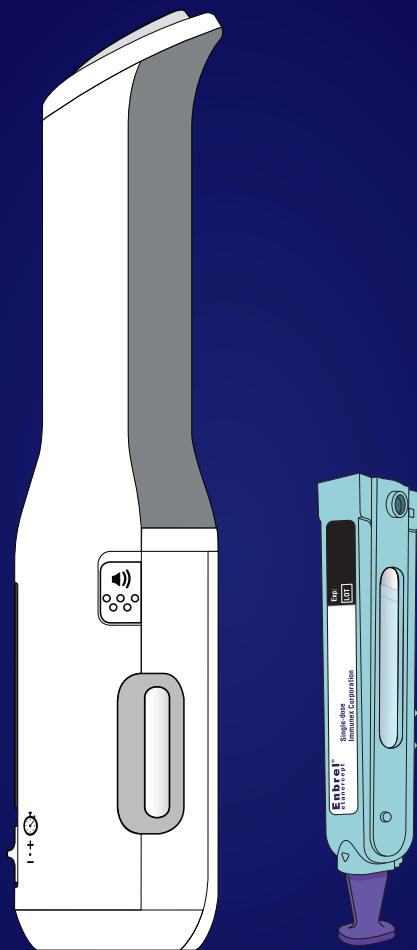


AutoTouch Connect™  
reusable autoinjector  
for use with  
Enbrel Mini® (etanercept)  
single-dose prefilled cartridge

# User Manual





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# Getting Started

This User Manual contains helpful information about your AutoTouch Connect™ reusable autoinjector (AutoTouch Connect). It includes resources, care details, and a troubleshooting guide to save for ongoing reference.

To learn how to inject using AutoTouch Connect, see your healthcare provider for injection training and use the Instructions for Use included in the carton.

## **Instructions for Use**

A fold-out, step-by-step Instructions for Use is provided in the carton, which provides you with full instructions to learn how to give yourself a safe, successful and accurate injection.

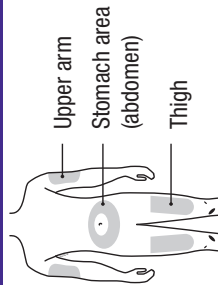
**Note: Please read the full Instructions for Use included in the carton.**

The Reference Guide on the next page should only be used when you have successfully completed an injection using the Instructions for Use.

# Reference Guide

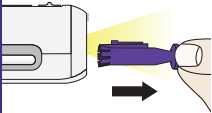
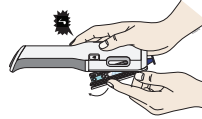
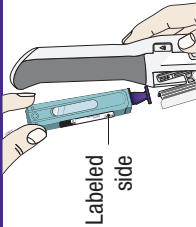
Prepare and clean your injection site.

1



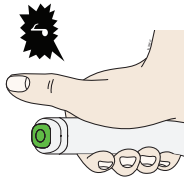
Hold the Enbrel Mini® single-dose prefilled cartridge with labeled side facing out and slide into door. Close door. Remove purple cap.

2



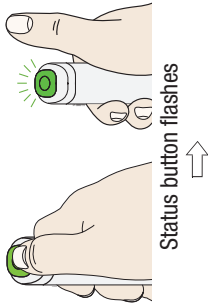
Place and hold on skin. Wait for the status button to turn green.

3



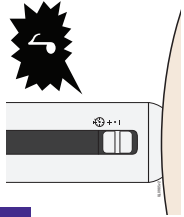
To start injection:  
Press and release the green status button.

4



Injection is finished when you hear a chime and all lights are turned off.

5



# Resources

***ENBREL Support***<sup>®</sup> provides personalized support services to ENBREL<sup>®</sup> patients, at no additional cost, including:

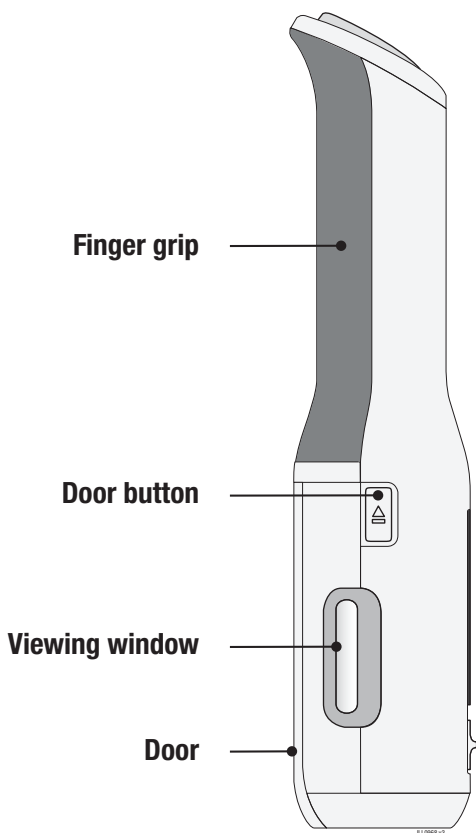
- Information about financial support options
- Supplemental injection training with an *ENBREL Nurse Partner*<sup>™</sup>
- Educational materials to help support you along the way

