

INFORMATION ABOUT ADVANCED THERAPY MEDICINAL PRODUCT

Product manufacturer	JSC „Froceth“
Number of manufacturing permission issued by SMCA	15/220321
Advanced therapy medicinal product name	NK cells
ATMP type	☐ AUTOLOGOUS ☒ ALLOGENEIC
ATMP receiving hospital name	
Patient's ID	PB-25-120
ATMP samples ID	PB-23-510 (1 st unit) PB-23-510 (2 nd unit) PB-23-510 (3 rd unit) PB-23-510 (4 th unit)
Patient file number	PB25/PB2512012
Number of manufactured doses (amount of cells in one dose)	4 doses (9×10^8 cells in 10 mL volume)
Date of ATMP expiry	2025-05-29
Pharmaceutical form	☐ INJECTION ☒ INFUSION

Description: product manufactured accordingly to doctor's prescription. Product manufacturing consist of lymphocytes separation from umbilical cord blood. During manufacture lymphocytes are activated by cytokines and stimuli of antibodies. Final product – heterogeneous population, NK.

Materials used for manufacturing: recombinant human interleukin (IL-2); Imukin (IFN- γ); antibody anti-CD3, antibody anti-CD2; antibody anti-CD335; PRIME-XV TCELL CDM medium; Fikol; Tetraspan 6%.

Storage conditions: NK product should be stored at least -80 °C temperature (freezer or dry ice). Product date of expiration is indicated above. Thawed products should be used immediately without storage.

BIOLOGICAL HAZARD!