This information is valid for the Slovak Republic and may differ for other countries. For detailed information, please contact the relevant foreign representative:

http://www.imuna.sk/en/o-nas/zahranicne-zastupenia-a-business-development/

Abridged Drug Information:

Name of drug: IMMODIN®. **Composition**: One dose (1 vial) of the lyophilised drug contains Leucocyti dialysatum 200x106 (Lyophilised dialysate from 200 million leukocytes). **Pharmaceutical form**: Powder and a dilluent for the injection dilution. **Therapeutic indications**: IMMODIN® is indicated in conditions with confirmed cellular immune disorder in children from 6 months of age, adolescent and adult population. Immodin is primarily intended to cure recurrent chronic infections, serious septic conditions, atopic eczema, psoriasis, chronic fatigue syndrome based on immunodeficiency, serious conditions due to allergy where defective cellular immunity has been demonstrated and usual immunotherapy has failed, and in severe injuries. **Dosage and route of administration**: The treatment dosage is based on the previous and continuous testing of the state of the patient's immune system. Mild disorders: 3 basic doses at weekly intervals are usually sufficient. Dose 4 should be administered 1 month after Dose 3. Severe immunodeficiency: substitution and long-term treatment with IMMODIN® is based on the results of continuous testing of the patient´s immune status. In septic conditions with antibiotic resistance a bolus therapy is recommended by administration of 3 – 5 doses in the course of one week. The dosage is identical in adult and child population including infants. **Contraindications**: Pregnancy and conditions in which an increase in cell immunity is undesirable. **Adverse events**: Temporary local pain, erythema and infiltrate with duration of no more than 24 hours. **Precautions**: Subcutaneous administration can cause local pain of varying intensity that usually resolves within 15 minutes. Store and transport at +2 to +8 °C in the original packaging that protects the drug from light. Keep out of reach and sight of children! **Drug and other interactions**: Interactions were not observed. **Use in pregnancy and lactation:** The drug should not be used in pregnancy; there is no contraindication during the lactation period. The influence on the ability to drive motorized vehicles or operate machinery is not likely. **Packaging**: 5x1 lyophylisate dose + 5x4 mL water for injection. **Marketing authorisation holder:** IMUNA PHARM, a.s, Jarková 269/17, 082 22 Šarišské Michaľany, Slovak Republic. The use of IMMODIN® should be based on official recommendations. This text does not replace full drug prescribing information. Full drug prescribing information is available upon request. **Date of last text revision:** October 2008.