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Breelib[®] information sheet

Breelib, being away from home and travel

Breelib information sheets are provided as part of the Breelib Patient Support Programme which is fully funded by Bayer

Please contact the Breelib Support Centre on
0800 0 463 255 for any Breelib related questions

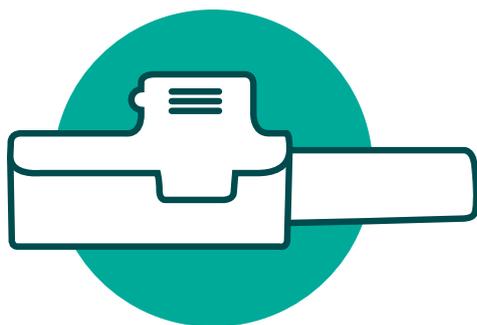
Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in Google Play or Apple App Store.

You can also report side effects and quality complaints to Bayer Plc. Further information is available on the “contact” tab at www.bayer.co.uk.

By reporting side effects you can help provide more information on the safety of this medicine.

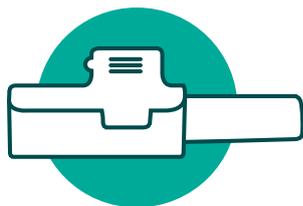
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Introduction to Breelib information sheet 10

The Breelib nebuliser (figure 1) and the associated patient support materials have been designed to minimise the impact that inhaled therapy can have on everyday life. This document will provide you with helpful information about using Breelib when you are away from home, travelling or if you are on holiday. For more information please see the travel section on www.Breelib.co.uk.

If you are planning to travel on holiday, always speak with your treating centre who can advise you further.

Figure 1
The Breelib nebuliser

- 1 Mouthpiece/Mouthpiece light
- 2 Battery light (Power LED)
- 3 Charging socket inlet
- 4 Air inlet
- 5 Base unit
- 6 ON/OFF button
- 7 Nebuliser unit
- 8 Reset button



1

The Breelib carry case

The Breelib carry case has been designed to help you look after your device and to make it as easy as possible to use Breelib when you are away from home.

a) Protecting Breelib from damage

When you are not using Breelib, the device should be stored in the carry case supplied in your Breelib Starter Pack (figure 2). To store, the mouthpiece should be inserted into the base unit as you would when you are putting Breelib together, before securing both parts inside the case using the elasticated straps. The nebuliser unit should then be placed in the allocated space next to the storage compartment.

Figure 2
Storing Breelib in the carry case in-between uses



b) Using the storage compartment inside the carry case

The storage compartment can be used to keep a tray of ampoules from your box of Ventavis (iloprost trometamol). The four edges from around the tray should be carefully cut off with scissors to ensure a good fit inside the compartment (figure 3). There will also be room to store a couple of plastic pipettes and ampoule opening devices.

Figure 3
Storage compartment in the carry case



c) Using the storage space in the net pocket of the lid to the carry case

Inside of the lid of the carry case is a net pocket which allows you to store important documents relating to Breelib. You should keep the Breelib Medical Device Quick Reference Card (QRC) (figure 5) stored here at all times. This is especially important if you are using Breelib away from the home setting.

d) Using the carry case when setting up Breelib when away from home

You should always use a flat surface to set up and fill Breelib. When you are away from home and you need to take a dose, the carry case can be opened up on your lap and used as a flat surface (figure 4).

Do not remove Breelib from the elasticated straps until you have attached the nebuliser unit, filled it with drug and closed the cap.

Figure 4
Carry case used as a flat surface on your lap



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When to use the Breelib Medical Device Quick Reference Card (QRC)

The Breelib Medical Device QRC (figure 5) provides the user with a helpful reminder about important aspects of using, charging and caring for Breelib. The QRC also holds information which can be helpful when you are using Breelib in public areas. If you are ever questioned by an official or a member of the public about why you are using Breelib, the QRC can be presented to provide information about the purpose of the device, without sharing any specific details about your condition. If further clarification is needed by a public official, please provide the contact details for the Bayer medical information department which can be found on the back cover.