**Call 1-888-4ENBREL (1-888-436-2735) to enroll or visit [www.EnbrelSupport.com](http://www.EnbrelSupport.com) to find out more.**



# Guide to Parts

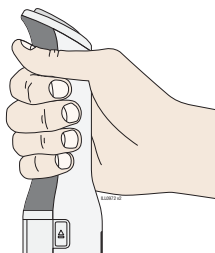
## AutoTouch Connect™ reusable autoinjector





## Finger grip

When injecting, hold the AutoTouch Connect™ reusable autoinjector with fingers wrapped around the gray finger grip.



## Door button

Press this button to open the door for insertion of the Enbrel Mini® single-dose prefilled cartridge. When your injection is finished, the door will open automatically.

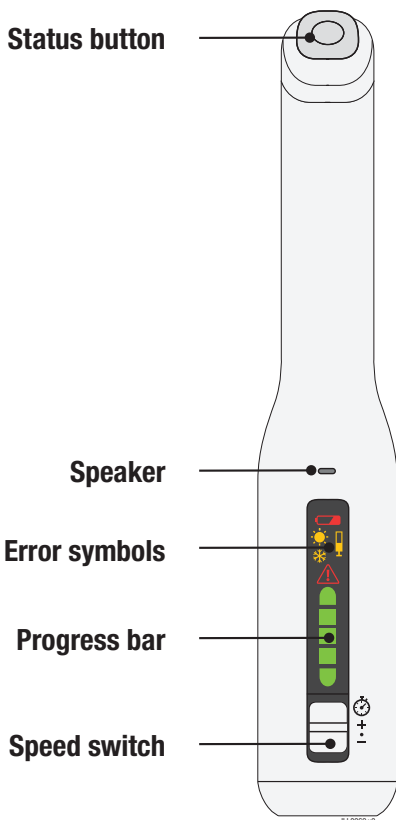
## Viewing window

During an injection, you can look through this window and see the plunger lowering to deliver your medicine. When AutoTouch Connect is awake, the viewing window will light up. If Enbrel Mini is in AutoTouch Connect, and the viewing window has no light, then press the status button to wake up AutoTouch Connect.

You will open this door and insert Enbrel Mini into AutoTouch Connect. The door will open automatically when your injection is finished. When inserted properly, Enbrel Mini will slide freely and completely into and out of the door.

# Guide to Parts

## AutoTouch Connect™ reusable autoinjector



## **Status button**

Press this button to begin an injection.  
Lights will indicate the status of  
your injection.

Green:

Ready to press and start injection.

Blinking green:

The needle is inserting and your injection  
is in progress.

Red:

An error has occurred. See the  
Troubleshooting section of this manual.

## **Progress bar**

These stacked green bars are fully lit  
when your injection starts, and the bar  
of lights decrease as your injection is in  
progress. The lights will disappear when  
your injection is finished.

## **Speed switch**

The AutoTouch Connect™ reusable  
autoinjector allows you to choose from  
three injection speeds. The pre-set speed  
is medium.

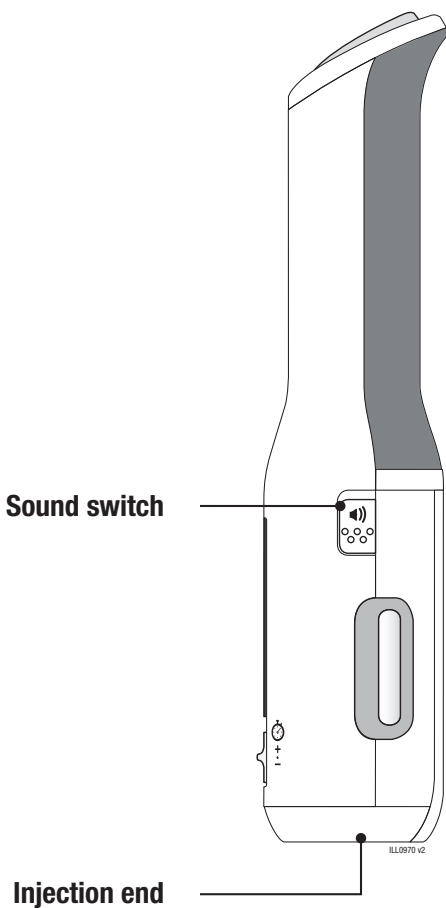
(+) is faster

(●) is medium

(−) is slower

# Guide to Parts

## AutoTouch Connect™ reusable autoinjector



## **Sound switch**

Sounds can be turned off and on.

