

# GMP Recombinant Human Interleukin-4

(rHuIL-4) 50 µg

## GMP CERTIFICATE OF ANALYSIS AND MATERIAL SAFETY DATA SHEET

**Lotnr** GMP-IL4: Lot# 017/LC/030526/PV

**Expiry date:** If stored at -20°C stable for one year after last test date.  
(last test date is 10/2005 by Brucells SA)

**Description:** Recombinant Human IL-4 produced in E.Coli is a single, non-glycosylated polypeptide chain containing 130 amino acids and having a molecular mass of 15000 Dalton. The rHuIL-4 is purified by proprietary chromatographic techniques.

**Source :** *E.coli*

**Molecular weight :** 15 KDa

**Identity :** rh IL-4 as measured by Elisa and Western Blot

**Specific activity :** > 5.10<sup>6</sup> units/mg compared to NIBSC standard . CT-h4.S cell proliferation assay.

**Purity :** > 98% as determined by SDS-PAGE and HPLC

**Endotoxin content :** < 0.1 EU/ µg of IL-4 (LAL test)

**Host DNA :** < 10 pg/ng protein

**Sterility :** sterile according to EP Test 2.6.1.

**Stabiliser :** contains Trehalose ; no preservative.

**Physical state :** freeze-dried

**Stability :** 12 months at -20°C to -80°C

3 months after reconstitution with water for injection ( as defined in EP Monograph 0169) when stored at -80°C

**Reconstitution :** use 500 µL water for injection in class A environment in order to keep the GMP grade .

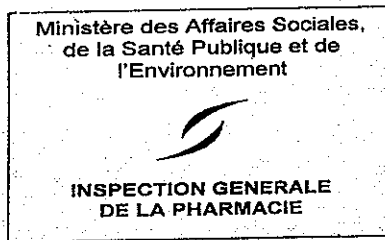
**Packaging unit :** 50 µg protein (Lowry test)

### **GMP**

GENTAUR rh IL-4 is manufactured in full compliance with cGMP in facilities approved by the Belgian Ministry of Health for the production and storage of medicinal products. GMP production at HENOGEN SA and GMP Lyophilisation at GSK Inc, Rixensart.



GlaxoSmithKline



REÇU LE 08 OCT. 2002



Autorisation N° : 1.535

Accordée le: 07 OCT. 2002

En application de l'article 2 de l'arrêté royal du 6 juin 1960 concernant la fabrication, la distribution en gros et la dispensation des médicaments.

La société: HENOGEN  
Siège Social: Rue des Prof. Jeener et Brachet 12 - 6041 GOSELIES

Représentée par: M. BOLLEN, Directeur-Général  
Est autorisé(e) à:

• fabriquer:

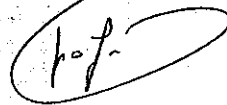
les médicaments non présentés sous forme de spécialités indiquées

sur l'annexe D (comprenant 1 feuille)

Sur chaque annexe est indiqué l'endroit où ont lieu des opérations renseignées ci-dessus. Toute modification que la personne autorisée désirerait voir apporter aux dénominations, lieux ou autres renseignements figurant sur la présente autorisation (annexes comprises) rend nécessaire le renouvellement de celle-ci.

POUR LE MINISTRE DE LA SANTE-PUBLIQUE,  
LE CONSEILLER GENERAL,

REDEVANCE DUE:
MONTANT: ..... 12,42
POUR: ..... autorisation n° 1535



*Use*

GENTAUR rh IL-4 is not an approved medicinal product and cannot be injected as such to patients. However this GMP IL-4 is used in clinical tests for DC Therapy today in Belgium, France, Denmark, USA and Japan.

CE CERTIFIED FOR EX VIVO CELL CULTURE AND DC THERAPY  
CLINICAL TESTS

GNT#04GMPHUIL450UG

Brussels, 10/10/2005

Lieven GEVAERT, Bio-ir. Scientific director

