



TCATF 190 05
(Relates to SOP No. TCATS CTL 003)



**CTL - NOTE TO BE DISTRIBUTED
WITH THE ANTI-EBV CTL PRODUCT**

UNLICENSED STATUS OF PRODUCT

The anti-EBV CTL supplied is an unlicensed product. There is a legal requirement that unlicensed products are issued and used with the understanding that they do not hold a UK product licence and are supplied on a strict named patient basis.

PATIENT CONSENT AND RECORD OF USE

As the treating clinician you have the responsibility of ensuring the patient is informed that the product is not licensed in the UK and gaining their consent. Please familiarise yourself with the Patient Information Leaflet (TCATF 189), which includes details of possible side effects and risks associated with this type of product. As with all plasma-derived medicinal products, it is recommended that you record the product name and batch number in the patient's notes.

BAG INTEGRITY

There have been some incidents reported of product bag leaks, due to faulty seals or snapped lines. If the integrity of the inner bag is compromised, please do not infuse the product. Quarantine the implicated bag and contact CTL staff (+44 (0)131 314 5545 or nss.ctlbank@nhs.scot) immediately for advice. We will send a replacement bag where available.

CHARGES APPLIED FOR SUPPLY OF ANTI-EBV PRODUCT

SNBTS apply a charge to recover cost of this product. As the treating clinician you should ensure that payment is authorised before ordering.

RETURN OF PAPERWORK

The supply of this unlicensed product is on the understanding that the requesting clinician takes responsibility to ensure completion and return of any forms requested by SNBTS.

- Patient consent form – TCATF 189
- Patient treatment forms should be returned (email or hardcopy) within one working day of each treatment.
- SNBTS must also be informed if the product was not used.

Return forms to

CTL Staff
SNBTS Tissues, Cells and Advanced Therapeutics (TCAT)
The Jack Copland Centre
52 Research Avenue North
Heriot-Watt Research Park
Edinburgh, EH14 4BE

Or scan and e-mail to nss.ctlbank@nhs.scot