(Sounds on) Slide switch down.

(Sounds off) Slide switch up so that the red bar is visible.

Note: Error sounds will still be heard if the sounds have been turned off.

## **Injection end**

The entire injection end must be touching your skin during injections. This is also where the needle will come out.

## **Skin sensor**

A skin sensor is located on the injection end. When the injection end is placed on skin the start button light will turn green. Hold the injection end flat and steady on your skin throughout the entire injection process.

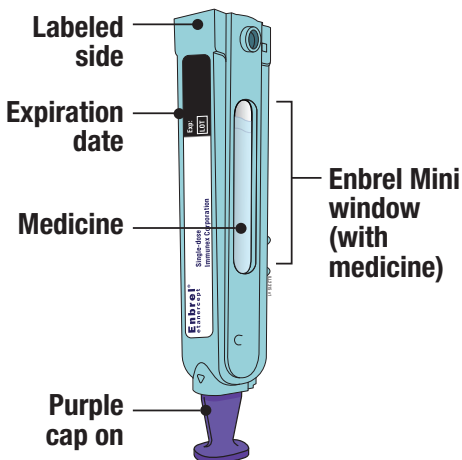
## **Site light**

When the Enbrel Mini® single-dose prefilled cartridge is loaded and the purple cap is removed, the injection end will light up to help you see your injection site.

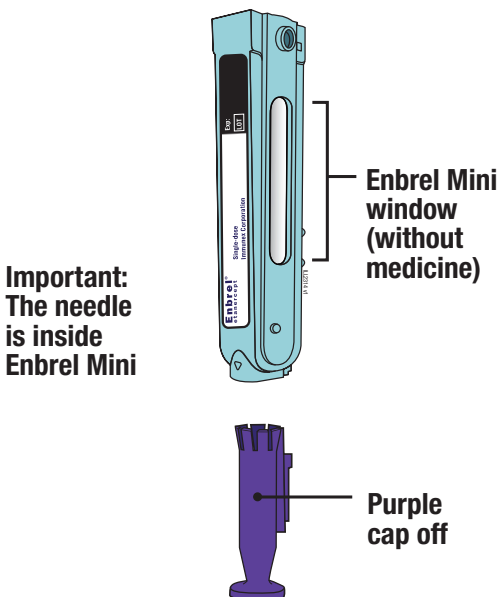
# Guide to Parts

## Enbrel Mini® single-dose prefilled cartridge

### Before use



### After use



## **Labeled side**

When inserting the Enbrel Mini<sup>®</sup> cartridge make certain that the labeled side is facing out. Then slide Enbrel Mini into the door. It will slide all the way down into the AutoTouch Connect<sup>™</sup> reusable autoinjector.

## **Expiration date**

Confirm expiration date printed on the label has not passed.

## **Enbrel Mini window**

This is where you will look to examine your medicine before starting an injection. See Instructions for Use for more information.

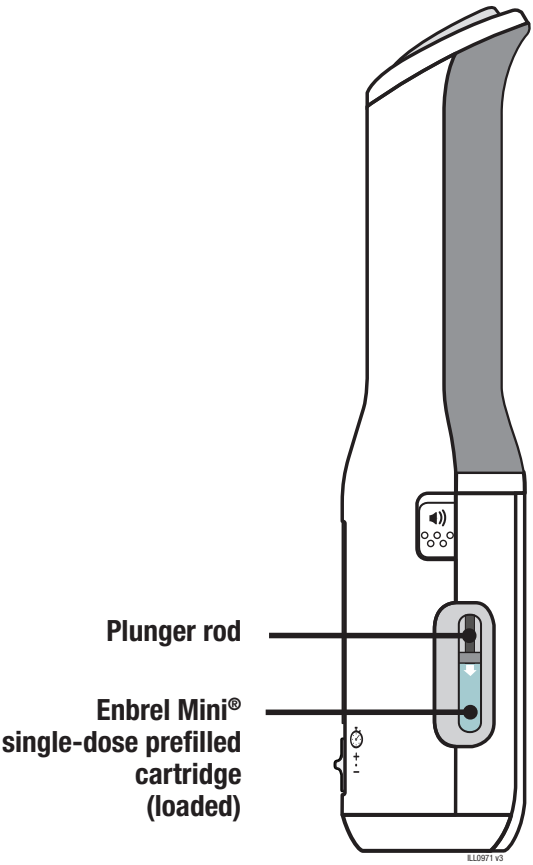
## **Purple cap**

The purple cap keeps your medicine safe. Do not remove the cap on Enbrel Mini before loading it into AutoTouch Connect. Load Enbrel Mini with the purple cap on, and remove the cap only when you are ready to give yourself the injection. **Do not** leave the purple cap off for more than five minutes. This can dry out the medicine.

