Leaflet

Human Platelet Lysate (hPL) PLATINUM

Clinical grade

Storage temperature: ≤ -70°C
No heparin addition required
Xeno-free
Reference number: see Certificate of Analysis

Product description

hPL is a growth factor-rich cell culture supplement prepared from human blood donations.

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 ≤ -70°C upon receipt. Thaw at room temperature or in a water bath ≤37°C. After thawing, prepare aliquots and store at -20°C or colder. It is recommended to store the product at -15°C to -30°C for no more than 1 year. For long term storage, temperatures ≤-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.
Filtration of complete media <0.4µm is recommended.

Precautions and safety

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

Because the product is a substance of human origin, there is a risk of transmitting infectious agents. Take care to handle the product accordingly.
The hPL is prepared from blood donations collected from consenting, non-remunerated voluntary donors of the Belgian Red Cross Flanders. Prior to donation, donor risk behavior is inquired via a medical questionnaire and a medical anamnesis. The donor is tested for carrying antibodies against the human immunodeficiency viruses (anti-HIV-1 and HIV-2), against hepatitis C virus (anti-HCV), hepatitis B virus surface antigen (HBsAg) and Treponema pallidum. Potential infection with HIV, HBV and HCV is tested by nucleic acid amplification.
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.

Animal Origin Statement

No animal derived substances are added at any point.

Reporting of complaints regarding the product or service

Customer satisfaction is our primary aim. We therefore consider it important that complaints or comments regarding our products or services are reported. Please report to TReC.Production@rodekruis.be.