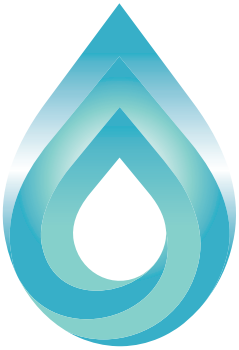
Patient Guide for the TrueTear® Intranasal Tear Neurostimulator



truetear®

NO OTHER WARRANTY

Unless modified in writing and signed by both parties, this warranty is understood to be the complete and exclusive agreement between the parties, superseding all prior agreements, oral or written, and all other communications between the parties relating to the subject matter of this agreement. No employee of Allergan or any other party is authorized to make any warranty in addition to those made in this warranty.

Contact Information

If you wish to report a problem, please contact the provider who provided you with the TrueTear® device, or contact Allergan:

Allergan, plc.
4410 Rosewood Drive
Pleasanton, CA 94588 USA
1-866-502-TEAR (8327)
TrueTear.com

truetear®

If your dry eye symptoms become intolerable or you experience any complications using the TrueTear® device, please contact your provider.

Allergan

Patient Guide for the TrueTear® Intranasal Tear Neurostimulator

Please read this entire guide. If you have any questions, discuss with your provider to make sure you understand how to use the TrueTear® Intranasal Tear Neurostimulator.

The TrueTear® Intranasal Tear Neurostimulator (TrueTear® device) provides a temporary increase in tear production during neurostimulation to improve dry eye symptoms in adult patients with severe dry eye symptoms.

Rx Only—Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Proper patient training on use of the device is required before home use.

The TrueTear® Intranasal Tear Neurostimulator Patient Guide

Table of Contents

Section 1: Patient Guide

Section 2: Quick Start Instructions

Glossary

Adverse event

Base unit

Cardiac demand pacemaker or defibrillator

Clinical studies

Contraindications

Cornea

Disposable tip

Dry Eye symptoms

Eligibility criteria

Hypersensitivity

Intranasal Tear Neurostimulator (TrueTear® device)

Neurostimulation

Precautions

Schirmer test

Temporary electrical discomfort

Warnings

An undesirable effect associated with use of a medical product.

The base unit produces the neurostimulation and provides a connection to the charger.

Device (cardiac demand pacemaker) placed in or in close proximity to (defibrillator) the heart to maintain cardiac rhythm.

Clinical studies are conducted to evaluate the use of a drug or device.

Cases where the TrueTear® device should not be used.

Clear tissue located in the front of the eye covering the colored area of the eye.

The disposable tip of the TrueTear® device connects to the base unit and is inserted into the nose.

Dry eye symptoms may include, but are not necessarily limited to, sensitivity to light, grittiness, pain or soreness, blurred vision, and poor vision. Dry eye symptoms may be caused by advanced age, contact lens wear, certain medications, eye diseases, other medical conditions, or environmental factors.

Characteristics or criteria used to determine whether a person can participate in a clinical study.

Allergy or reaction to materials that may come into contact with the skin or to medications taken.

A device that provides small electrical pulses to stimulate tear production.

Delivery of small electrical currents to activate the nerves in the nose.

A precaution provides information regarding any special care to be exercised by the provider and/or the patient for the safe and effective use of the device.

A test in which a paper strip inserted inside the eyelid for several minutes to evaluate tear production.

Temporary (short-term) discomfort resulting from electrical stimulation.

A warning alerts the user about serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

Introduction

This guide is intended to help you decide whether to use and how to use the TrueTear® device to provide a temporary increase in tear production and improvement in dry eye symptoms. This device provides small electrical pulses to stimulate production of your own natural tears. The electrical pulses are delivered by a disposable tip attached to the TrueTear® device that you will place in your nose for short periods of time.

Your provider has determined that the TrueTear® device may work for you. Please read this entire guide and discuss your questions with your provider. You can then consider the expected benefits versus the risks and make an informed decision.

Facts About Dry Eye Symptoms

Dry eye symptoms may include, but are not necessarily limited to, sensitivity to light, grittiness, pain or soreness, blurred vision, and poor vision. Dry eye symptoms may be caused by advanced age, contact lens wear, certain medications, eye diseases, other medical conditions, or environmental factors. In some people, dry eye symptoms may be improved by increasing the amount of tears produced.

Indications for Use

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

Potential Benefits of the TrueTear® Device

Use of the TrueTear® device will temporarily increase your tear production and improve your dry eye symptoms, though not all patients may respond to this device to the same degree.

Potential Complications With Using the TrueTear® Device

Potential complications include the following:

- Nasal pain, discomfort, or burning sensation
- Short-term electrical discomfort
- Nosebleeds
- Trace blood in nostril
- Nose stuffiness (nasal congestion)
- Excessive sneezing
- Irritation or numbness of the nose

- Infection, scrape (abrasion), sore formation (ulceration) or inflammation inside the nose
- Irritation or sensitivity inside the nose
- Lightheadedness
- Headaches
- Sinus pain
- Sore eye
- Facial pain or pain around the eye
- Increased saliva production
- Sensation of teeth vibrating
- Excessive runny nose
- Temporary increase in symptoms associated with nasal allergies
- Allergic reaction to contact materials
- Potential permanent scarring of the inside of nose with prolonged use

Contraindications, Warnings, and Precautions

CONTRAINDICATIONS

Contraindications are situations where it is advisable not to use the TrueTear® device. If you have any of the following, you should NOT use the TrueTear® device:

- 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), or another condition that can lead to increased bleeding
- A known hypersensitivity (allergy) to the stainless steel material that comes into contact with the inside of your nose

WARNINGS

Warnings alert the user about serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur, as identified below:

- Follow the Instructions for Use when using the TrueTear® device.
- Do not use the TrueTear® device if electronic monitoring equipment is being used. This type of equipment includes heart monitors or electrocardiogram (ECG) alarms since this equipment may not operate properly when the TrueTear® device is being used.