See the Instructions for Use for more detail about loading Enbrel Mini and when to remove the purple cap.

# Guide to Parts

## AutoTouch Connect™ reusable autoinjector





## **How it works.**

When you push the status button to start an injection, the AutoTouch Connect™ reusable autoinjector pushes a hidden needle out of the Enbrel Mini® single-dose prefilled cartridge into your skin. Then, a plunger rod will push into Enbrel Mini, injecting medicine into your body. After the medicine is injected, the rod will pull back up and the needle will withdraw from your skin. After a successful injection all lights will turn off and the door will open. The needle stays hidden at all times during the injection process.

## **What you will hear.**

Needle insertion and plunger rod are operated by motors. You will hear a motor noise as the rod moves down and then back up again. Whenever you hear a motorized noise, you will know that an injection is in progress.

## **What you will see.**

During the injection, the viewing window light will be on, and the plunger rod will move through the window. Also during the injection, the status light will be flashing green, and the progress bar will decrease. After a successful injection, the progress bar, and status button will turn off, and AutoTouch Connect will open the door.

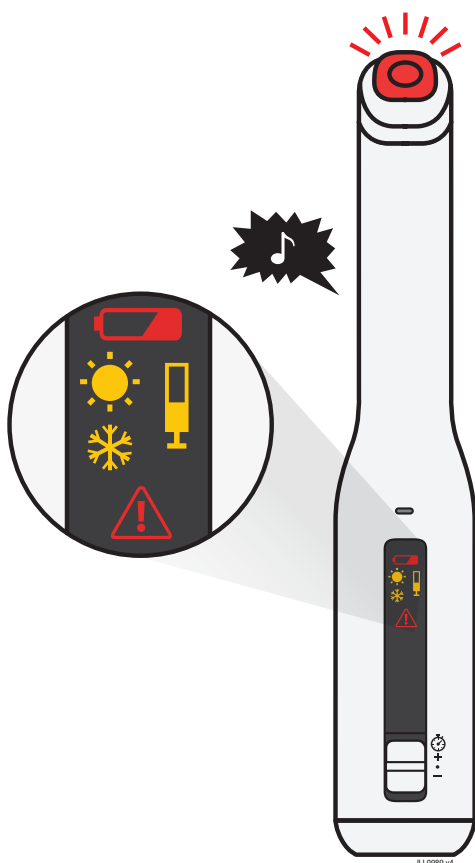
If the status light turns red, and beeps for more than a few seconds, an error has occurred. Use the troubleshooting section of this manual to see what to do if this happens.

# Troubleshooting: Error Symbols

## Error Symbols

The AutoTouch Connect™ reusable autoinjector makes a chime sound, lights the status button red, and displays an error symbol if there is a problem.

See the following description of each error symbol, possible reasons for the error, and actions you can take.





## Low battery

**Symbol:** Red battery and error sound.

**Problem:** The battery is running very low. Less than three weeks or three injections remain. The battery is not replaceable or rechargeable.

**Action:** Call 1-888-4ENBREL (1-888-436-2735) for a replacement AutoTouch Connect™ reusable autoinjector.



## Battery dead

**Symbol:** Red battery and red triangle with exclamation point, red status button, and error sound.

**Problem:** The AutoTouch Connect reusable autoinjector battery is dead.

**Action:** Call the 1-888-4ENBREL (1-888-436-2735) for a replacement AutoTouch Connect reusable autoinjector.



## Too hot or cold

**Symbol:** Orange sun and a snowflake, and an error sound.

**Problem:** AutoTouch Connect is too hot or too cold. This will lock the door.

**Action:** Place AutoTouch Connect at room temperature in a safe, dry place and allow it to naturally cool or warm to room temperature. Then try again. Store the AutoTouch Connect reusable autoinjector in a dry, safe place, such as a cabinet or drawer at 50 °F to 104 °F (10 °C to 40 °C).

# Troubleshooting: Error Symbols



## Enbrel Mini® problem

**Symbol:** Orange Enbrel Mini single-dose prefilled cartridge with blinking red status button and error alert sound.

**Problem:** There are five possible reasons you are getting this error. Please read below.

**Problem #1:** The purple cap was removed before inserting Enbrel Mini.

**Action:** Wait for the error to clear and close the door without Enbrel Mini in, and try again with a new Enbrel Mini. Make sure to leave the purple cap on until Enbrel Mini has been placed inside the AutoTouch Connect™ reusable autoinjector and the door is closed. Call 1-888-4ENBREL (1-888-436-2735) for a replacement Enbrel Mini.

