
Safety & Performance Information for Bliss DTx

You must always use Bliss DTx strictly in accordance with the information provided in the instructions for use or by your doctor or pharmacist.

Bliss DTx is a reusable active medical device, Class I (Rule 11).

It is preferable to use Bliss DTx in a calm environment to ensure the best effect of the medical device.

The different durations of the virtual reality programs integrated into Bliss DTx are pre-programmed. There is no limit to the frequency of sessions.

The duration of use of Bliss DTx is defined by the medical procedure and the associated protocol.

Intended Use

Bliss DTx is a medical device intended to reduce pain and anxiety before, during, and after painful medical procedures.

The use of Bliss DTx is strictly reserved for use under the supervision of a healthcare professional trained in the use of this medical device. Bliss DTx is intended for use in patients aged 12 years and older.

- The Bliss DTx device may be used alone or in combination with local anesthesia, including but not limited to the following uses:
- During diagnostic or sampling procedures such as endoscopies, punctures (pleural, ascites, lumbar puncture, myelogram), biopsies.
- During surgical procedures in oncology (port-a-cath insertion), urology (bladder procedures), vascular surgery (varicose vein surgery), orthopedics (knee, hand, hallux valgus surgery), oral surgery (wisdom tooth extraction), etc.
- During painful post-surgical care (dressing changes, burns, mobilization, etc.).

Possible Adverse Effects

Bliss DTx may cause mild discomfort at the beginning of a session, related to the adaptation period to the medical device. This potential sensation of discomfort must be explained to the patient.

Adverse effects related to the use of Bliss DTx are limited to the three symptoms that may be caused by a virtual reality headset: headaches, dizziness, and nausea. These effects are infrequent and are managed by temporarily interrupting the virtual reality session.

If the patient experiences any of the symptoms listed above:

Until the symptoms have completely disappeared, it is recommended not to drive, operate machinery, or engage in visually or physically demanding and potentially dangerous activities (i.e., any activity during which the occurrence of such symptoms could result in death, bodily injury, or property damage), or activities requiring good balance or hand-eye coordination (sports, cycling, etc.).

Wait several hours after the complete disappearance of symptoms before resuming a session that was interrupted due to the occurrence of the described symptoms.

If you observe any side effects related to the use of Bliss DTx, please contact support@neodtx.com by email.

Any serious incident related to the use of the product must be reported to the manufacturer as well as to the competent authority of the country in which the patient and/or user is established.

No interactions are known to date.

Warnings and Contraindications

The use of Bliss DTx requires an explanation provided by trained personnel to ensure its analgesic and/or anxiolytic effects.

In individuals with visual impairments, the use of Bliss DTx must be approved by a healthcare professional.

Bliss DTx is strongly discouraged for patients with fragile vision and/or hearing (glaucoma, very young patients under 6 years of age), and for photosensitive and/or epileptic patients.

Driving and Use of Machinery

If the patient drives after a Bliss DTx session, ensure that they are sufficiently alert. The patient's level of alertness can be assessed using the Glasgow Coma Scale. A score of 15 on the Glasgow Coma Scale indicates sufficient alertness.

Precautions for Use and Handling

Keep away from open flames.

The Neo DTx support team remains at your disposal for any questions.