Contraindications, Warnings, and Precautions

WARNINGS (continued)

- Do not use the TrueTear® device when in the bath or shower.
- Do not use the TrueTear® device while driving, operating machinery, or during any activity in which sneezing or watery eyes may put you at risk of injury.
- Do not apply the TrueTear® device to the neck, chest, or areas other than the nose.
- Do not continue using the TrueTear® device if your nose is irritated since further use may cause injury to the tissues inside your nose.
- Do not use the TrueTear® device within 3 feet of shortwave or microwave therapy equipment since this equipment may make the stimulation from the TrueTear® device unstable.
- Do not use the TrueTear® device in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide as there is a remote possibility (comparable to the risk of a mobile phone) it could ignite the gas.
- Use only manufacturer's supplied accessories.
- The TrueTear® device is limited only to the improvement in dry eye symptoms as the safety and effectiveness in the treatment of dry eye disease has not been established.
- In a clinical study, the safety and effectiveness of the TrueTear® device was evaluated over a 6-month period of time. The safety and effectiveness of the TrueTear® device for longer periods of use have not been established. Your provider may periodically check your nose if the TrueTear® device is used over a longer period of time.
- The clinical study was not designed to evaluate any changes in nerve sensitivity.
- The safety of the TrueTear® device has not been established in the following conditions and patient populations:
    - Pregnancy
    - Patients under 22 years of age
    - Nasal (nose) or sinus surgery, including a history of nasal cautery, or significant trauma
    - Severe nasal airway obstruction (such as severe septal deviation or inferior turbinate hypertrophy) or vascularized polyp (abnormal nasal mucosa with dense network of blood vessels)

WARNINGS (continued)

- Disabling arthritis, neuropathy, severe dexterity impairment or limited motor coordination that would affect your ability to use or handle the TrueTear® device
- Active and severe:
  - Systemic allergy
  - Chronic seasonal allergies
  - Rhinitis or sinusitis requiring treatment such as antihistamines, decongestants, oral or aerosol steroids
  - Untreated nasal infection

PRECAUTIONS

Precautions provide information regarding any special care to be exercised by the provider and/or patient for the safe and effective use of the TrueTear® device.

- Consult your provider before using the TrueTear® device.
- If you feel pain, discomfort, or numbness in your nose with higher levels of stimulation or a longer duration of stimulation, reduce the level and/or the number of times you use the TrueTear® device. If symptoms persist, discontinue use and contact your provider.
- Discard the disposable tip every 28 days and replace with a new tip for proper operation and good hygiene.
- Remove any studs, nose rings, or other piercings from the nose prior to using the TrueTear® device as this could obstruct the device and/or cause discomfort if the electrical stimulation is conducted to surrounding areas.
- Do not use prescription eye medications (eye drops, gels, or ointments) or nasal sprays within 30 minutes before or after using the TrueTear® device.
- Consult your provider before use if you have suspected or diagnosed heart disease.
- The TrueTear® device should be kept out of the reach of children.
- If you have a severe fear of placing anything in your nose, you may not be able to use the TrueTear® device.
- Follow the cleaning and caring instructions provided.
- Failure to replace the tip as directed will prevent the device from providing stimulation.

Are You a Good Candidate for Use of the TrueTear® Intranasal Tear Neurostimulator?

You are a good candidate for the TrueTear® device if you:

- Are at least 22 years old.
- Have dry eye symptoms.
- Are able to use the TrueTear® Intranasal Tear Neurostimulator.
- Do not have a cardiac demand pacemaker, implanted or wearable defibrillator, or other implanted metallic or electronic device in the head or neck.
- Do not have a known hypersensitivity to the any of the device materials that contact you.
- Do not have chronic or recurrent nosebleeds, a bleeding disorder or another condition that can lead to increased bleeding.

Questions to Ask Your Provider

You may want to ask your provider the questions below to help you decide if the TrueTear® device is right for you.

- What other options do I have for my dry eye symptoms?
- What are the benefits of the TrueTear® device?
- Can I use the TrueTear® device as often as I want?
- Will I be able to use artificial tears, gels and ointments in addition to using the TrueTear® device?
- Will I be able to use dry eye drugs in addition to using the TrueTear® device? Are there any risks if I use the TrueTear® device with dry eye drugs?

Summary of Important Information

- The TrueTear® device provides a temporary increase in tear production during use resulting in an improvement in dry eye symptoms in adult patients with severe dry eye symptoms.
- You should not use the TrueTear® device if you have any of the following conditions:
    - A cardiac demand pacemaker, implanted or wearable defibrillator, or other implanted metallic or electronic device in the head or neck
    - Chronic or recurrent nosebleeds, a bleeding disorder or another condition that can lead to increased bleeding
    - A known hypersensitivity (allergy) to the stainless steel material that comes into contact with the inside of your nose
- You should follow all instructions to make sure you use the TrueTear® device correctly.
- Please call 1-800-433-8871 to report an adverse event.

Instructions for Use

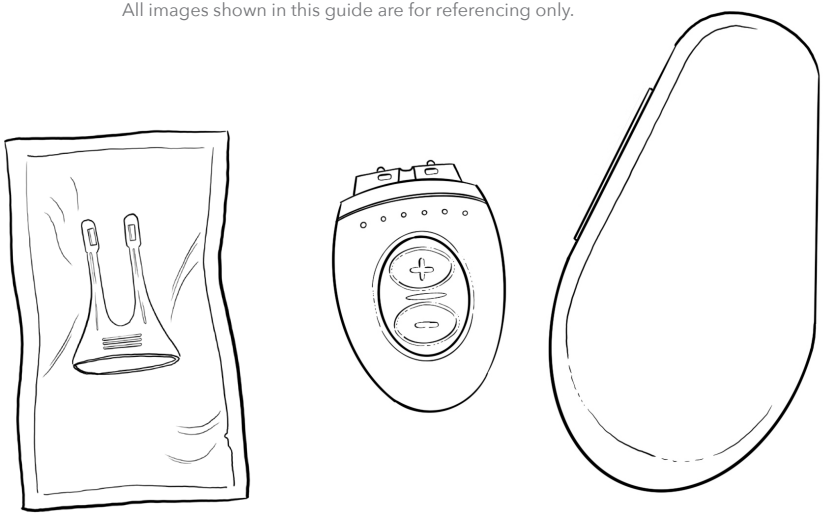
OVERVIEW OF THE TRUETEAR® DEVICE COMPONENTS

The TrueTear® device consists of three parts.

