MediMergent

IMPRIS
ENGAGING IMMUNO-PROTECTION INTERVENTION STUDY

PHARMACY MANUAL

STUDY ESR 22-21698

Real World Evaluation of the Effectiveness of AZD7442 for Prevention of SARS-CoV-2 Infection in Immuno-Suppressed Cancer Patients

Short Title:
AZD Immuno-Suppressed Program (AISP)

Document Approved by:

Bruce Garrett, MD Chief Operating Officer, MediMergent	Date

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1. EIMPRIS AZD7442 INVESTIGATIONAL PRODUCT RECEIPT, STORAGE, ACCOUNTABILITY AND RETURN

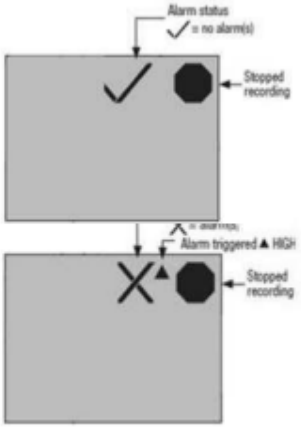
Manufactured for: AstraZeneca Pharmaceuticals, L.P.

Product: AZD7442 (Evusheld) is a combination of two long-acting antibodies tixagevimab (AZD8895) co-packaged with cilgavimab (AZD 1061). Refer to Section 23.4 to 23.7 of the ESR 22-21698 study protocol for additional background information on AZD7442. Additionally, the Fact Sheet for Patients, Parents and Care Givers and the Fact Sheet for Healthcare Providers: Emergency Use Authorization For Evusheld™ (tixagevimab co-packaged with cilgavimab) revised 06/2022 information is available in Attachment #2. A copy is also available in the EIMPRIS Resource Library through the following pathway:

EIMPRIS System Clinical Trials Management dashboard → Studies → Study name (EIMPRIS) →Resource → Drug Fact Sheets

PRODUCT RECEIPT PROCEDURES

1. Upon receipt of the study product at the study site, the shipping container should be immediately opened by the pharmacist (or other study staff trained on the study protocol).
2. Remove the TempTale from the package and follow the Shipment Receipt Instructions. NOTE:
   - Check the display of the TempTale for the presence of an alarm:



If the Stop icon and the '✓' icon are present, the shipment has arrived in acceptable condition. Store the supplies in the appropriate temperature-controlled conditions.

If the '✕' Alarm icon is visible, the temperature has been outside the desired range. Quarantine the supplies in the appropriate temperature-controlled conditions and follow the Sponsor's instructions for reporting a Temperature Out-of-Range event.

3. Insert USB drive into your computer and download the TempTale storage data. Upload a copy of the TempTale data report to your SharePoint regulatory file. See the TempTale® Ultra Temperature Monitor Instructions for Use in Appendix 1 for instructions on how to upload and save the TempTale data.
4. Upload a copy of the packing list/product shipment documentation and your TempTale data to your SharePoint regulatory file.

PRODUCT STORAGE

- Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. The refrigerator must be temperature monitored.
- Do not freeze. Do not shake
- This product is preservative-free and therefore, at time of drug administration, the prepared syringes should be administered immediately.
- If immediate administration is not possible, and the prepared tixagevimab and cilgavimab syringes need to be stored, the total time from vial puncture to administration must not exceed 4 hours:
    a. in a refrigerator at 2ºC to 8ºC (36ºF to 46ºF), or
    b. at room temperature up to 25°C (77°F)

PRODUCT ACCOUNTABILITY AND RETURN

AZD7442 is provided by Thermo Fisher and is designated only for treatment of patients enrolled in this study.

Product receipt at sites will be recorded on the EIMPRIS Investigational Product Accountability Log. This document can be accessed through the following pathway should you need a copy of the log (Sample log in Attachment #1):

EIMPRIS System Clinical Trials Management dashboard → Studies → Study name (EIMPRIS) →Resources → Study Logs/forms

Product use will also be accounted for by drug administration in the patient dashboard.

MediMergent will provide instructions and the form for return/destruction of unused product at the end of the study.

