

Leaflet

Human Platelet Lysate (hPL) PLATINUM

Reference number: P480R Storage temperature: ≤ -70°C No heparin addition required Xeno-free Research grade

Product description

hPL is a growth factor-rich cell culture supplement prepared from human blood donations. Each batch of hPL contains material from maximally 480 donors.

The product is fibrinogen depleted and does not contain heparin.

This hPL was manufactured under a quality management system based on ISO-13485. The principles, recommendations and requirements of ISO-20399 and of the European Pharmacopoeia (Chapter regarding raw materials of biological origin for the production of cell-based and gene therapy medicinal products) have been applied.

See also the enclosed Certificate of Analysis.

Instructions for use

Storage/Stability

This product should be stored at \leq -70°C upon receipt. Thaw at room temperature or in a water bath \leq 37°C. After thawing, aliquot at will and store aliquots at -20°C or colder. It is recommended to store the products at -15°C to -30°C for no more than 8 weeks. For long term storage, temperatures \leq -70°C are recommended.

Multiple freeze/thaw cycles may lead to increased turbidity and lower efficiency.

The expiry date of the product is indicated on the product label.

Preparation

For use in cell culture media, we recommend an optimal dilution of 10% (vol/vol) in basal medium. In rare cases, a concentration of hPL >10% (vol/vol) may cause salt precipitation if used in basal media containing high phosphate concentrations (e.g. RPMI) combined with certain cell types. For assistance in selecting your basal media, contact trec@rodekruis.be.

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Precautions and safety

- For research use only.
- Not for use in the rapeutic or diagnostic procedures, animal nor human.
- Not intended for direct use in animals or humans.
- The products should be handled and treated as potentially infectious
- Apply GLP according to biosafety regulations.

The hPL is prepared from blood donations collected from consenting, non-remunerated voluntary donors of the Belgian Red Cross Flanders.

The source products for production of hPL are prepared according to Belgian legislation.

The hPL production process includes a pathogen inactivation step (using the INTERCEPT method from Cerus) on the final product. This reduces the risk of transmission of HIV, HCV and HBV to almost zero. Due to its broad spectrum of action, pathogen inactivation also significantly protects against transmission of less or unknown pathogens ("emerging infectious diseases"). However, such transmission can never be excluded.

Prions are not eliminated by pathogen inactivation and cannot be detected in donors by routine lab tests. Protection against transmission of prions by transfusion relies on careful donor selection.

Although these donor screening, testing and pathogen inactivation procedures are in place to minimize the risk of transmitting infections, they cannot completely eliminate this risk. Therefore the products should be handled and treated as potentially infectious.

Reporting of complaints regarding the product or service

Customer satisfaction is of primary importance. We therefore consider it important that complaints or comments regarding the products or services are always reported to us. In this way, these complaints can be followed up and can lead to improvement.

Please report any complaints or comments to tinc@rodekruis.be.

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