1. A **disposable tip**, which is inserted into the nasal cavity and provides the contact surface for the stimulation in the nose
2. A **base**, which produces the stimulation
3. A **case** that protects and charges the device in between uses

The disposable tip (tip) is connected to the base for stimulation. The tip provides the contact for conducting the stimulation current, which is produced by the base.

All images shown in this guide are for referencing only.



Disposable Tip Base Case

Figure 1. TrueTear® components.

USING AND CHARGING THE DEVICE

NOTE: Only use the provided AC adapter.

1. Open the case and place the base with the attached tip inside the case. the base (front) should face up.
2. Close the case. If the case is not closed, the base may not charge properly.
3. Connect the provided cable and adapter to the case and plug the adapter into an active (120-240V) outlet.
4. The case bottom will glow orange when the device is charging and glow blue when the device is fully charged.

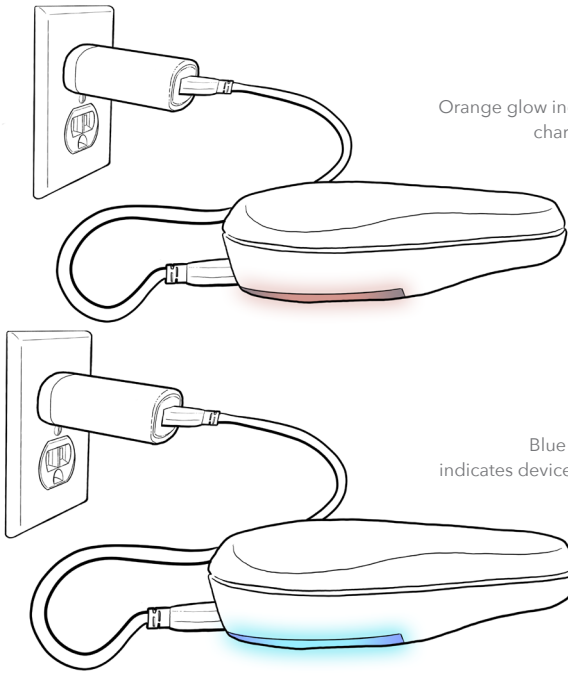


Figure 2. Charging the TrueTear® device.

STIMULATION INSTRUCTIONS

1. Remove a new disposable tip from the pouch.

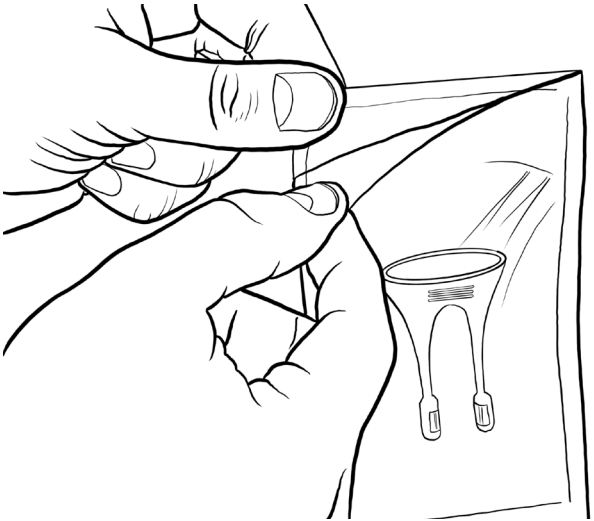


Figure 3.

3 Connect the tip to the base by aligning the post on the underside of the tip with notch on base, then rotate forward until the tip snaps into place, as shown in Figure 4.

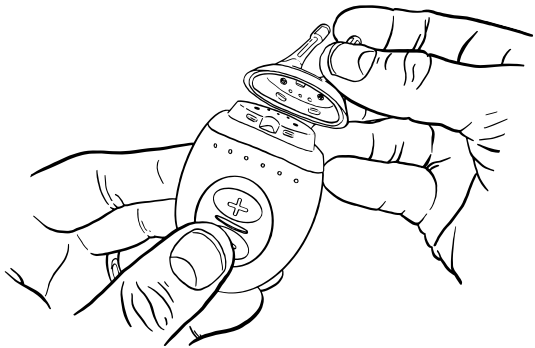
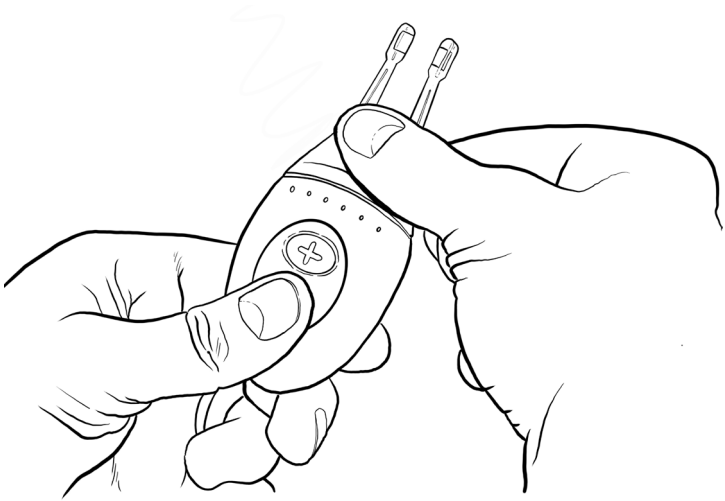


Figure 4. Align the tab to the notch for setup. The tip only fits one way.



There are 5 stimulation intensity levels. The base vibrates briefly when the **+** or **-** button is pressed to indicate an increase or decrease in stimulation level. The blue lights will be lit to indicate the stimulation level selected.