Please note, this document has been adapted from the QRC which is supplied in your Breelib Starter Pack.

Figure 5
Breelib Medical device QRC



3

Rinsing the nebuliser unit and mouthpiece when you are away from home

When you are away from home, the plastic bottles (figure 6) should be filled with filtered water from your ZeroWater jug.

If you are ever away from home for an extended period of time, always make sure you have enough ZeroWater to rinse the nebuliser unit after each dose. The mouthpiece can be rinsed with tap or bottled water if necessary.

Additional plastic bottles can be requested by calling the Breelib Support Centre.

Figure 6
Plastic bottles



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Making ZeroWater when you are staying away from home

If you are staying away from home for any length of time, a ZeroWater travel beaker can be requested from the Breelib Support Centre.

a) **The ZeroWater travel beaker**

The travel beaker (figure 7) is a smaller portable version of the filter jug provided by your treating centre. The travel beaker can be requested free of charge by calling the Breelib Support Centre at least 2 weeks before you need to travel. The travel beaker uses a smaller portable ZeroWater filter, one of which is supplied with the beaker.

Figure 7
ZeroWater travel beaker



b) Replacement portable ZeroWater filters

As well as the portable filter which is included with the travel beaker, you will also receive a box containing 2 replacement portable filters (figure 8). The 2 portable filters you will receive have the capacity to make up to 42 litres of ZeroWater, enough to care for Breelib for up to 3 weeks. You can request additional portable filters free of charge by calling the Breelib Support Centre.

The ZeroWater from the travel beaker should only be used to care for Breelib whilst staying away from home. Using the travel beaker for other purposes will reduce the lifespan of the portable filter and may affect how well your nebuliser unit works.

Figure 8
Replacement portable ZeroWater filters



c) Setting up the ZeroWater travel beaker

The travel beaker is set up in a similar way to the ZeroWater jug you keep at home. The portable filter is screwed into the bottom of the reservoir (figure 9) which then sits inside the beaker (figure 10).

When your travel beaker arrives, remove the packaging and unscrew the lid to remove the plastic straw. Lift out the reservoir from the beaker then push the portable filter out. Using hot soapy water, wash the lid, the reservoir and the beaker before rinsing and leaving to air dry. The plastic straw is not needed and should be placed in the household recycling or waste bin.

Figure 9
Attach the portable filter to the reservoir

When the travel beaker is dry, wash your hands and remove the wrapping from the portable filter before screwing it tightly into the bottom of the reservoir so that a complete seal is formed.



Figure 10 Completing set-up

With the filter now attached, lower the reservoir into the beaker. The travel beaker is now ready to use to make ZeroWater.



d) Making ZeroWater with the travel beaker

To ensure the water you use to care for Breelib is more sterile, you should first boil the water in a kettle and once it has had time to cool down, use it to make ZeroWater.

If you are in a country where the tap water is safe to drink it can be used to make ZeroWater. However, in countries where it is advised not to drink the tap water, bottled drinking water should be used instead.

The travel beaker is not designed to transport water. After using the travel beaker to make ZeroWater, you should transfer it into the plastic bottles provided. Additional plastic bottles can be requested from the Breelib Support Centre should you need them.

e) When to replace the ZeroWater portable filter

You do not need to monitor the purity of your travel beaker's ZeroWater with the blue water meter, as you do with the jug at home. Instead, the travel beaker uses a colour-change system.

The portable filter has a rectangular window on the bottom half of the filter (figure 11). As you use the travel beaker the colour inside the filter will slowly change to red/orange from top to bottom.

When the colour inside the whole window has changed it is time to replace the filter. Unscrew the used filter and place it in the household waste before attaching a new filter. Alternatively, some supermarkets have recycling points for used water filters.

It is advised to clean the travel beaker at the end of every week and each time the filter is changed.