**Problem #2:** Sensor lost skin contact during injection.

**Action:** Hold the injection end of AutoTouch Connect on your skin throughout the entire injection until the green status button turns off, even if the motor sounds stop. Lifting or shifting on your skin during injection may lead to an incomplete injection. Call your healthcare provider if you feel you have given yourself an incomplete injection.

**Problem #3:** Enbrel Mini® single-dose prefilled cartridge is defective or not recognized as an Amgen product.

**Action:** Remove Enbrel Mini.

Replace with a new Enbrel Mini.

Call 1-888-4ENBREL (1-888-436-2735) for a replacement Enbrel Mini.

**Problem #4:** Door is held closed for more than one minute.

**Action:** Remove your hand from the door.

When the door opens, remove Enbrel Mini from AutoTouch Connect™, if present.

Wait for the error symbol to stop blinking and close the door. If you have not given yourself an injection, place a new Enbrel Mini in AutoTouch Connect and continue. If the error symbol remains on, call 1-888-4ENBREL (1-888-436-2735).

**Problem #5:** AutoTouch Connect has been dropped.

**Action:** A dropped AutoTouch Connect is not safe to use. Call 1-888-4ENBREL (1-888-436-2735) for a replacement.

# Troubleshooting: Error Symbols



## Needle Exposure

**Symbol:** Orange Enbrel Mini® single-dose prefilled cartridge, a red triangle with an exclamation point, red status button, and error sound.

**Problem:** A problem occurred during an injection and the needle may be exposed.

**Action:** If there is still fluid in Enbrel Mini, an incomplete dose may have been injected. Call your healthcare provider if you feel you have given yourself an incomplete injection. Call 1-888-4ENBREL (1-888-436-2735) for further assistance with your AutoTouch Connect™.

Use caution when both Enbrel Mini problem symbol and the AutoTouch Connect reusable autoinjector failure symbols are lit as the needle may be exposed. Take special care when removing and handling Enbrel Mini. Remove Enbrel Mini then put it in an FDA-cleared sharps disposal container.



## **AutoTouch Connect™**

### **Reusable Autoinjector Failure**

**Symbol:** Red triangle with an exclamation point, red status button, and error sound.

**Problem:** Several errors have occurred or AutoTouch Connect has stopped working.

**Action:** Reset AutoTouch Connect.

#### **To reset AutoTouch Connect:**

Hold AutoTouch Connect away from skin and press the status button to wake AutoTouch Connect. The failure symbol should begin blinking and a chime should sound.

While the failure symbol is blinking, press and hold door button until all symbols are temporarily displayed and the status button blinks green. The door button should be held for at least 10 seconds. After a successful reset, if an Enbrel Mini® single-dose prefilled cartridge is still inside AutoTouch Connect, remove it. Close the AutoTouch Connect door. Then, for the next injection, start by pressing the door button to open Enbrel Mini door.

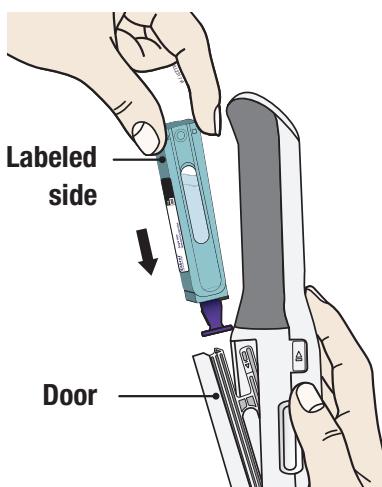
If AutoTouch Connect does not respond after three attempts to reset, call 1-888-4ENBREL (1-888-436-2735).

# Troubleshooting: Common Problems

## Common Problems

**Enbrel Mini® single-dose prefilled cartridge is difficult to insert into the door.**

Never force Enbrel Mini into the door. When positioned correctly, it will fall freely and completely into and out of the door. If it is difficult to load, double check that you are holding Enbrel Mini as shown.



- Purple cap is facing down
- Label facing outwards (away from the handle)



## **Injection does not start when pressing the status button.**

**Reason #1:** Place the AutoTouch Connect™ reusable autoinjector on your skin and wait for the status button to turn green. A skin sensor is located on the injection end. You cannot start an injection unless the injection end of AutoTouch Connect is touching your skin. Hold the injection end on your skin throughout the entire injection.

**Reason #2:** AutoTouch Connect may be asleep. To conserve battery power, AutoTouch Connect goes into a “sleep mode” after three minutes of no activity. If it seems unresponsive/asleep, remove AutoTouch Connect from your skin and press the status button to wake it up.

---

## **An Enbrel Mini® error symbol appears immediately after loading the Enbrel Mini single-dose prefilled cartridge.**

**Reason:** This will happen if the purple cap has been removed before inserting Enbrel Mini into the door. Do not reuse or recap. Begin again using a new Enbrel Mini.

Do not remove the purple cap until after Enbrel Mini has been inserted into AutoTouch Connect.

