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## **Frequently Asked Questions**

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## THE DEVICE

### **Do I need a prescription to use the device?**

Yes. You need a prescription from your eye care professional to use the TrueTear® device.

### **How and where can I purchase the device?**

The TrueTear® device is a prescription-only device. Ask your eye care professional about TrueTear®.

### **Is there a warranty available for my device?**

Allergan warrants to the original purchaser of the TrueTear® device that your device is free from defects in materials and workmanship for three (3) years from the date of original purchase. This warranty extends to only the original purchaser and is not transferable. Keep your invoice or receipt safe as this is your proof of purchase, and the date marked on it shall be deemed the date of purchase. For all warranty terms and conditions, please see the Instructions for Use that accompanied your TrueTear® device or [truetear.com](http://truetear.com).

## USING THE DEVICE

### **How far do I need to insert the tip into my nose?**

Insert the tip into your nose as far as is comfortable. Make sure the tip is inserted all the way to the top and front of the nose.

### **How do I know if the stimulation is working?**

You are stimulating the correct location if you feel a tingling sensation in your nose and your eyes begin to tear.

### **How soon will I feel my eyes tear?**

Tearing can occur within seconds. Depending on your individual anatomy and tear deficiency, tearing can take a shorter or longer time.

### **What stimulation level do I have to use to tear?**

Each intensity level is different for every patient and can vary on any given day. The TrueTear® device allows you to adjust your intensity level according to your own needs. Most patients started at level 2 in a clinical trial.

***Please see Indication and Important Safety Information on page 6.***

**Does it matter if I use the device for 30 seconds or 3 minutes?**

Use of the device can vary depending on the individual patient. Use until you see/feel tears coat the surface of your eye. Using the device longer than 3 minutes is not recommended, and the patient should wait for at least 60 minutes before inserting into the nose again.

**How often and how long do I need to use the device?**

The device is capable of single-day use up to a limit of 30 minutes. Use longer than 3 minutes per session is not recommended, and the patient should wait for at least 60 minutes before inserting into the nose again. For most patients, using the device at least twice a day as needed is recommended. Refer to the **Instructions for Use** or check with your eye doctor.

**Can I use the device in the shower?**

No. Do not use the TrueTear® device when in the bath or shower.

**How long do I need to charge the device?**

Charging time is dependent on how often you use the device. It normally takes 4 hours to complete a full charge. We recommend charging the device when changing the tip.

**My device shuts off automatically after 1 minute. Is this normal?**

Yes. The TrueTear® device has a built-in timer allowing for 1 minute of use each time. To use longer than 1 minute, simply start another cycle, although using the device longer than 3 minutes per session is not recommended, and the patient should wait for at least 60 minutes before stimulating again.

## SIDE EFFECTS

**Will I experience nasal pain when using TrueTear®?**

In a 180-day study, 10 out of 97 patients (10.3%) reported nasal pain, discomfort or burning. If you experience pain, discomfort or burning while using TrueTear®, remove the device immediately and report this adverse event to 1-800-678-1605 and talk to your doctor.

**Is it possible to feel an electrical shock in my nose when the TrueTear® tips are inserted?**

In a 180-day study, 5 out of 97 patients (5.2%) reported temporary electrical discomfort (a mild shock). If you feel a mild shock while using TrueTear®, remove the device immediately and report this adverse event to 1-800-678-1605 and talk to your doctor.

***Please see Indication and Important Safety Information on page 6.***

**Can using TrueTear® cause nosebleeds?**

In a 180-day study, 5 out of 97 patients (5.2%) reported a device-related nosebleed. If your nose begins to bleed while using TrueTear®, remove the device immediately and report this adverse event to 1-800-678-1605 and talk to your doctor.

**Should I be aware of any other side effects?**

There were additional side effects reported during the clinical studies. For a complete list of additional adverse events, please consult the Instructions for Use.

**DISPOSABLE TIP****How long can I use one tip?**

The tip should be replaced every two days or every 48 hours. The tip contains a hydrogel that wears down after two days of use. Once the hydrogel is dried out, the tip will no longer work. Additionally, make sure to use the tip before the expiration date printed on the packaging.

**Can I clean the tip by running it under hot or cold water?**

No. To clean the TrueTear® device, you can use an alcohol pad to gently wipe the disposable tip, being careful not to rub the hydrogel areas.

**How do I clean my base unit, charger, and carry cover?**

Use alcohol pads to clean the durable parts of the device including the base, charger, and cover. Clean the inside of the cover weekly or more often if needed to ensure proper hygiene.

**Are the tip and cover dishwasher safe?**

No, they are not. The best way to clean them is by wiping them with alcohol pads.

**Can I throw the tip away in a regular trashcan?**

Yes. The TrueTear® disposable tip can go in the regular trash for disposal.