Your provider will confirm that you understand these instructions, including having you demonstrate the stimulation technique and the tearing response, prior to prescribing the TrueTear® device and, if necessary, at subsequent visits:

1. With the TrueTear® device fully assembled, hold the **+** button for 2 seconds to turn on the device. A steady white light will apear on the base indicating that the device is on. as shown in Figure 5.

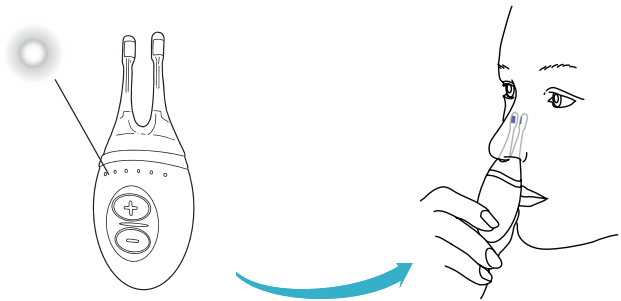


Figure 5. Turning on the TrueTear® device and placing it into the nose.

2. Press the + button to select a desired stimulation intensity level. Blue lights show the level selected. **Always start on level 1.**

3. Place thumb near buttons of base and gently insert the tip into the nose with the back of the base facing out, as shown in Figure 5.

4. For effective stimulation, insert the tip toward the top and front of the nose, as shown in Figure 6.

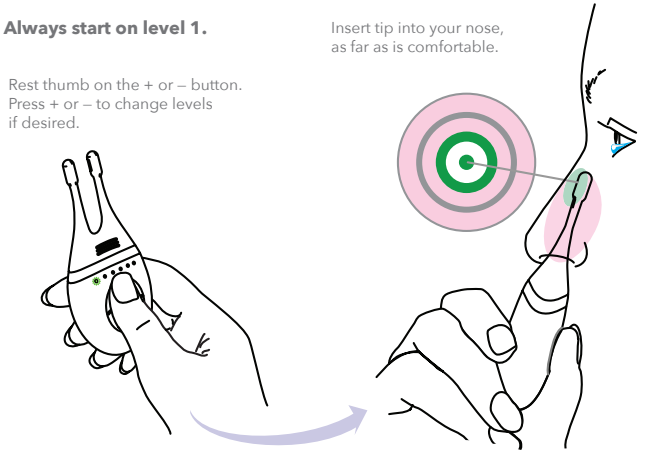


Figure 6. Target zone for correct insertion of disposable tip.

5 The + button is for increasing the intensity and the – button is for decreasing the intensity. You may gradually increase and adjust intensity (using the + and – buttons) until you feel a gentle tingling in your nose; this feeling lets you know that you are stimulating the correct tissue location and tears will form.

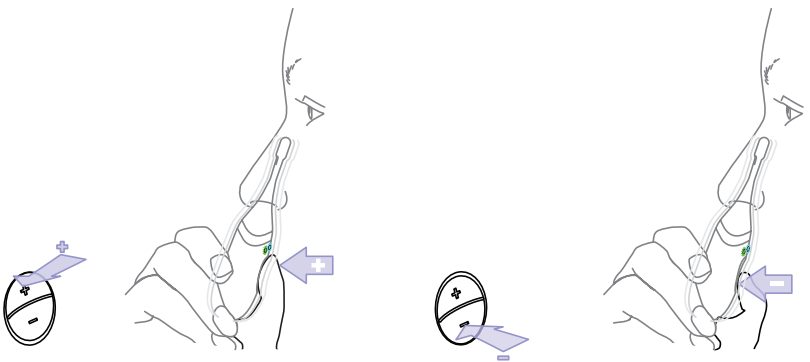


Figure 7. Adjust stimulation by pressing the + or – buttons.

6. You may reposition the tip inside the nose for desired stimulation. The feeling should be mild at its maximum intensity.

7. Remove the tip from your nose at any time if you feel uncomfortable during stimulation.

8. The device turns off automatically after three (3) minutes. You can also turn it off manually by pressing the - button for 2 seconds. The device will vibrate and the lights will turn off to indicate the device is off.

   Note: You can turn the device off as soon as tears start forming.

9. When finished, clean the TrueTear® device with an alcohol wipe, if needed (see CARING FOR YOUR DEVICE), and store the device in the case provided.

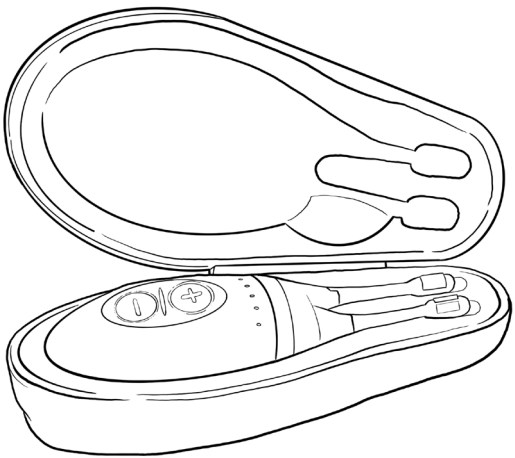


Figure 8. Cover attached to base unit to protect disposable tip.

RECOMMENDED STIMULATION SCHEDULE

Use the TrueTear® device at least twice a day, as needed. Stimulation longer than 3 minutes is not recommended, and you should wait for at least 60 minutes before proceeding to the next application. The device has a built-in single-day usage limit of 30 minutes. If this daily limit has been reached, the TrueTear® device will turn on and then off immediately. The device will not deliver stimulation.

Replace the tip every 28 days with a new tip. When a tip has 7 days of usage left before expiration, the device will vibrate 3 times when the device is turned on or off. If the device is turned on without a tip or with an expired tip, the device will vibrate 3 times but will not deliver stimulation.

WHAT YOU'LL SEE	WHAT IT MEANS
A single, steady white light when device is turned on.	Device is on. No stimulation is delivered.
A single, flashing white light when the device is turned on.	Battery is running low. Place base in case.
All lights flash on and off.	Daily stimulation limit of 30 minutes has been reached.