# Troubleshooting: Common Problems

## **Injection aborts or an error symbol appears while the injection is in process.**

The AutoTouch Connect™ reusable autoinjector will abort an injection if the sensor loses skin contact. Avoid adjusting or moving AutoTouch Connect during an injection. Hold AutoTouch Connect on your skin until the green status light turns off and the injection is finished. Shifting, repositioning or lifting from your skin during injection may lead to an incomplete dose.

---

## **AutoTouch Connect door will not remain closed.**

**Reason #1:** At the end of an injection, the door cannot be closed with a used Enbrel Mini® single-dose prefilled cartridge inside.

**Reason #2:** When AutoTouch Connect experiences a failure, the door will open and remain open. If this occurs, call 1-888-4ENBREL (1-888-436-2735).

---

## **A chime is repeating but no error lights are showing.**

If the door is left open for more than 45 seconds, a chime will sound. Close the door to silence the chime.

---

## **AutoTouch Connect is not producing chiming sounds.**

The sound setting may be off. Turn on by sliding the sound switch down.

## **Enbrel Mini® single-dose prefilled cartridge will not eject.**

**Reason #1:** If the viewing window has no light, press the status button to wake up AutoTouch Connect™. Then press and hold the door button for at least two seconds to eject.

**Reason #2:** If Enbrel Mini does not eject automatically at the end of an injection, there may be a problem. Call 1-888-4ENBREL (1-888-436-2735).

---

## **The purple cap is very hard to remove.**

The purple cap should not be removed outside of the AutoTouch Connect reusable autoinjector. It should be removed after it is loaded into AutoTouch Connect, when you are ready to inject. If Enbrel Mini is loaded and the purple cap is difficult to remove, call 1-888-4ENBREL (1-888-436-2735).

---

## **The injection speed will not change during injection.**

Once the injection starts, the speed cannot be changed. Always set the speed prior to injection.

---

## **The injection is faster or slower than expected.**

The speed switch may have been moved unintentionally. Check the speed setting prior to starting each injection.

# Storage & Handling

## Storage

### AutoTouch Connect™ reusable autoinjector

Do	Do Not
<b>Do</b> store AutoTouch Connect in dry, safe place at room temperature such as a cabinet or drawer.	<b>Do not</b> store AutoTouch Connect in the refrigerator with the Enbrel Mini® single-dose prefilled cartridges.
<b>Do</b> store AutoTouch Connect in its carton when not in use.	<b>Do not</b> store AutoTouch Connect in extreme heat or cold, or in highly humid environments like the bathroom.

## Handling

### AutoTouch Connect reusable autoinjector

Do	Do Not
<b>Do</b> inspect AutoTouch Connect for physical damage or defects before each use.	<b>Do not</b> use AutoTouch Connect if it has been dropped on a hard surface.
	<b>Do not</b> use AutoTouch Connect if any part appears cracked or broken.
	<b>Do not</b> leave AutoTouch Connect door open for more than 45 seconds when not in use. (Chime will sound and AutoTouch Connect will go to sleep).
	<b>Do not</b> crush, burn, heat, or incinerate the battery as this may cause a risk of fire or explosion.
	<b>Do not</b> use AutoTouch Connect if it has been dropped on a hard surface. Call 1-888-4ENBREL (1-888-436-2735) for a replacement.

**Storage and Handling**  
**Enbrel Mini® single-dose**  
**prefilled cartridge**

Do	Do Not
<b>Do</b> store unused Enbrel Mini in the refrigerator.	<b>Do not</b> freeze the unused Enbrel Mini. <b>Do not</b> warm Enbrel Mini using a heat source such as hot water or a microwave.
<b>Do</b> make sure to hold Enbrel Mini with the labeled side facing out and slide into the door.	<b>Do not</b> force Enbrel Mini into the door. <b>Do not</b> use Enbrel Mini if it has been dropped on a hard surface.
<b>Do</b> put Enbrel Mini in the door before removing the purple cap.	<b>Do not</b> remove the purple cap before inserting into AutoTouch Connect™. <b>Do not</b> re-use or recap Enbrel Mini.
<b>Do</b> discard the purple cap immediately after removing to avoid a choking hazard.	<b>Do not</b> use Enbrel Mini if any part appears cracked or broken.

# Cleaning Instructions

## Cleaning

### AutoTouch Connect™ reusable autoinjector

Do	Do Not
<b>Do</b> use an alcohol wipe to clean the injection end of AutoTouch Connect before and after injections.	<b>Do not</b> clean AutoTouch Connect with water.
<b>Do</b> use an alcohol wipe to clean all other areas of AutoTouch Connect as desired.	<b>Do not</b> immerse AutoTouch Connect in water.
	<b>Do not</b> wipe AutoTouch Connect with household cleanser or soap.