***Please see Indication and Important Safety Information on page 6.***

## MOBILE APP

### **What does the TrueTear® mobile app do?**

The app is designed to help you view and track your device usage and battery level, learn more ways for using the device, and get assistance if you encounter any problems with the device. Since environmental conditions such as humidity, temperature, pollen count, and pollution index may affect your eyes, these and other local weather information are shown throughout the app.

### **Do I have to use the TrueTear® mobile app in order to use my TrueTear® device?**

No. The TrueTear® mobile app is not required in order to use your TrueTear® device.

### **How much does the TrueTear® mobile app cost, and does it work on both iOS™ and Android®?**

The TrueTear® mobile app is a free app that is currently available for iOS only. We are working on one for Android.

### **How do I pair and sync my TrueTear® device and App?**

Make sure Bluetooth® is enabled on your mobile device. Once you have created an account, the app will walk you through the pairing process. Enter the serial number located on the back of the base unit, into the app. Hold down the “-” button on the base unit for 3 seconds until a blue LED indicator flashes, then tap the “Pair Now” button in the app.

To sync after use: with your mobile device nearby, simply use the TrueTear® device as usual or place the base unit into the charger. During these times the TrueTear® device will automatically connect with your paired mobile device.

### **Can I pair my TrueTear® device with more than one mobile device?**

Yes. You can pair your TrueTear® device with multiple mobile devices; however, your device can only be actively paired with one mobile device at any given time.

### **Why are all of the icons greyed out?**

To protect your device data, most of the features within the app such as pairing a device require you to have an account and an active internet connection. Make sure you’re signed in to your account and are either connected to a Wi-Fi network or have good cell service.

### **What do the trend charts do?**

Trend charts in the TrueTear® mobile app summarize your use over the last two weeks by time of day and day of the week. You can use these charts yourself or share them with your healthcare provider to get feedback on your prescribed usage.

***Please see Indication and Important Safety Information on page 6.***

## TRUETEAR® INDICATION AND IMPORTANT SAFETY INFORMATION

### INDICATION

TrueTear® provides a temporary increase in tear production during neurostimulation to improve dry eye symptoms in adult patients with severe dry eye symptoms.

### IMPORTANT SAFETY INFORMATION

#### CONTRAINDICATIONS

Do not use TrueTear® if you have a cardiac demand pacemaker, implanted or wearable defibrillator, or other implanted metallic or electronic device (eg, cochlear implant) in the head or neck, chronic or recurrent nosebleeds, a bleeding disorder (eg, hemophilia), a condition that can lead to increased bleeding, or a known hypersensitivity (allergy) to the hydrogel material.

#### WARNINGS

Do not use TrueTear® around electronic monitoring equipment (eg, heart monitors or electrocardiogram alarms), in the bath/shower, while driving, operating machinery, or during activity in which sneezing/watery eyes may cause risk, areas other than the nose, within 3 feet of shortwave or microwave therapy equipment, around flammable anesthetic mixture (air, oxygen or nitrous oxide). Do not continue using TrueTear® if your nose is irritated. The device is limited only to the improvement in dry eye symptoms, as the safety and effectiveness for neither the treatment of dry eye disease nor use for periods longer than 6 months has been established. Safety not established in pregnancy, patients under 22 years of age, patients with nasal or sinus surgery (including nasal cautery) or significant trauma, severe nasal airway obstruction or vascularized polyp; active, severe systemic or chronic seasonal allergies; rhinitis or sinusitis requiring treatment; untreated nasal infection; and disabling arthritis, neuropathy, severe dexterity impairment or limited motor coordination. Use only manufacturer's supplied accessories.

#### PRECAUTIONS

Consult your doctor on TrueTear® instructions before use and on discontinuing use if pain, discomfort or numbness in the nose persists after reducing for higher levels/longer sessions. Remove studs, nose rings, or other nose jewelry before use. Do not use prescription eye medications or nasal sprays 30 minutes before or after using TrueTear®. Consult your doctor before use if you have suspected or diagnosed heart disease. Keep away from children. Clean as directed. Failure to replace the tip as directed will cause the device to not work properly.

#### ADVERSE EVENTS

Nasal pain, discomfort or burning; short-term electrical discomfort; nosebleed; nasal congestion; headaches; trace blood in nostril; facial pain; sore eye; sinus pain; pain around the eye; runny nose; nasal ulcers; and light-headedness.

Caution: Federal law restricts this device to sale by or on the order of a licensed physician. Proper patient training on use of the device is required before home use. For the full Directions for Use, please visit [www.allergan.com/truetear/usa.htm](http://www.allergan.com/truetear/usa.htm) or call 1-800-678-1605. Please call 1-800-433-8871 to report an adverse event.

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