2. TEMPERATURE EXCURSIONS

If at any time (in-transit or during storage at the study site) a temperature excursion is noted from the allowable temperature range provided above, complete the EIMPRIS Temperature Excursion Report (Sample report in Attachment #2). This report can be accessed through the following pathway:

EIMPRIS System Clinical Trials Management dashboard → Studies → Study name (EIMPRIS) →Resources → Drug Fact Sheets.

Email the report as soon as possible to your MediMergent contact and be sure to copy Audrey Gamble at MediMergent. Her email is - agamble@MediMergent.com.

Quarantine affected product (clearly displayed as quarantined and not for use) under appropriate storage conditions & do not use until notified by MediMergent whether or not the product can be used. MediMergent will complete the bottom section of the Temperature Excursion Report and provide you with a copy documenting the final determination of whether the product can be used or not.

A copy of the report will be uploaded to the SharePoint Regulatory Portal for your site.

3. STUDY TREATMENT ADMINISTRATION INSTRUCTIONS

AZD7442 treatment will be administered at Baseline and Day 180 of the study (See Protocol Section 9.3 schedule of activities). Refer to Section 9.2 of the ESR 22-21698 study protocol for AZD7442 treatment administration instructions. Additionally, you may review drug administration videos in the Provider Training Portal (provider.eimpris.com). Go to Provider Training Portal → Treatment Appointment.

ATTACHMENT #1 - Sample EIMPRIS Investigational Product Accountability Log

EIMPRIS
ENGAGING IMMUNO-PROTECTION INTERVENTION STUDY

INVESTIGATIONAL PRODUCT ACCOUNTABILITY LOG

Sponsor Name/Study Name: _____ **Protocol:** _____

Principal Investigator: _____ **Site No.:** _____

Product Receipt						Product Utilization			Product Dispensation		
Investigational Product	Quantity Received	Investigational Product Number	Expiration Date	Date Received	Received by (Initials)	Patient Number	Date Dispensed	Quantity used, returned or disposed	Date Returned	Date Disposed	Initials

_____ _____

Research Coordinator's Signature Date

Include date of return/disposal and initials of person returning/disposing the product.

Investigational Product Accountability Page: 1 of 1

ATTACHMENT #2 - Sample EIMPRIS Temperature Excursion Report

EIMPRIS Temperature Excursion Report

Protocol: ESR 22-21698
Product: AZD7442
Manufacturer: AstraZeneca

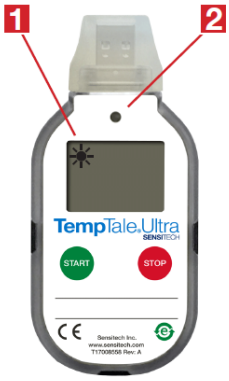
SITE INFORMATION		
PI Name		
Site #		
Date Reported		
TEMPERATURE EXCURSION INFORMATION		
Lot #		
Expiry Date		
Date(s) of Excursion: Start Date - End Date		
Excursion Type: (select one – high or low temp)	☐ High Temperature	☐ Low Temperature
	Maximum Temp (°C or°F):	Minimum Temp(°C or°F):
	Duration(days, hrs or min):	Duration(days, hrs or min):
Excursion Location:	☐ In Transit (Provide Temp Tale data)	☐ In storage at site
Was product placed in Quarantine?	☐ Yes	☐ No (explain below)
Product Continues to be Stored under Appropriate Conditions?	☐ Yes	☐ No (explain below)
Excursion details:		

** Email report to agamble@medimergent.com and to your MediMergent project contact**

Section 2 (Completed by MediMergent)	
Product can be used?	☐ - Yes, upon reviewing the details of the excursion and drug stability documentation, it is concluded the drug can be used and the site may continue to enroll patients (remove from quarantine & continue to store under required conditions) ☐ - No (complete product return form and return to clinical supply depot)
Name (print)	
Signature/Date	
Comment(s):	

APPENDIX 1 - TempTale® Ultra Temperature Monitor Instructions

The TempTale® Ultra temperature monitor can be programmed with custom start-up delays, measurement intervals, and time-temperature alarm settings.



Starting a TempTale® Ultra Monitor

- Press and hold the Start button (1 – 3 seconds) until the Sunshine icon appears in the upper left corner of the LCD screen (1). The LED (2) will blink GREEN (if LED startup option was programmed) to indicate that the monitor has started.
- The TempTale Ultra will begin to record data after the programmed start-up delay period has passed.