CARING FOR YOUR TRUETEAR® DEVICE

1. Use alcohol wipes to clean the device and store the device in the case between uses.

   Use alcohol wipes to clean tthe case as needed.

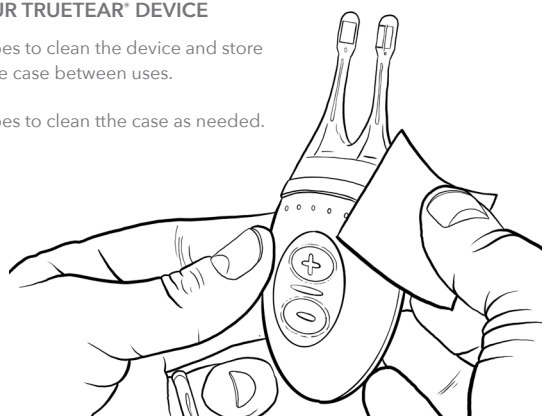


Figure 9. Cleaning with alcohol wipes.

3. Do NOT place or submerge any part of the device or the case in water or other liquid.

4. Handle with care. Store the TrueTear® device in its case in a clean, cool, and dry location. Avoid exposure to extreme temperatures and humidity.

   CAUTION: Avoid touching the metal contacts on the tip if the device has been exposed to high temperature extremes (such as in a hot car).

   The expected service life for the base and case is 3 years from the date of purchase. The expiration date of the disposable tips is provided on the product packaging.

DISPOSAL AND REPLACEMENT

The base, case, and AC adapter should be recycled and disposed in accordance with any applicable local, state, and national regulations for disposal of electronic equipment.

The tips may be discarded with regular trash.

Bluetooth®

The TrueTear® device includes *Bluetooth*® Smart wireless technology. This optional feature can be turned on to allow you to view your TrueTear® device data and track your usage on your smartphone via the TrueTear® mobile app. The *Bluetooth*® feature does not have to be on for you to use the TrueTear® device. For more information on using *Bluetooth*® and the TrueTear® mobile app, please visit **www.truetear.com/app.**

FCC COMPLIANCE

This device contains FCC ID: 2AUA2-OCUTT20. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. Any changes or modifications will void the user's authority to operate this equipment.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

ELECTRICAL SPECIFICATIONS

Base unit output	Max current Max voltage Max pulse width Frequency	5mA 13V AC 300 µs 30-60 Hz
Charger	Input Output	5V DC 6V AC
AC adapter	Input current Input voltage Output current Output voltage	0.2A 100-240V AC 1.0A 5.0V DC

ELECTROMAGNETIC COMPATIBILITY

The TrueTear® device has been tested for immunity to electrostatic discharge, radio frequency interference, proximity RF fields from wireless equipment, and power frequency magnetic fields as specified in the table below. Emissions of energy are not likely to cause interference with nearby electrical equipment.

IEC 60601-1-2: 2014-02		
Basic Standard	**Phenomenon**	**Test Specification**
IEC 61000-4-2	Electrostatic discharge	Contact discharge: ± 8 kV
		Air discharge: ± 15 kV
IEC 61000-4-3	Radiated RF EM fields	10 V/m, 80-2700 MHz, 80% AM at 1 kHz
IEC 61000-4-6	Proximity fields from RF wireless communications equipment	3 Vrms, outside ISM bands between 0.15 MHz-80 MHz 6 Vrms, inside ISM bands between 0.15 MHz-80 MHz 80% AM (1 kHz)
IEC 61000-4-8	Power frequency magnetic fields	30 A/m at 50 Hz/60 Hz

ENVIRONMENTAL OPERATING CONDITIONS

Ambient temperature range: 5°C-37°C (41°F-98.6°F)
Relative humidity range: 20%-90%

SYMBOLS AND MARKINGS

Symbol	Description	Symbol	Description
	Type BF applied part		Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.
IP22	Base unit is protected against solid foreign objects of 12.5 mm and greater. Protection against vertically falling water drops when enclosure tilted up to 15°.	IP21	Charger is protected against solid foreign objects of 12.5 mm and greater. Protection against vertically falling water drops.
	Nonionizing electromagnetic radiation		*Bluetooth*®*/Bluetooth*® Smart mark

Summary of Clinical Studies

Two pivotal clinical studies have been conducted with the TrueTear® device. Both studies evaluated the device's safety and effectiveness in dry eye patients. Both pivotal studies (OCUN-009 and OCUN-010) demonstrated the device's capability temporarily to increase tear production during stimulation. OCUN-010 also demonstrated the TrueTear® device's capability to improve dry eye symptoms as a result of stimulation.

The next section summarizes both pivotal studies.

CLINICAL STUDY OCUN-009—SINGLE STUDY VISIT (ONE-TIME USE)

This clinical study was designed to evaluate the effectiveness and safety of the TrueTear® device during use at a single study visit.

To qualify for enrollment in this study, potential participants were required to be 22 years of age or older and have dry eye symptoms based on the level of dryness in the eye(s) measured on a dry eye symptom scale. Potential participants were excluded from the study if the surface of the cornea had severe irregularities due to dry eye disease; if they had bleeding from the nose or previous sinus surgery or trauma; if they had coagulation problems (bleeding problems), a cardiac demand pacemaker, implanted defibrillator, or another implanted electronic device. Potential study participants with disabling arthritis or limited motor coordination were also excluded from participating in the study since these conditions could interfere with use of the TrueTear® device.

This study was conducted at two sites in the United States, and 48 people were tested. The study population, on average, was 57 years old. The majority of people who participated in the study were female. Each patient in the study underwent three applications of stimulation. On the study day visit, each subject received 3 applications in random order, with the TrueTear® device applied correctly, i.e., inside the nose, an inactive TrueTear® device applied inside the nose, i.e., no stimulation, and the TrueTear® device applied outside of the nose with stimulation.

In this study, the TrueTear® device used as intended resulted in a large increase in tear production. This is shown in the graph in Figure 13. The average Schirmer score (a standard measurement of Dry Eye that measures tear production) was approximately 25 mm during neurostimulation, compared with approximately 9 mm , i.e., less tear production, for the inactive control application and in people who used the TrueTear® device on the outside of the nose, where it would not be effective.