# Warnings

No modification of the AutoTouch Connect™ reusable autoinjector is allowed.

No part of AutoTouch Connect can be repaired or replaced, including the battery.

Do not put anything inside the door other than an Enbrel Mini® single-dose prefilled cartridge.

Do not immerse AutoTouch Connect in water.

Do not reach inside AutoTouch Connect.

Do not crush, burn or heat AutoTouch Connect.

AutoTouch Connect contains moving parts. Keep your fingers out of openings in the injection end or open door.

Keep AutoTouch Connect and Enbrel Mini out of the reach of children.

If AutoTouch Connect fails, the maximum amount of medicine you could receive is the contents of the full Enbrel Mini, which is the correct dose.

Use caution if an error occurs as the needle may be exposed.

Carefully dispose of Enbrel Mini in an FDA approved sharps container.

Call your healthcare provider if you have any concerns regarding an incomplete injection.

When travelling, keep AutoTouch Connect with you, in your carry-on bags.

Do not dispose of AutoTouch Connect in the household trash.

Call 1-888-4ENBREL (1-888-436-2735) for a replacement.

# What is the *Bluetooth*<sup>®</sup> wireless feature?

This AutoTouch Connect<sup>™</sup> reusable autoinjector has an optional *Bluetooth*<sup>®</sup> wireless feature to automatically record your injections. **This wireless feature will not affect your injection steps.** Whether or not you use this wireless feature, please make sure you follow steps in the Instructions for Use. To use this feature, download and set up the Embark<sup>®</sup> – Patient Support app. After Embark is set up and paired with AutoTouch Connect, follow all injection instructions as you normally would.

AutoTouch Connect transmits a signal to the Embark app on your mobile device and keeps track of your Enbrel injections.

For questions about the Embark app and this feature, go to [www.enbrel.com](http://www.enbrel.com).

Remember, this feature is optional and you can inject without using the Embark app. Always follow all steps found in the Instructions for Use.

## Embark – Patient Support app



The Embark app is a medication reminder that allows you to schedule and record your injections using your mobile device.

With Embark you can:

- Set up medication and appointment reminders.
- Record your Enbrel injection sites.
- Sign up for ENBREL Support<sup>®</sup> programs.
- Access Enbrel educational materials.



## **Pairing AutoTouch Connect™**

When setting up the Embark® app, bring AutoTouch Connect next to your mobile device, then open and close the AutoTouch Connect door.

The Embark app will guide you through pairing your AutoTouch Connect reusable autoinjector. The AutoTouch Connect uses standard *Bluetooth*® authentication and encryption for its wireless data security.

Once paired, AutoTouch Connect will try to sync with the Embark app for up to 48 hours after every injection. To sync at any time, bring AutoTouch Connect next to your mobile device, then open and close the AutoTouch Connect door.

No patient information is stored.

## **What to do if you lose your phone or get a new phone**

The Embark app can only be synced to one mobile device at a time. If you lose your mobile device (or get a new one), you can download and log in to the Embark app on your new mobile device.

You can sync AutoTouch Connect to your new mobile device and retrieve all your previous injection history, reminders, and notifications on the Embark app.

Once you have synced the Embark app to your new mobile device, you cannot access the Embark app on your old mobile device. You will not receive medication, refill, and appointment reminders from the Embark app on your old mobile device.

# What is the *Bluetooth*<sup>®</sup> wireless feature?

## **Important Information Required by the Federal Communications Commission (FCC)**

FCCID: 2AGZ4–ATCONNECT

The AutoTouch Connect<sup>™</sup> reusable autoinjector contains a *Bluetooth*<sup>®</sup> wireless feature.

AutoTouch Connect complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

1. AutoTouch Connect may not cause harmful interference.
2. AutoTouch Connect must accept any interference received, including interference that may cause undesirable operation.

Modification to AutoTouch Connect shall not be made without the written consent of Amgen.

Unauthorized modification may void the authority granted under FCC rules permitting the operation of AutoTouch Connect.

AutoTouch Connect 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. AutoTouch Connect 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.

If AutoTouch Connect™ does cause harmful interference to radio or television reception, which can be determined by moving AutoTouch Connect far away and back, 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 AutoTouch Connect and interference receiver.
- Consult the dealer or an experienced radio/TV technician for help.

The *Bluetooth*® word mark and logos are registered trademarks owned by Bluetooth Special Interest Group (SIG) Inc. and any use of such marks by Amgen is under license. Other trademarks and trade names are those of their respective owners.

# Technical Information

## **International Protection Rating**

The international protection code for the AutoTouch Connect™ reusable autoinjector when stored in its carton is IP52. Which means it is protected from limited dust ingress and from limited dripping water. AutoTouch Connect is not rated for dust or fluid ingress when not stored in its carton.

