contact with a specific nurse, please call 1800 276 646 to facilitate your request.

The ANSSER Program is administered by ASCOTT Sales Integration. ABN 96 094 015 255. 141 Walker Street, North Sydney NSW 2060. Tel: (02) 9439 9770.

The ANSSER nursing service can only be engaged after a decision to prescribe Apomine® has been made.

For further details please email info@ansser.com.au

This booklet has been produced by InterPharma in the interests of patient education.

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Reference: 1. D-mine® Pump Instructions for Use.

Further information is available from InterPharma Medical Information at 1300 308 213 or medinfo@interpharma.com.au.

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