

The following information is intended for healthcare professionals only:

Precautions to be taken before handling or administering the medicinal product

Kymriah should be transported within the facility in closed, break-proof, leak-proof containers.

This medicinal product contains human blood cells. Healthcare professionals handling Kymriah must take appropriate precautions (wearing gloves and eye protection) to avoid potential transmission of infectious diseases.

Preparation prior to administration

Before administration, it must be confirmed that the patient's identity matches the unique patient information on the Kymriah infusion bags and accompanying documentation. The total number of infusion bags to be administered should also be confirmed with the patient specific information on the batch specific documentation accompanying the medicinal product.

The timing of thaw of Kymriah and of infusion should be coordinated. The infusion start time should be confirmed in advance and adjusted for thaw so that Kymriah is available for infusion when the recipient is ready. Once Kymriah has been thawed and is at room temperature (20°C-25°C), it should be infused within 30 minutes to maintain maximum product viability, including any interruption during the infusion.

Inspection and thawing of the infusion bag(s)

Do not thaw the product until it is ready to be used.

The infusion bag should be placed inside a second, sterile bag during thawing to protect ports from contamination and avoid spills in the unlikely event of the bag leaking. Kymriah should be thawed at 37°C using either a water bath or dry thaw method until there is no visible ice in the infusion bag. The bag should be removed immediately from the thawing device and kept at room temperature (20°C-25°C) until infusion (the infusion should be ended within 30 minutes from thawing). If more than one infusion bag has been received for the treatment dose (refer to the batch certificate for number of bags constituting one dose), the next bag should only be thawed after the contents of the preceding bag have been infused.

Kymriah should not be manipulated. For example, Kymriah should not be washed (spun down and resuspended in new media) prior to infusion.

The infusion bag(s) should be examined for any breaks or cracks prior to thawing. If the infusion bag appears to have been damaged or to be leaking, it should not be infused and should be disposed of according to local guidelines on handling of biological waste.

Administration

Kymriah intravenous infusion should be administered by a healthcare professional experienced with immunosuppressed patients and prepared to manage anaphylaxis. In the event of cytokine release syndrome (CRS), ensure that at least one dose of tocilizumab per patient and emergency equipment are available prior to infusion. Hospitals must have access to additional doses of tocilizumab within 8 hours. In the exceptional case where tocilizumab is not available due to a shortage that is listed in the Ministry of Health website, ensure that suitable alternative measures to treat cytokine release syndrome are available on site.

The patient's identity should be matched with the patient identifiers on the infusion bag. Kymriah is intended solely for autologous use and must not, under any circumstances, be administered to other patients. Kymriah should be administered as an intravenous infusion using latex-free intravenous tubing without a leukocyte depleting filter, at approximately 10 to 20 mL per minute by gravity flow. All contents of the infusion bags should be infused. Sterile sodium chloride 9 mg/mL (0.9%) solution for injection should be used to prime the tubing prior to infusion and rinse it after infusion. When the full volume of Kymriah has been infused, the infusion bag should be rinsed with 10 to 30 mL sodium chloride 9 mg/mL (0.9%) solution for injection by back priming to ensure as many cells as possible are infused into the patient.

If the volume of Kymriah to be administered is ≤ 20 mL, intravenous push may be used as an alternative method of administration

Measures to take in case of accidental exposure

In case of accidental exposure, local guidelines on handling of human-derived material should be followed. Work surfaces and materials which have potentially been in contact with Kymriah must be decontaminated with appropriate disinfectant.

Precautions to be taken for the disposal of the medicinal product

Unused medicinal product and all material that has been in contact with Kymriah (solid and liquid waste) should be handled and disposed of as potentially infectious waste in accordance with local guidelines on handling of human-derived material.