Figure 11
Window on the portable filter



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Breelib and air travel

This section will provide you with helpful information if you are intending to travel overseas by air. During travel ensure that you have everything you need in your hand luggage to take your doses and rinse Breelib.

On the day of travel, you may want to schedule your doses to maximise convenience in relation to navigating the airport and consider the following:

- Are there any stages of travel more physically demanding where a dose would be beneficial?
- Will you have access to a space where you feel comfortable using Breelib?
- Will you have access to ZeroWater to rinse Breelib after finishing your dose?

a) Things to do before you travel to the airport

- Charge Breelib until the green battery light stops blinking. This can take up to 4 hours and after a full charge, the battery should last up to 1 week
- If the correct plug adaptor for your destination is not supplied in your Breelib Starter Pack, purchase one
- Place a full tray of ampoules, 2 pipettes and 2 ampoule opening devices in the storage compartment of the carry case (figure 3)
- Place the Breelib Medical device QRC (figure 5) in the net pocket of the lid of the Carry Case
- Fill your plastic bottles with ZeroWater (figure 6) to use up to the point where you go through security where the large bottle should be emptied out
- Pack the Breelib Cloth and sheets of kitchen roll in your hand luggage to help with drying parts after rinsing
- Ensure you will have access to the medication you need if you experience long delays
- Pack your RESERVE Breelib device and charger

b) Breelib and navigating airport security checks

Due to restrictions on the amount of liquids that can be taken through to Departures, any ZeroWater inside the large (500ml) plastic bottle (figure 6) must be emptied out before going through to the security area. The ZeroWater inside the small (100ml) plastic bottle is allowable, as long as you place it inside the resealable plastic bag along with the tray of Ventavis ampoules inside the carry case. Breelib can be placed in the trays and go through the security scanner.

Once you have cleared security make sure that you collect all of your belongings before going through to the Departures area.

c) Breelib and the Departures area

Once you are through to Departures, use your travel beaker to make enough ZeroWater to last for the duration of your travel, making sure you factor in any possible delays. It is always better to have too much ZeroWater than not enough.

If you intend to take a dose before boarding the plane, you should find a place where you will feel comfortable using Breelib.



Using Breelib on a plane

Airlines and airline regulatory agencies have certain requirements for what kind of electrical items are allowed in either checked or carry on hand luggage. Important considerations for Breelib are the kind of rechargeable batteries allowed and how Breelib is protected from being accidentally turned ON. This section will provide you with technical information about Breelib which your airline may request as well as helpful information about using Breelib to take a dose in-flight.

a) The rechargeable battery inside Breelib

The power inside a battery is measured by units called Watt Hours. Personal electrical gadgets with batteries up to 100 Watt Hours can be taken onboard in your carry on luggage and can be used in-flight. Breelib has a consumer-sized lithium polymer battery of 6.75 Watt Hours which is within the allowable range.

It is highly unlikely that Breelib could be turned ON accidentally and remain ON for long enough to overheat. Unless Breelib has been put together and filled with drug, Breelib would not turn ON if the ON/OFF button were to be accidentally pressed. If Breelib was assembled and filled with drug, the device would turn itself OFF if it had not been used for 5 minutes.

If you are on a long-haul flight you may want to pack your RESERVE Breelib device in your carry on luggage, but it can also be packed in your checked luggage. Breelib will not turn ON at temperatures below 0°C.

b) Using Breelib to take a dose on the plane

Once you have boarded the plane you should inform the cabin crew if you intend to use Breelib during the flight. Have your documentation ready in case you are asked to provide any further details.

You should agree with the cabin crew where you can use Breelib making sure it is in a place where you will feel comfortable. This could be the toilet compartment or the cabin crew area. Always use Breelib away from other passengers, especially pregnant women and children, just in case any drug mist were to escape into the air around you. Should you get asked about why you are using Breelib, you can show them the Breelib Medical device QRC (figure 5). Breelib should only be used to take a dose when in-flight, when the overhead seat belt sign has been turned OFF. Do not use Breelib when the plane is taking off or landing.

