

Leaflet

Human Platelet Lysate (hPL) GOLD

Reference number: G150C Storage temperature: ≤ -70°C No heparin addition required Xeno-free Clinical grade

Product description

hPL is a growth factor-rich cell culture supplement derived from human platelet concentrates. Each batch of hPL contains material from maximally 150 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. A concentration of hPL >10% (vol/vol) may cause salt precipitation if used in basal media containing high calcium concentrations (e.g. DMEM, α -MEM) combined with certain cell types. For assistance in selecting your basal media, contact trec@rodekruis.be.

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Precautions and safety

- Not intended for direct use in animals or humans.
- Apply GLP according to biosafety regulations.

Because these products contain human derived materials, they may carry a risk of transmitting infectious agents.

The hPL is derived from human platelet concentrates prepared from donations collected from consenting, non-remunerated voluntary donors of the Belgian Red Cross Flanders. With each donation, the donor is approved by a physician (based on a medical questionnaire) and tested for antibodies against the human immunodeficiency viruses (anti-HIV-1 and HIV-2), for antibodies against the hepatitis C virus (anti-HCV), for hepatitis B virus surface antigen (HBsAg) and for antibodies against Treponema pallidum. HIV, HBV and HCV are also detected by NAT testing.

The platelet concentrates are prepared according to Belgian legislation, including pathogen inactivation.

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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