

9. HOW SUPPLIED/STORAGE AND HANDLING

KYSLECEL is a suspension containing a minimum of 9,999 autologous pancreatic islet equivalents (IEQs) in HEPES buffer solution and human serum albumin with heparin and ciprofloxacin added (unless otherwise requested by the prescribing physician). Depending on the number of IEQs obtained from the patient's pancreas, KYSLECEL is supplied in one or more sealed 200 mL infusion bags, labeled for the specific recipient.

KYSLECEL is shipped directly to the infusing provider in a cardboard shipping box with a special insulated container inside. A product **Infusion Summary** form is included in the box which will include the patient's medical record number and Koligo-assigned Lot number.

Monitors are placed inside the insulated container to monitor temperature and pressure during shipment. The insulated container and gel packs within the container are designed to maintain the appropriate transportation and storage temperature of KYSLECEL between 15-30°C until infusion.

Immediately prior to KYSLECEL infusion, open the insulated container and match the patient's identity with the patient identifiers on the product **Infusion Summary** form and the KYSLECEL infusion bag label. Verify temperature and pressure gauge information and record the data on product **Infusion Summary** form. Review expiration time, temperature, and pressure conditions prior to infusion.

After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations. Return a completed copy of the product **Infusion Summary** form to Koligo.

Distributed by:

Koligo Therapeutics, Inc.
204 South Floyd Street
Louisville, KY 40202

Manufactured by:

Koligo Therapeutics, Inc.
302 East Muhammad Ali Blvd., Suite 208
Louisville, KY 40202