

Breelib[®] information sheet

Breelib and Ventavis (iloprost trometamol) Frequently asked questions (FAQ)

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

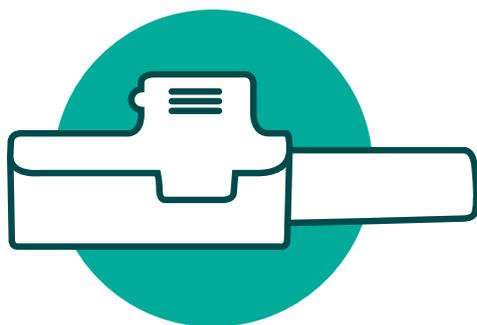
Reporting of side effects

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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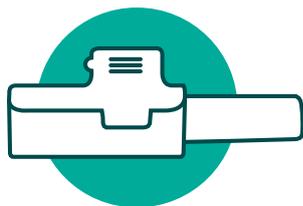
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For more information about Ventavis please refer to the Patient Information Leaflet (PIL)



Introduction to Breelib information sheet 11

The Breelib and Ventavis FAQ document provides the answers to frequently asked questions which can arise when using the device to take the drug. If you are unable to find the answer to any Breelib related questions, please call the Breelib Support Centre or for questions relating to Ventavis or healthcare advice, please speak with your healthcare professional.

1

Why is Breelib used to take Ventavis?

Breelib is a medical device known as a nebuliser which turns the liquid drug into a fine mist which you breathe in; this can help to minimise drug getting elsewhere in your body.

2

How long should it take to finish a dose of Ventavis using Breelib?

With short breaks in-between breathing in through the mouthpiece, a dose of Ventavis can be finished in less than 3 minutes.

3

How can I fit using Breelib into my everyday life?

Breelib is discreet, portable and easy to use with short dose times that can allow you to fit taking Ventavis into everyday life. The Breelib carry case can be used to keep everything you need to take a dose and can be used as a flat surface on which to set up Breelib when you are away from home.

The Breelib patient support materials have been designed to minimise the impact that nebulisation can have on daily life. For more practical considerations please see Breelib information sheet 10.

You can view UK Breelib patient experience videos by visiting the 'Breelib patient videos' area at www.Breelib.co.uk.



Can I use Breelib at work?

You can use Breelib to take a dose wherever you feel comfortable and where it is safe to do so. When at work, you should inform your manager of your intention to use Breelib as well as your dosing schedule and any other device-related needs.

Whilst you are at work, store Breelib in a safe place which is at room temperature. Do not store Breelib in your car as during the summer and winter months the device can get too hot or too cold and it will not turn ON until it has adjusted to room temperature. For more practical considerations, please see Breelib information sheet 10.



I cannot get my PRIMARY Breelib device to work, what should I do?

If you experience a problem with Breelib which prevents you from taking your dose you should call the Breelib Support Centre as soon as possible on freephone 0800 0 463 255 (Monday to Thursday 9am – 5pm, Friday 9am – 4pm).

If you experience a problem with Breelib outside of business hours you can go to www.Breelib.co.uk and select 'Troubleshooting' from the homepage. To use the Breelib troubleshooting feature, read through the seven categories and select the one which sounds like the problem you are having. Carefully read and answer the onscreen questions to help identify what is causing your problem and how to resolve it.

If you are unable to get your PRIMARY Breelib device working, use your RESERVE Breelib device and contact the Breelib Support Centre as soon as possible who can advise you further.

Please do not hesitate to contact your healthcare professional should you have concerns about your treatment or for healthcare advice.

6

I did not receive a new Monthly Pack with my drug delivery, what should I do?

A nebuliser unit and mouthpiece set is known as a Monthly Pack because they should only be used for 4 weeks. When you use Breelib you should be prescribed the Ventavis Co-pack. Inside the Co-pack box are 4 boxes of 42 ampoules of Ventavis and a Breelib Monthly Pack.

If you have been sent an ordinary box containing just Ventavis, use the Monthly Pack from your RESERVE Breelib Starter Pack and call the Breelib Support Centre as soon as possible who will arrange for a replacement but who will also contact your treating centre to ensure that the Co-pack is delivered moving forward.

7

Can I use Breelib and oxygen therapy at the same time?

Breelib will only deliver drug when you breathe in through your mouth. If you are using oxygen therapy through a nasal cannula, you may be tempted to take in air through your nose whilst using Breelib. If you start breathing in through your nose before the end of a 3-second breathing cycle, Breelib will click OFF and stop the breathing cycle short. If this happens, remove the mouthpiece and breathe out normally, either through your mouth or nose. Wait at least a few seconds before breathing in through the mouthpiece.

If using Breelib with your oxygen therapy is challenging, speak with your treating centre about temporarily removing the nasal cannula when you use Breelib. If you do not want to or cannot remove your oxygen therapy, try alternating breathing in through your mouth for a full 3-second cycle when using Breelib, then breathing in through your nose to take in oxygen. Your healthcare professional will be able to advise you on this matter.