## **Environmental Operating Range**

AutoTouch Connect will operate in the temperature range of 50 °F to 104 °F (10 °C to 40 °C), and 20% to 90% relative humidity, and at elevations from 197 feet below sea level to 11,483 feet above sea level (-60 m to 3500 m).

## **Environmental Storage Range**

Transport and store AutoTouch Connect in its carton, in a dry place at room temperature: 50 °F to 104 °F (10 °C to 40 °C). AutoTouch Connect has been tested to a brief exposure at -40 °F to 158 °F (-40 °C to 70 °C), 50% relative humidity, and pressure equivalent of 14,000 feet (4267 m).

## ***Bluetooth®* Characteristics**

The AutoTouch Connect is designed to communicate with the Embark® app running on a Bluetooth enabled mobile device. The Bluetooth technology in the AutoTouch Connect complies with the Bluetooth Core Specification v5.0 and is qualified by Bluetooth SIG. The AutoTouch Connect has been designed to transmit default OdBm standard industrial, scientific and medical (ISM) 2.4 GHz band radio frequency (RF) and covers up to 10 meters communication range.

## **Quality of Service and Security Information**

The AutoTouch Connect™ autoinjector establishes an authenticated and encrypted connection with the Embark® app running on a mobile device. Initial setup requires physical access to the autoinjector labeled serial number for user input at initial pairing/secure bonding. The app will walk you through this setup process.

Data is transferred from the autoinjector on a one-to-one paired mobile device for ensuring data integrity and quality of service (QoS). Data transferred is read-only and no patient information is stored on the autoinjector.

Data can be sent at any time, and temporary loss of proper QoS will be resolved upon resumed connection to the app. If connection with the app drops and re-establishes, data transfer resumes with data integrity verification. Data transfer latency or asynchronization does not affect drug delivery tracking as data will be confirmed upon reconnection.

## **Electromagnetic Compatibility**

Portable and mobile RF communications equipment can affect medical electrical equipment. Avoid operating AutoTouch Connect near microwave ovens, wireless routers, baby monitors or other common household electronics that operate using RF transmission, including RFID emitters. A minimum distance of 30 cm (12 inches) is recommended.

Avoid operating AutoTouch Connect near high magnetic or other fields such as those around MRI, CAT, or PET scanners.

AutoTouch Connect emits RF.

# Technical Information

## Electromagnetic Emissions

The autoinjector is intended for use in the electromagnetic environment specified below. The user of the autoinjector should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions (CISPR 11)	Group 1	The autoinjector uses RF energy for its internal and system interface functions. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions (CISPR 11)	Class B	The autoinjector is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

## Electromagnetic Immunity

The autoinjector is intended for use in the electromagnetic environment specified below. The user of this autoinjector should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	$\pm 8$ kV Contact $\pm 15$ kV Air	$\pm 15$ kV Contact $\pm 20$ kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Power Frequency 50/60 Hz Magnetic Fields IEC 61000-4-8	30 A/m	30 A/m at 60 Hz	Power frequency magnetic fields should be that of typical commercial or hospital environment.
RF Electro-magnetic Field IEC 61000-4-3	10 V/m 80 MHz – 2.5 GHz	(E1) = 10 V/m 26 MHz – 2.7 GHz	Portable and mobile RF communications equipment should be separated from the device by no less than the distances of 30 cm.

# Technical Information

## **Electrical characteristics**

The AutoTouch Connect™ reusable autoinjector uses a non-replaceable, non-rechargeable DL123 Lithium battery. The battery has a nominal voltage of 3.0 V with a capacity of 1400 mAh.

The autoinjector enclosure is a Type BF applied part: The skin sensor and other electronics are isolated from the skin.

## **Dimensions and weight**

AutoTouch Connect weighs 0.4 pounds (180 grams), and is 9 inches (228 mm) tall by 1.5 inches (38 mm) wide by 1.8 inches (45 mm) deep.

## **Biocompatibility and electrical isolation**












The autoinjector enclosure is intended to come into contact with the skin (see Guide to Parts). It is a Type BF applied part. This means that it is electrically isolated from the battery. The injection end and finger grip of AutoTouch Connect are made of ABS plastic. This material has been biocompatibility-tested for skin sensitivity and irritation.

## **Contraindications**

This device is contraindicated for use in a Magnetic Resonance (MR) environment. For contraindications of ENBREL® please refer to ENBREL prescribing information.



# Symbol Table

	Do not re-use
	Use-by date (Exp. date)
	Lot number
	Keep dry
	Serial number
	Type BF applied part The autoinjector enclosure is a Type BF applied part.
	CAUTION, consult accompanying documents
	Refer to instructions for use
	Do not use if package is damaged
	This product contains dry natural rubber
	Magnetic Resonance (MR) Unsafe



**Manufactured by:**

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