

# Leaflet

## Human Platelet Lysate (hPL) GOLD

### Clinical grade

Storage temperature:  $\leq -70^{\circ}\text{C}$

No heparin addition required

Xeno-free

Reference number: see Certificate of Analysis

### Product description

hPL is a growth factor-rich cell culture supplement derived from human platelet concentrates.

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  $\leq -70^{\circ}\text{C}$  upon receipt. Thaw at room temperature or in a water bath  $\leq 37^{\circ}\text{C}$ . After thawing, prepare aliquots and store at  $-20^{\circ}\text{C}$  or colder. It is recommended to store the product at  $-15^{\circ}\text{C}$  to  $-30^{\circ}\text{C}$  for no more than 1 year. For long term storage, temperatures  $\leq -70^{\circ}\text{C}$  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

As a supplement to cell culture media, we recommend a final dilution of 10% (vol/vol). hPL Gold is validated for use with DMEM/F-12, RPMI, Ham's F-12 and IMDM. Combination of hPL Gold with DMEM, MEM or similar can cause salt deposits impacting normal cell division. If the use of DMEM or MEM is required, hPL Platinum might be a better fit. Please contact [trec@rodekruis.be](mailto:trec@rodekruis.be) for help selecting appropriate media. Filtration of complete media  $<0.4\mu\text{m}$  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 manufactured from human platelet concentrates prepared from 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. 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.

## **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](mailto:TReC.Production@rodekruis.be).