8

Where should I store Breelib?

Breelib should be stored at room temperature and out of reach and sight of children.

9

What should I do if I accidentally lose or break my Breelib device(s)?

Do not worry, accidents do happen. The most important thing is that you have access to two working devices. Should you lose or damage Breelib or any of its parts, use the spare from your RESERVE Breelib Starter Pack and call the Breelib Support Centre as soon as possible who will arrange a replacement.

10

What should I do if I lose or break one of my patient support items?

The items which are provided as part of the Breelib patient support programme are there to help you take Ventavis. If you lose or break any support item please call the Breelib Support Centre as soon as possible on 0800 0 463 255 who can arrange for replacements to be sent to your home address.

11

What should I do if Breelib gets wet and stops working?

If the base unit gets wet and stops working properly or will not turn ON, use the base unit from your RESERVE Breelib Starter Pack and call the Breelib Support Centre as soon as possible who will arrange a replacement and for the collection of the faulty base unit.

Always keep the base unit away from water to prevent damage. To clean the base unit wipe the surfaces with a clean damp cloth or disinfecting wipe.

12

I have noticed the battery is not lasting as long as it used to, why is this?

Over time, the rechargeable battery inside Breelib will lose its ability to hold charge and you may notice that after using the device for over 18 months you are needing to charge Breelib more often. If you routinely charge the battery for longer than is necessary this can also affect how well the battery performs.

If you notice a change in how well the battery holds its charge, please call the Breelib Support Centre who can advise you on what to do.

13

I am travelling overseas/staying away from home with Breelib

At least two weeks before you travel/stay away from home, call the Breelib Support Centre and request a ZeroWater travel beaker. For more information about the travel beaker and for practical considerations for being away from home with Breelib, please see the travel section at www.Breelib.co.uk and view Breelib information sheet 10.

14

Can I put Breelib through the security scanners at an airport?

Yes. Putting Breelib through the security scanners should not affect the device. For practical considerations when travelling with Breelib please see Breelib information sheet 10.

15

What kind of battery is inside Breelib?

Breelib uses a lithium polymer rechargeable battery. The power inside a battery is measured in units called Watt Hours. Personal electrical gadgets with batteries of up to 100 Watt Hours can be carried onboard planes in hand luggage and used whilst in-flight. The battery charge inside Breelib is 6.75 Watt Hours.

16

Can I use Breelib to take a dose whilst on a plane?

Yes, but only whilst in-flight when the overhead seat belt sign has been switched OFF. Never use Breelib during take-off or landing. Do not use Breelib to take a dose when you are near other passengers, especially pregnant women and children. You should inform the cabin crew of your intention to use Breelib when you board the plane. For more practical considerations for using Breelib on a plane or during travel please see Breelib information sheet 10.

17

I use Breelib but I still have my old I-neb devices, what should I do?

Please call the Philips Patient Support Team on FREEPHONE 0800 130 0857 who can arrange for your I-neb devices to be collected free of charge, at a time which is convenient for you.

You should never use your old I-neb devices to take Ventavis once you start using Breelib as your dose may have changed. Speak with your healthcare professional if you have any questions.

18

What should I do with my Breelib devices if I stop taking Ventavis?

If your treating centre decides to stop Ventavis therapy they will let the Breelib Support Centre know who will then contact you to arrange the collection of your Breelib devices and patient support materials.

If the Breelib Support Centre has not been made aware that you no longer use Breelib and you call them to let them know, an agent will confirm this with your treating centre before arranging for the collection of your Breelib devices and patient support materials.

19

What is Bluetooth used for on Breelib?

Bluetooth is wireless technology that allows Breelib to send information it stores about the doses you take to an app called BreeConnect®. BreeConnect is completely optional and you do not need to use BreeConnect to use Breelib to take Ventavis. For more information about the BreeConnect app, please see www.Breelib.co.uk or speak with the Breelib Support Centre.

20

How does Ventavis work?

Ventavis works by widening the blood vessels in your lungs, helping you to get more oxygen to your body so you feel less breathless.

21

How often can I take Ventavis?

You should take Ventavis as often as your treating centre has advised you to but there should be at least a 2-hour gap in-between doses and you should never take more than 9 daily doses.

22

Where should I store Ventavis?

Ventavis should be stored at room temperature and out of reach and sight of children.

23

When opening an ampoule of Ventavis it shattered, what should I do?

Carefully place any shattered glass ampoules in your sharps bin and open a new ampoule of Ventavis. This will prevent any shards of glass from being transferred into the nebuliser unit. To help prevent ampoules from shattering when they are opened, use an ampoule opening device provided by your treating centre. If you do not have an ampoule opening device, please call the Breelib Support Centre on 0800 0 463 255 who can arrange supply.

24

What do I do if I miss a dose of Ventavis?