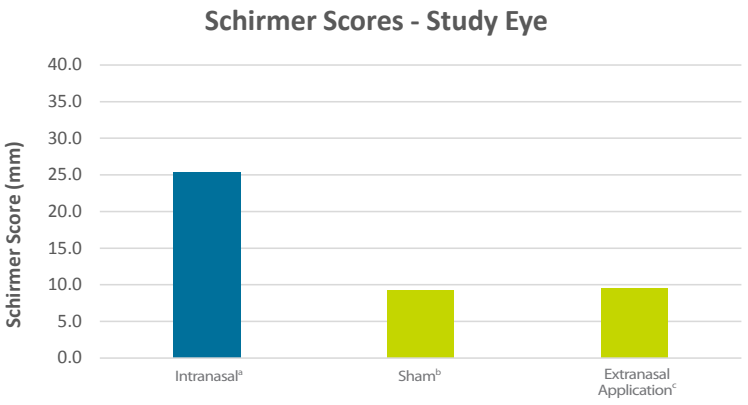


Figure 10. Tear production score (Schirmer).

[a] Intranasal = TrueTear® device applied correctly inside the nose [b] Sham = Inactive TrueTear® device applied inside the nose
[c] Extranasal = TrueTear® device applied outside of the nose with stimulation

The direct clinical benefit of temporarily increasing tear production as a therapy for patients with dry eye disease was not assessed as part of this clinical trial.

There were no adverse events that led to discontinuation from the study. Two adverse events were deemed related to or possibly related to the TrueTear® device. These included transient lightheadedness and intermittent nose itching. No changes of nasal tissue were observed with examination of the nasal cavity.

CLINICAL STUDY OCUN-010–6-MONTH STUDY

This study was designed to evaluate the safety and effectiveness of the TrueTear® device to increase tear production at multiple time points during the study (Baseline and 7, 30, 90, and 180 days) for patients with dry eye symptoms.

Eligibility for enrollment in this study required potential participants to be 22 years of age or older and have Dry Eye based on the level of dryness in the eye(s) measured on a dry eye symptom scale.

Potential participants were excluded from the study if the surface of the cornea had severe irregularities due to dry eye disease; if they had bleeding from the nose or previous sinus surgery or trauma; if they had coagulation problems (bleeding problems), a cardiac pacemaker, implanted defibrillators or another implanted electronic device. Potential study participants with disabling arthritis or limited motor coordination were also excluded from participating in the study since these conditions could interfere with use of the TrueTear® device.

Eligible participants were enrolled in the study and provided with a TrueTear® device for home use. Participants were instructed to use the TrueTear® device at least two times a day and as often as 10 times per day, as needed, and no more than three minutes per use. Study participants were examined at Baseline and days 7, 30, 90, and 180.

Ninety-seven (97) people with dry eye symptoms were enrolled at three sites in the U.S. The study population, on average, was 61 years old, and the majority of people who participated in the study were females.

Tear production at Baseline and each follow-up visit including 180 days (6 months) is shown in Figure 11. At 180 days, the study participants used the TrueTear® device with active stimulation and then without stimulation to evaluate whether there was a difference in tear production with and without active stimulation. In this study, tear production was much greater with active stimulation than without stimulation. In comparing the stimulated vs unstimulated tear production during the study, following the initial stimulation, there was a trend toward decreased effectiveness (tear production) with time with the use of the TrueTear® device; this trend appeared to plateau toward the end of the study. The mechanism for this decrease has not been identified and was not analyzed as part of the study. The average difference in Schirmer score (stimulated vs unstimulated) was 18.0 mm at Baseline (the first day of use), 13.1 mm at day 7, 8.1 mm at day 30, 8.3 mm at day 90, and 9.4 mm at day 180.

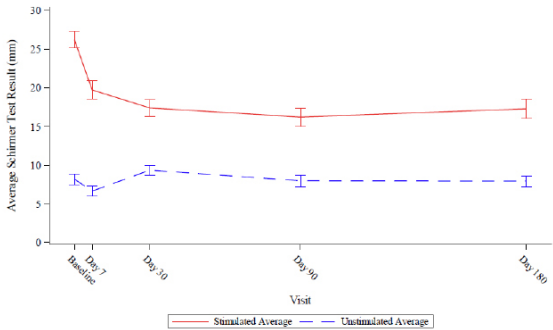


Figure 11. Acute tear production at day 180.

Symptom improvement from the start of the study was assessed at study day 7 and day 30 using a commonly used questionnaire called the Ocular Surface Disease Index (OSDI). Of the 97 subjects enrolled, 77 had severe dry eye symptoms at the start of the study and were seen following treatment. Of these subjects, between 18 (23%) and 33 (43%)

were shown to have meaningful improvement in their symptoms. There were more subjects with severe dry eye symptoms that had a meaningful improvement in symptoms from baseline as measured with the OSDI than the number with meaningful worsening of symptoms at day 7 and at day 30.

Safety and effectiveness of intranasal electrical stimulation was evaluated over a 6-month period of time. The safety and effectiveness of the TrueTear® device for longer periods of use has not been established.

In this study, safety was acceptable with no serious adverse events that were largely nasal in nature. The types and percentages for each type of AEs are presented in Table 1.

All device-related AEs (mostly mild discomfort or nosebleed) were evident to the patients and therefore self-limiting (with the exception of one case of chapped skin around the nostrils which resolved with over-the-counter medication) since patients could remove the device and discontinue stimulation at any time. The incidence of device-related AEs decreased over the course of the study, with the highest number occurring in the first month.