It is also important to use Breelib where you are able to rinse the nebuliser unit and mouthpiece immediately after you have finished taking your dose. Always make sure you have enough ZeroWater to rinse your nebuliser unit after finishing each dose. Normal tap or bottled water can be used for the mouthpiece if necessary. If you run out of ZeroWater in-flight, filter bottled water not tap water from the plane.

After emptying out leftover drug from the nebuliser unit and rinsing both parts, it will not be possible to leave them out to air dry. To make sure the parts are dry in time for your next dose:

1. Shake away excess water from both parts and wipe away any water from the plastic surfaces, making sure not to touch the metal area on the nebuliser unit
2. With the cap open and drug-dosing system up, wrap the nebuliser unit in kitchen roll and store in the carry case
3. Lightly tap the front end (figure 12a) and gently press the back end (figure 12b) of the mouthpiece on fresh kitchen roll to remove excess water (figure 12)
4. Wrap the mouthpiece in fresh kitchen roll and store in the carry case

Figure 12

Removing water from the mouthpiece



Safely handle and dispose of any broken glass from the empty ampoules used in-flight. A compact travel sharps bin can be carried in your hand luggage but there is sometimes a sharps bin available onboard. Speak with your cabin crew who can advise you further.

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Using Breelib whilst away on holiday

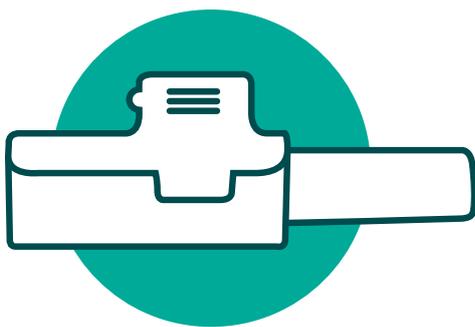
This section will provide you with helpful information about keeping Breelib safe and in good working order once you have arrived at your destination.

To opportunistic criminals Breelib may appear to be of value so it is important to keep both your PRIMARY and RESERVE Breelib devices somewhere safe. It is also important to store Breelib in a place where the device cannot get either too hot, or too cold. If Breelib is stored outside of its normal operating conditions, between 0 - 40°C, it will not turn ON or charge until it has adjusted to more suitable surroundings.

It is important to keep the base unit dry. Should water get inside the base unit it can damage the electrics and cause Breelib to malfunction or stop working completely. If this happens, use your RESERVE device and make sure you keep it dry. When you return home call the Breelib Support Centre as soon as possible and they will arrange a replacement and for the collection of your damaged device.

If you are in a country where it is extremely humid and the moisture from the air settles on your skin, the moisture can also get onto the electrics inside the base unit. If this happens Breelib will not turn on or charge until it has dried out in more suitable less humid conditions. Moving Breelib quickly between extremes of temperature can also cause moisture to settle on the electrics and stop Breelib from working until it has had chance to dry out.

For more information why Breelib will not turn ON or charge please see Breelib information sheet 8.



Further support; Breelib information sheets 1 - 11

The series of Breelib information sheets have been designed to cover specific topics to help you when you are using Breelib. The documents can be viewed or downloaded from the Patient Resources area of www.Breelib.co.uk or you can request a hard copy by calling the Breelib Support Centre on freephone 0800 0 463 255.

- 1 Information about the battery and charging of Breelib

- 2 Why Breelib beeps when the ON/OFF button is pressed and how it can be avoided

- 3 Why Breelib can turn OFF when you do not expect it to, without beeping

- 4 How to avoid Breelib clicking OFF before the end of a 3-second breathing cycle

- 5 Why doses may be taking you longer than usual to finish

- 6 Why the mouthpiece can feel blocked when you are using Breelib

- 7 What the different lights on Breelib mean

- 8 Why Breelib may not do anything when you try and turn it ON or charge the battery

- 9 Why Breelib may be doing something unusual or unexpected

- 10 Breelib, being away from home and travel

- 11 Breelib and Ventavis Frequently Asked Questions (FAQ)