Do not worry if you miss a dose of Ventavis, simply take a dose the next chance you get. Always leave at least a 2-hour gap in-between doses but if you are still unsure of what to do, please speak with your healthcare professional.

25

Do I need to wake up in the night to take Ventavis?

You should take Ventavis during the hours that you are awake. Some patients may choose to take a dose if they wake up during the night but you should talk to your healthcare professional regarding a dosing schedule that works for you. You should always leave a gap of 2 hours in-between doses and never take more than 9 doses in a day.

26

Can I take Ventavis in a room with other people?

As Breelib only delivers Ventavis when you breathe in through the mouthpiece, there is less chance that drug can escape into the air around you. However, where possible it is important that you only use Breelib in a well ventilated room; this will stop anyone around you from breathing in any drug that may escape into the surrounding air. You should never use Breelib in the presence of pregnant women or children.

27

What if I get tired when taking a dose of Ventavis?

If you get tired when taking a dose of Ventavis you can take a break until you feel OK to continue. If you do not use Breelib for 5 minutes it will turn itself OFF to save battery. If this happens, lightly press the ON/OFF button once to turn Breelib back ON and finish taking your dose.

Try not to break for longer than 5 minutes in case you forget to finish taking your dose or if the drug starts to dry up inside the nebuliser unit. When you breathe in through Breelib the metal disc on the nebuliser unit vibrates to make the fine mist of drug you breathe into your lungs. If the tiny holes become blocked it will take you more breaths and more time to finish taking your dose.

If you have any concerns about your health, please speak with your treating centre.

28

I accidentally got Ventavis in my eyes or on my skin, what should I do?

You should immediately rinse the affected areas with clean water and seek medical advice should you become concerned.

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 yellowcard.mhra.gov.uk or search MHRA Yellow Card in Google Play or Apple App Store.

All side effects of medicines should be reported. For side effects on Bayer medicines, please contact Tel: 0118 206 3500 or Email: pvuk@bayer.com.

29

Can I drink Ventavis?

No. Although Ventavis is a liquid it must only be taken using the nebuliser provided by your treating centre. You should inform your healthcare professional immediately if you have taken Ventavis in any other way.

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 yellowcard.mhra.gov.uk or search MHRA Yellow Card in Google Play or Apple App Store.

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30

What should I do if I take too much Ventavis?

It is important that you take Ventavis as you have been advised to by your treating centre. If you take more Ventavis than the recommended dosage and frequency, you may experience pronounced headache, flushing (redness) in your face, dizziness, nausea, vomiting and diarrhoea. If this happens, stop taking Ventavis until your symptoms stop.

Should your symptoms persist contact your healthcare professional immediately.

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 yellowcard.mhra.gov.uk or search MHRA Yellow Card in Google Play or Apple App Store.

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What side effects could I experience when taking Ventavis?

Possible side effects related to taking Ventavis can include:

- Red cheeks/face (flushing)
- Headaches
- Nausea
- Vomiting
- Jaw pain
- Increased cough
- Dizziness/fainting due to low blood pressure

If you feel light-headed after taking Ventavis, you should stand up slowly or wait until the feeling passes. Speak with your treating centre if symptoms of dizziness and fainting become worse. If you experience episodes of dizziness and fainting whilst taking Ventavis you should avoid driving or operating heavy machinery.

Please refer to the Ventavis PIL (Patient Information Leaflet) for the full list 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 yellowcard.mhra.gov.uk or search MHRA Yellow Card in Google Play or Apple App Store.

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32

I am having trouble breathing after taking Ventavis, what should I do?

In some cases, taking Ventavis can cause the muscles of your airways to tighten (bronchospasm). Should you experience this problem, immediately seek medical attention.

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 yellowcard.mhra.gov.uk or search MHRA Yellow Card in Google Play or Apple App Store.

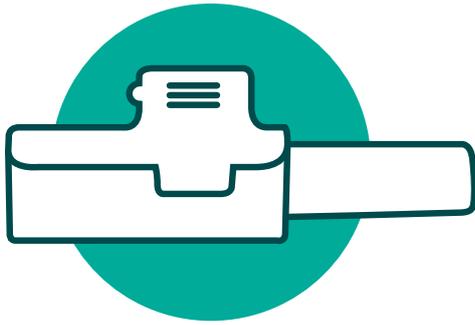
All side effects of medicines should be reported. For side effects on Bayer medicines, please contact Tel: 0118 206 3500 or Email: pvuk@bayer.com.

33

Can the higher dose of Ventavis (20mcg/ml) be used with I-neb?

Ventavis 20 mcg/ml dose should only be used with Breelib, never with I-neb.

If you are using the Breelib nebuliser but still have your old I-neb devices, please call the Philips Patient Support Team on FREEPHONE 0800 130 0857 who can arrange for your I-neb devices to be collected free of charge, at a time which is convenient for you.



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)