Table 1. Proportion of Study Patients Experiencing Adverse Event Related or Possibly Related to TrueTear® Device

Adverse Event Description	Number of Study Patients (Number of patients = 97)	Percentage
Nasal pain, discomfort, or burning	10	10.3%
Temporary electrical discomfort	5	5.2%
Nosebleed	5	5.2%
Nasal congestion	3	3.1%
Headaches	2	2.1%
Trace blood in nostril	2	2.1%
Facial pain	2	2.1%
Sore eye	1	1.0%
Sinus pain	1	1.0%
Pain around the eye	1	1.0%
Runny nose	1	1.0%
Nasal ulcers	1	1.0%
Lightheadedness	1	1.0%
*Some patients had more than one adverse event.		

The device was applied for an average of 1.7 times per day with an average daily application time of 130 seconds/day (2.16 minutes/day). Subjects applied the device a total of 27,338 times during the study, and the total device application time for the study was 34,726 minutes. Therefore, this small number of device-related mild AEs occurred in a large number of stimulation events. In all, 30 study patients (30.9% of those studied) had at least one of the adverse events listed in the above table.

Warranty Information

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.**

If during this three (3)-year period, the TrueTear® device does not function properly because of a defect in materials or workmanship, Allergan will replace it with a new device or equivalent product free of charge.
The warranty of the replacement TrueTear® device will expire on the date of the original warranty expiration. The purchaser's exclusive remedy with respect to the TrueTear® device shall be replacement.

This warranty covers the original purchaser and cannot be transferred with sale or other transfer of the TrueTear® device to any other person or entity.

EXCLUSIONS

This warranty does not apply if the TrueTear® device has been:

- Changed or modified by any person or entity other than Allergan.
- Serviced or repaired by any person or entity other than Allergan.
- Damaged by an act of God, external causes, misuse, abuse, negligence, accident, wear and tear, unreasonable use, use not in accordance with product instructions, failure to perform required maintenance, involvement of parts or components not supplied by Allergan or by other causes unrelated to defective materials or workmanship.

WARRANTY CLAIM PROCEDURE

You must notify Allergan of the claimed defect within the warranty period by writing or calling: Allergan, 4410 Rosewood Drive, Pleasanton, CA 94588; Telephone: 1-866-502-TEAR (8327) and Fax: 1-855-637-4959.

The claim must include the date of purchase, model number, serial number, and a description of the claimed defect. Allergan's authorization must be obtained prior to returning the TrueTear® device. If authorized, the TrueTear® device must be properly packaged and returned in the TrueTear® Return Kit to Allergan. Allergan will pay all freight and transportation charges, where applicable, incurred in returning and replacing your TrueTear® device under this warranty.

MISCELLANEOUS

REPLACEMENT AS PROVIDED UNDER THIS WARRANTY IS YOUR EXCLUSIVE REMEDY. ANY APPLICABLE IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS WARRANTY. IN NO EVENT SHALL ALLERGAN, ITS SUPPLIERS, OR ITS DISTRIBUTORS BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES FOR BREACH OF ANY EXPRESS OR IMPLIED WARRANTY ON THE TrueTear® DEVICE. Some states do not allow limitation on how long an implied warranty lasts, and some states do not allow the exclusion or limitation of consequential or incidental damages, so the above limitations or exclusions may not apply to you.

This warranty gives you specific legal rights, and you may also have other rights, which vary from state to state. This warranty is valid only in the United States.

Quick Start Instructions

Getting started with your
TrueTear® device

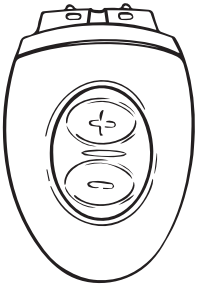
truetear®

Do I have everything I need?

a. Base
b. Case
c. USB cable
d. AC adapter

All images shown in this guide are for referencing only.

a.



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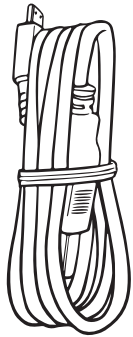
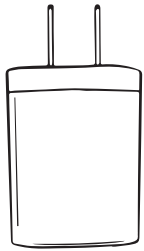


b.

d.

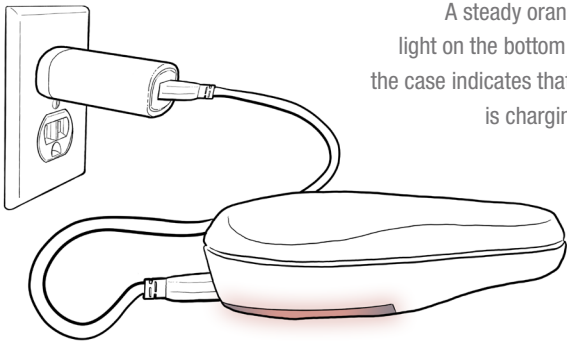


1. Get ready.

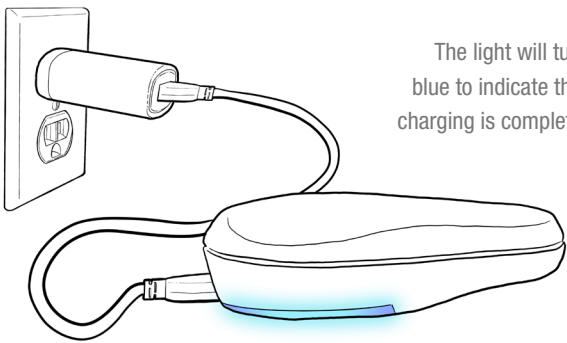
Plug case into wall outlet. Place the TrueTear® base in the case. Close the case to charge.

Ensure the base is fully charged before first use.

A full charge typically takes less than 4 hours.



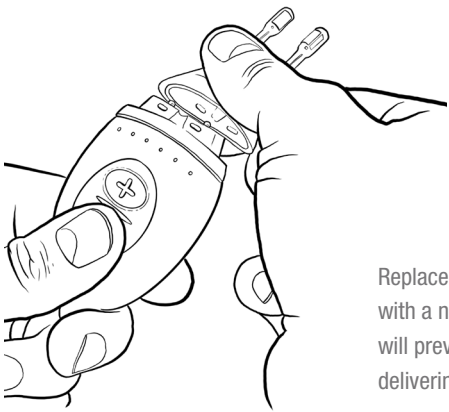
A steady orange light on the bottom of the case indicates that it is charging.



