

FAQ

ReliefBand® Device Frequently Asked Questions

Q: How does the ReliefBand® Device work?

A: It works by gently stimulating the nerves in your wrist, which interferes with your body's nausea and vomiting process.

Q: What are the medical conditions for which the ReliefBand® Device has FDA clearance?

A: The ReliefBand® Device is a Class II electronic medical device. It is a non-drug, non-invasive prescription treatment for nausea and vomiting due to chemotherapy, pregnancy and as an adjunct to antiemetics for post-operative nausea. The ReliefBand® Device also provides relief of nausea from motion sickness and is available without prescription for this condition.

Q: Why do I need a prescription for nausea and vomiting from pregnancy, chemotherapy and post-operative nausea usage?

A: There are four reasons why these indications require a prescription.

1. Because these conditions are always managed by a physician, the ReliefBand® Device must be prescribed to assure that it is part of an overall regimen for each patient.
2. The prescription ReliefBand® Device has a higher power output.
3. It could be your advantage to obtain ReliefBand® Device by prescription since many insurance companies cover it.
4. Your doctor will need to assess your vomiting symptoms as an indicator of a more serious health condition.

Q: How do I use the ReliefBand® Device?

- A:**
- Press the On/Off button located in the center of the ReliefBand® Device face, once. There should be a flashing light inside, or near the number 1. Pressing the button again will increase the stimulation level to the next highest number. There are five stimulation levels (1, 2, 3, 4, and 5). The higher the number, the higher the stimulation level. The flashing light is not synchronized with the tingling sensation you will feel. (The tingling sensation will cycle every four seconds).
 - To turn off, press and hold On/Off button, in the center of the face for at least 3 seconds. This will turn off the device and put the unit into a battery-save mode for future use.

Q: How do I know if the ReliefBand® Device is applied correctly?

A: After identifying the correct area: Two finger widths below the crease in the wrist, between the two tendons. Be sure to apply the conductivity gel on the wrist per instructions. Place the ReliefBand® Device over the gelled area. You should feel a gentle pulsing or tingling in the palm and/or middle fingers of your hand. This sensation tells you that the device is placed correctly.

Q: Do I always have to use the conductivity gel? How much should I use?

A: Conductivity gel should always be used. The gel helps enhance the conductivity between the electrode and the skin, allowing the impulses to stimulate the nerves. You should use a drop, about the size of a pea. The drop should be spread onto the skin, until a sheen remains, covering an area the size of a quarter. Gel should be reapplied every 6-8 hours or when the band is reapplied after washing the wrist area.

Q: What do I do if I cannot feel the tingling?

A: Move the device slowly around the underside of the wrist over the area two-finger widths below the crease in the wrist. If tingling is still not felt, increase the power level setting and repeat movement. If you are at the highest setting on the device, and still do not feel the tingling try the following:

- Follow instructions for use carefully to ensure device is applied in the correct starting position.
- Remove the device, clean the electrodes and wrist gently with a clean cloth and reapply the gel and device. Be sure gel is rubbed to sheen, not in a pea shaped glob on your wrist. Note: too much gel can cause tingling sensation to stop.
- Switch wrists.

Q: What is the proper setting for me?

A: You must feel some "tingling" in order for the device to work. The proper setting varies by individual. You should feel a gentle pulsing or tingling in the palm and/or middle fingers of your hand. This sensation tells you that the device is placed correctly. Increase setting to the highest comfortable setting for you.

FAQ *continued*

Q: Will this tingling feeling always be there?

A: You must continue to feel the tingling for the ReliefBand® Device to work. Worn over timer (like a watch or ring), you will become accustomed to the sensation and it will become less noticeable. The tingling sensation does vary with arm movements.

Q: When do I wear the device?

A: Turn it on when you feel nausea; turn it off when you feel better. Note: You may leave it on the wrist after you turn it off if you are concerned that the nausea may return.

Q: How quickly does it work?

A: When applied correctly, many patients begin to feel relief within minutes.

Q: How long can I wear the ReliefBand® Device?

A: The ReliefBand® Device can be worn as long as necessary, during the life of the batteries. Suggestion: wear the device in the proper position and turn it on as needed.

Q: How long does ReliefBand® Device last?

A: The ReliefBand® Device is both available in both limited use and replaceable battery models. At the average setting (3) the limited use device has an active life of approximately 150 hours. At the average setting (3) the reusable device lasts for 150 hours before the batteries need to be replaced. Be sure to turn the Reliefband® Device “off” when it is not in use, allowing you to use it over several days, weeks or months.

Q: What types of batteries are used in the reusable ReliefBand® Device and where can I purchase them?

A: The reusable ReliefBand® Device uses two 3 volt lithium batteries (CR2025) which are available at your local drug store, or whenever camera batteries are sold. Batteries are not replaceable in the limited use device.

Q: Are there any side effects using the ReliefBand® Device?

A: The only known side effect is a slight skin irritation under the electrodes. If local skin irritation occurs beneath or around the electrode sites, switch wrists. If symptoms persist discontinue use. If irritation does not disappear within 24 hours, consult your doctor or pharmacists. For more information about warnings, please see instructions for use or go to www.reliefband.com

Q: Can I use any other kinds of gel for contact, for example, K-Y jelly?

A: Only use the conductivity gel specifically provided with the ReliefBand® Device. The conductivity gel tube included with the ReliefBand® Device should last for approximately 75 applications.

Q: Is the ReliefBand® Device waterproof?

A: The Reliefband® Device is NOT waterproof, however it is splash resistant. This means that it should continue to perform in most cases of splash contact with water. It should not be submerged, or subjected to long periods of continual exposure to water.

Q: Are there any other uses for the product? May I wear it anywhere else on the body?

A: No. The ReliefBand® Device is only intended/indicated for use as specified in the manufacturer's instructions for use.

Q: I have heard stories of people wearing two devices at one time (i.e., one on each wrist). Can this help?

A: No. The ReliefBand® Device is only intended/indicated for use as specified in the manufacturer's instructions for use.

WARNINGS: The ReliefBand® Device should only be used on the designated area. • Do Not Use the ReliefBand® Device when the cause of nausea and vomiting symptoms are undiagnosed. • Nausea and vomiting are serious medical conditions; seek medical attention if symptoms continue. • The ReliefBand® Device is not a curative and should always be used under medical supervision. Treatment outcome may vary depending on patient characteristics and use of medications. • The ReliefBand® Device should be kept out of reach of children. • Pacemaker Users - Use the device only as directed on the wrist to prevent possible interference with your pacemaker. Avoid placing the electrodes directly on your chest or near the pacemaker.

CAUTION: The ReliefBand® Device contains metal electrodes. Consult hospital policies regarding metal contact with the patient's skin during electrocautery surgical procedures.

SIDE EFFECTS: If local skin irritation occurs beneath or around the electrode sites, discontinue use. If irritation does not disappear within 24 hours, consult your doctor or pharmacist. • Isolated cases of skin irritation may occur at the site of electrode placement following long term application. Persistent use of the device in the presence of skin irritation may be injurious.