Marking an Important Event (Date Stamp)

- To mark an event while the monitor is recording, press and release the Start button. An Arrow icon will appear briefly in the top of the LCD screen and trip summary data will appear.
- Press and release the Start button to cycle through the trip summary data. Data appears in the following order:
  1. *Average temperature*
  2. *Min. recorded temperature*
  3. *Max. recorded temperature*
  4. *Total time above high limit*
  5. *Total time below low limit*
  6. *Current temperature reading (This is a programmable option.)*

Alarming

When the TempTale Ultra monitor is exposed to temperatures outside the programmed alarm limits, an X will appear at the top of the screen. The ▲ icon will display if the high alarm was triggered, the ▼ icon will display if the low alarm was triggered.

Stopping a TempTale Ultra Monitor

There are two ways to stop a TempTale Ultra monitor:

- Press and hold the Stop button (1 – 3 seconds) until the Stop icon appears in the upper right corner of the screen.
- Plug the monitor into a USB port on a computer or printer.

Receiving a TempTale Ultra Monitor

- Recover the TempTale Ultra monitor, then press and hold the RED Stop button (1 – 3 seconds) to manually stop the unit.
  NOTE: If the monitor is not stopped manually, the TempTale Ultra monitor will continue to record data until it is plugged into a USB port on the computer or until the programmed trip length is reached.
- Verify the "Stop" icon is visible on the display.

Retrieving TempTale Ultra Monitor Data Files

- Plug the monitor into a USB port on the computer. The LED will blink RED while the Adobe® PDF report and TTV data file are being created. When the RED LED stops blinking and displays solid GREEN, the file generation process is complete. The files are now accessible on a removable drive (Windows® 7, 8.1, and 10).
  NOTE: Do not disconnect the monitor from the USB port while the RED LED is blinking.

Managing and Viewing TempTale Ultra Monitor Files

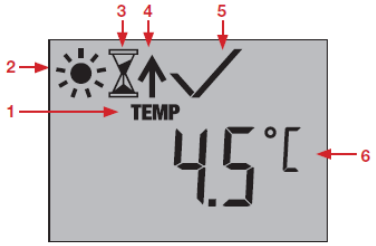
- If the computer has Adobe PDF compatible reader software installed, double-click the PDF file icon to open and view the PDF file.
- If the computer has Sensitech's TempTale Manager® Desktop Software installed (8.0 or higher), double-click the TTV file icon to open and view monitor configuration information, summary statistics, and time-temperature data graph.
- Both the PDF and TTV files can be copied, saved, or emailed as an attachment.

Direct USB Printing of PDF Reports

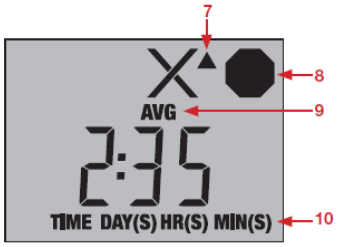
- To place the monitor in Direct Print mode, press and hold the Start and Stop buttons simultaneously until the RED LED starts blinking. The monitor is now in Direct Print mode.
  NOTE: Direct Print times out after approximately 10 seconds. If time out occurs before the monitor is connected to a USB port, repeat the previous step.
- While the LED is blinking, plug the monitor into the USB port located on the exterior of a USB-enabled printer, and then print the PDF report.
  NOTE: Not all USB printers support USB-direct printing of PDF documents. Consult your printer's user manual for support.

Displayed Information

Sample running display, no alarm



Sample stopped display, with alarm



1. Temperature display indicator
2. Running
3. Start-up delay
4. Marked point
5. Alarm Status
   X = alarm(s), ✓ = no alarm(s)
6. Current temperature (pre-programmed to display °C or °F)
7. Alarm triggered ▲ HIGH / ▼ LOW
8. Stopped recording
9. Avg/Min/Max temperatures recorded
10. Total time above/below alarm limits

APPENDIX 2 - Fact Sheet for Patients, Parents, Caregivers and Fact Sheet for Healthcare Providers: Emergency Use Authorization For Evusheld™ (tixagevimab co-packaged with cilgavimab) revised 06/2022