

malaise, weight loss, vomiting, depression, thrombocytopenia, insomnia, diarrhea, body pain, itching have also been reported. On rare occasions, other mild reactions have been reported. If it appears, the dose should be reduced or treatment discontinued, depending on the clinical situation of the patient.

## POSODOLOGY

*For adults:* the dose varies between 3 MIU and 20 MIU depending on the disease. The usual dose is between 3 MIU and 6 MIU.

*For children:* the usual dose is between 3 and 6 MIU/m<sup>2</sup> of body surface.

The frequency of administration and the duration of treatment vary depending on the disease.

## ADMINISTRATION

Intramuscular, subcutaneous, intravenous, intrathecal, intralesional and intraperitoneal.

## PERIOD OF VALIDITY AND STORAGE CONDITIONS

Stable at a temperature of 2 to 8 °C; for 24 months. Do not freeze or shake.

## PRESENTATION

- Case of 1 or 25 colorless glass vials with 0.3 mL; 0.5 mL or 1 mL.
- Case of 10 individual cases per 1 colorless glass vial with 0.3 mL; 0.5 mL or 1 mL.
- Case of 6 cases for 25 colorless glass vials with 0.3 mL; 0.5 mL or 1 mL.

# Heberon<sup>®</sup> Alfa R

HUMAN RECOMBINANT  
ALPHA 2B INTERFERON

**CIGB** CENTRO  
DE INGENIERÍA GENÉTICA  
Y BIOTECNOLOGÍA

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MAXIMUM SAFETY  
AND EFFICIENCY



## MAXIMUM SAFETY AND EFFICIENCY

- **HEBERON® ALFA R** IS AN IMPORTANT MODIFIER OF THE BIOLOGICAL RESPONSE.
- ANTIVIRAL, ANTIPROLIFERATIVE AND IMMUNOMODULATOR EFFECTS.
- IT OFFERS AN EXCELLENT RESPONSE TO VIRAL NEOPLASIC AND IMMUNOLOGICAL ILLNESSES AND IT ALSO HAS AN ANTIFIBROTIC EFFECT.
- THE ALBUMIN-FREE FORMS DO NOT CONTAIN ANY BLOOD DERIVATIVE AND ARE LESS IMMUNOGENIC.

### PHARMACEUTICAL FORMS

- Lyophilized drug for IM, IV, SC, IP, IT injection.
- Solution for IM, IV, SC, IP, IT injection.

### STRENGTHS

3 MUI; 5 MUI; 10 MUI

### COMPOSITION:

Each 0.3 mL bulb; 0.5 mL or 1 mL, contains: Hu-rec interferon alpha 2b: 0.3 mL; 0.5 mL or 1 mL, respectively; benzyl alcohol 3.0 mg; 5.0 mg or 10 mg, respectively; sodium chloride; polysorbate 80; disodium hydrogen phosphate ( $\text{Na}_2\text{HPO}_4$ ); sodium dihydrogen phosphate dihydrate ( $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$ ).

### INDICATIONS

- *Viral diseases:* human papillomavirus, hepatitis B and C, human immunodeficiency virus and dengue.
- *Neoplasms of hematopoietic tissue:* hairy cell leukemia, chronic myeloid leukemia, multiple myeloma, low

and medium malignancy non-Hodgkin lymphoma, cutaneous T lymphomas (mycosis fungoides, Sézary syndrome and others).

- *Other hematological diseases:* polycythemia vera, thrombocythemia and hypereosinophilia.
- *Solid tumors:* basal cell carcinoma of the skin, superficial carcinoma of the bladder, melanoma, carcinoid tumors, childhood hemangioma, Kaposi's sarcoma associated with AIDS, metastatic renal carcinoma.
- *Fibrosis diseases:* La Peyronié's disease, liver cirrhosis and keloids.
- *Diseases of the central nervous system:* paranoid schizophrenia and multiple sclerosis.

### CONTRAINDICATIONS

- Patients with hemoglobinopathies or hypersensitivity to interferon alpha or to any of the components of the pharmaceutical preparation.
- Treatment should not be started in patients with uncontrolled hypo or hyperthyroidism.
- **Heberon® Alfa R** contains benzyl alcohol, therefore it should not be given to children under three years of age.

### PRECAUTIONS

Administer under the supervision of a specialist doctor. Administer with caution in patients with a history of severe heart disease, with myelosuppression, with compromised renal function or a history of severe renal disorders, with a history of seizures or other functional alteration of the central nervous system, with a psychiatric history, with a history of autoimmune or allergic diseases. In the presence of pulmonary infiltrates or pulmonary function disorders, treatment should be discontinued.

### ADVERSE REACTIONS

Adverse reactions are reversible. The main ones have been headache and fever. Asthenia, myalgias, anemia, arthralgia, chills, leukopenia, anorexia, nausea, general