The light will turn blue to indicate that charging is complete.

2. Get set.

Remove a new disposable tip from the pouch. Align tab on disposable tip with notch on base, and connect.



Replace the tip every 28 days with a new tip. Failure to do so will prevent the device from delivering stimulation.

3. Activate!

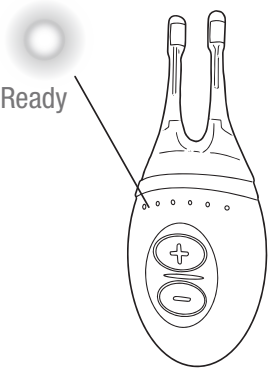
a. Hold the + button on the base for 2 seconds to turn on the device.

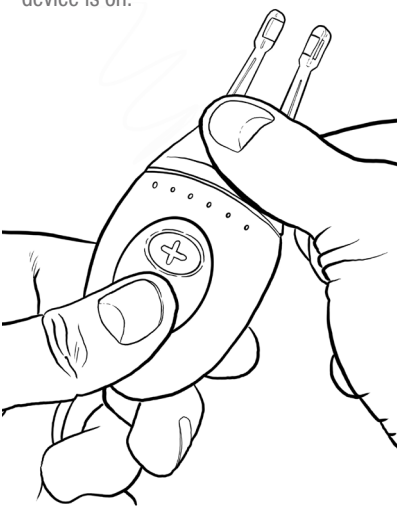
b. Use the + and – buttons to select the desired stimulation level.

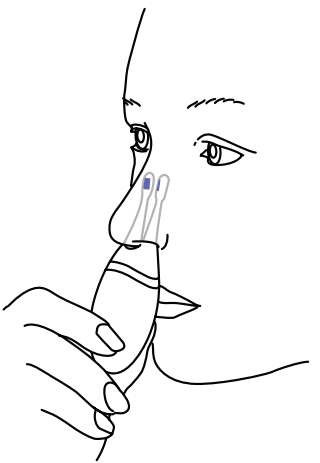
c. Place thumb near buttons of base, and gently insert the tip into the nose with the back of the base facing out.

A steady white light will appear on the base indicating that the device is on.

d. For effective stimulation, insert the tip towards the top and front of the nose.

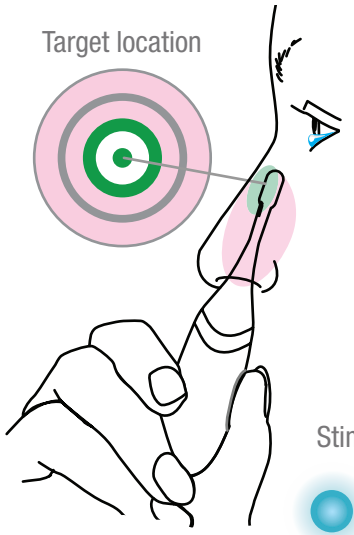




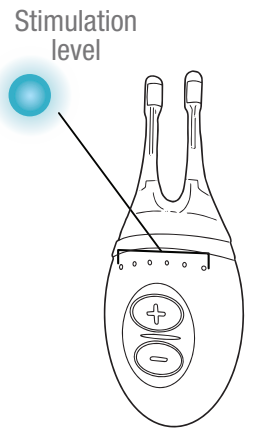


e. Gradually adjust the intensity (using the + and – buttons) until you feel a gentle tingling sensation in your nose. This feeling indicates you are stimulating the correct tissue location and tears will form.

f. The device turns off automatically after three (3) minutes. You can also turn it off manually by pressing the - button for 2 seconds.



The tip may be repositioned in your nose to achieve desired stimulation.



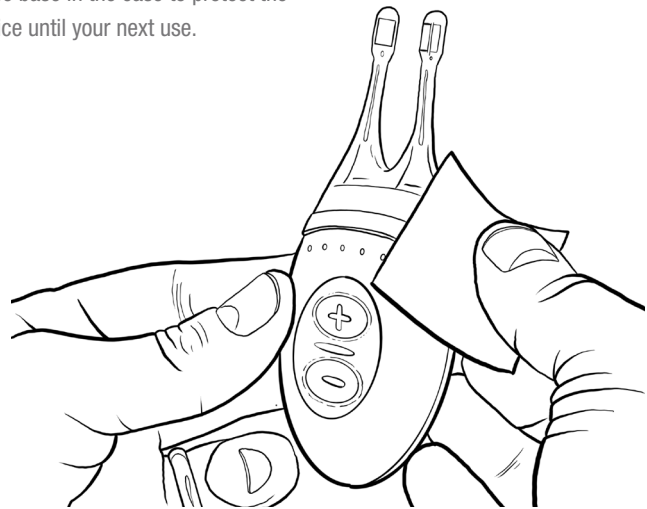
There are 5 stimulation levels. The base vibrates briefly and the blue lights indicate an increase or decrease in stimulation level. Consult your Patient Guide for additional information.

4. Keep it clean.

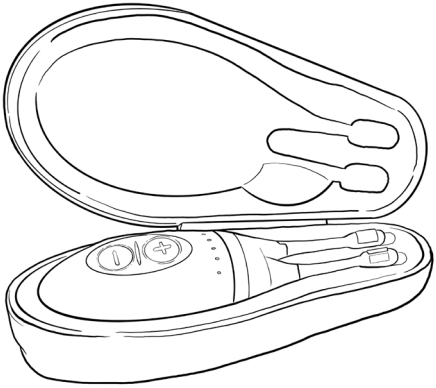
Wipe base, disposable tip, and case with an alcohol pad after use.

Place base in the case to protect the device until your next use.

Do not submerge or immerse the base & AC adapter in water or any other liquid.



Keep device in a clean, cool, and dry location. Avoid exposure to extreme temperatures and humidity.



truetear®

Please refer to your Instructions for Use for additional details or call Allergan® at 1-866-502-TEAR(8327).

Allergan

C-0530 Revision A (Sep 2019)