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Prothymosin α Factor

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PROTHYMOSIN α FACTOR

Injection, 2 mg

Description: Prothymosin α Factor for subcutaneous injection is a purified, sterile, lyophilised, virus free preparation derived from the thymus gland. Each vial of Prothymosin α Factor contains 2 mg prothymosin α.

Characteristics: Prothymosin α Injection is an acetylated peptide with the following sequence: NH2- Ser- Asp- Ala- Ala- Val- Asp- Thr- Ser-Ser- Glu- Ile- Thr- Thr- Lys- Asp- Leu- Lys- Glu- Lys- Lys- Glu- Val- Val- Glu- Glu- Ala- Glu- Asn- Gly- Arg- Asp- Ala- Pro- Ala- Asn- Gly- Asn- Ala- Asn- Glu- Glu- Asn- Gly- Glu-Gln- Glu- Ala- Asp- Asn- Glu- Val- Asp- Glu- Glu- Glu- Glu-Glu- Gly- Gly- Glu- Glu- Glu- Glu- Glu- Glu- Glu- Glu- Gly- Asp- Gly- Glu- Glu- Glu- Asp- Gly- Asp- Glu- Asp- Glu- Glu- Ala- Glu- Ser- Ala- Thr- Gly- Lys- Arg- Ala- Ala- Glu-Asp- Asp- Glu- Asp- Asp- Asp- Val- Asp- Thr- Lys- Lys-Gln- Lys- Thr- Asp- Glu- Asp- Asp- COOH. It has a molecular weight of 12,200 D and a Ip of 3,55.

Clinical Pharmacology: The mechanism of action of Prothymosin α Factor Injection in the treatment of chronic hepatitis B/C and carcinomas is not completely understood yet. In various in vitro assays, the peptide shows promotion of T-cell maturation through mitogen-stimulated peripheral blood lymphocytes; an increase in production of various lymphokines such as interferon, interferon gamma, interleukin 2 (IL-2), and interleukin 3 (IL-3) through T-cells following antigen or mitogen activation; and an increase in the levels of lymphokine receptors on T-cells. It also enhances both allogeneic and autologous human mixed lymphocyte reactions through the activation of T4

(helper/inducer) cells. Prothymosin α Factor may influence the recruitment of prenatural killer (NK) cells which then become cytotoxic after exposure to interferon. In vivo, Prothymosin α Factor enhances IL-2 receptors and the production of IL-2 in concanavalin A-stimulated mouse lymphocytes. At 900 µg/m2, Prothymosin α Factor given subcutaneously results in peak plasma concentrations of 25-30 ng/ml approximately one hour after injection. Peak levels are maintained for 6 hours and return to the baseline over the following 18 hours. Repeated injection twice a week for 15 weeks results in a very slight increase in baseline plasma Prothymosin α Factor concentration.

Indications: Prothymosin α Factor Injection is indicated for the treatment of chronic hepatitis B and C with compensated liver disease, hepatitis B/C virus (HBV, HCV) replication (serum HBV/HCV DNA positive), and carcinomas.

Studies do with patients who have been serum hepatitis B/C surface antigen (HBsAg, HCsAg) positive for at least 6 months with elevated serum alanine aminotransferase (ALT) have demonstrated that the treatment with Prothymosin α Factor Injection therapy can produce virological remission (loss of serum HBV/HCV DNA) and normalization of serum aminotransferases. Prothymosin α Factor Injection therapy resulted in the loss of serum HBsAg/HCsAg in some responding patients.

Contraindications: Prothymosin α Factor Injection is contraindicated in patients with a history of hypersensitivity to Prothymosin α Factor or any component of the injection. Because Prothymosin α Factor Injection therapy appears to work by enhancing the immune system, it should be considered contraindicated in patients who are being deliberately immuno-suppressed, for example transplant patients, unless the potential benefits of the therapy clearly outweigh the potential risks.

Warnings: None.

Precautions: Information for Patients: Patients receiving Prothymosin α Factor Injection treatment should be instructed on its appropriate use and be

informed of the benefits and risks associated with treatment. If home use is prescribed, the patient should be supplied with a puncture-resistant container for the disposal of used syringes and needles. Patients should be well instructed about the importance of proper disposal and be cautioned about reusing any syringes or needles.

Laboratory Tests: Liver function tests, including serum ALT, albumin and bilirubin, should be conducted periodically during treatment. Special Information BIOFACTOR PROTHYMOSIN α Factor

HBeAg/HCeAg (Hepatitis B/C envelope antigen), HBsAg/HCsAg, HBV/HCV DNA and ALT should be evaluated at the end of treatment as well as 2, 4, and 6 months after treatment, since patients may become virologic responders during the 6 months following treatment.

Drug Interactions: Interactions between Prothymosin α Factor Injection and other drugs have not been fully evaluated.

Carcinogenesis, Impairment of Fertility, Mutagenesis: Long term studies with Prothymosin α Factor Injection have not been done to determine carcinogenicity. Mutagenicity studies with Prothymosin α Factor Injection showed no adverse findings.

Pregnancy: Prothymosin α Factor Injection should be given to a pregnant woman only if clearly needed.

Nursing Mothers: Because many drugs are excreted in human milk, extreme caution should be exercised when Prothymosin α Factor Injection is administered to a nursing woman.

Pediatric Use: Safety and effectiveness have not been established in patients under the age of 18 years.

Adverse Reactions: Prothymosin α Factor Injection is generally well tolerated. During clinical studies involving individuals distributed over all age groups, no clinically significant adverse reactions attributable to Prothymosin α Factor administration were reported. In one early study using a formulation of prothymosin α different from

Prothymosin α Factor Injection, burning at the injection site was seen in three patients and transient loss of muscle mass in one patient. All of these patients were treated using a single lot of the drug. Symptoms disappeared with use of a new lot.

As with any new drug, it is possible that expanded commercial use of the drug could reveal rare adverse reactions not observed in clinical trials.

A transient increase in ALT to more than twice baseline value (flare) can occur during Prothymosin α Factor Injection therapy for chronic hepatitis B/C and carcinomas. When an ALT flare occurs, Prothymosin α Factor Injection should generally be continued unless signs and symptoms of liver failure are observed.

Overdose: There are no reported instances of deliberate or accidental overdose in humans. Animal toxicology studies have shown no adverse reactions in doses of 10 mg/kg, the highest level studied.

Dosage and Administration: The recommended dosage of Prothymosin α Factor Injection for the treatment of chronic hepatitis B/C and carcinomas is 2 mg administered subcutaneously 5 times a week for a duration of 6 months. The therapy should then be continued with twice a week for six months without interruption. Prothymosin α Factor Injection should be given intramuscularly or intravenously. Immediately prior to use it should be reconstituted with 2.0 ml of the diluent provided. This consists of 2.0 ml solvent for injection,. At the discretion of the physician, the patients may be taught to self-administer the medication.

How Supplied: Prothymosin α Factor Injection is supplied in single use vials containing 2 mg of lyophilised Prothymosin α per vial. It is available in cartons containing 10 vials of Prothymosin α Factor Injection. Each carton also contains ten ampoules of diluent for Prothymosin α Factor Injection, containing 2 ml solvent for injection, which are to be used to reconstitute the Prothymosin α Factor for injection.

Storage: Store Prothymosin α Factor Injection between 2° to 8° C (36° to 46° F). It should be

used immediately after reconstitution.

LITERATURE

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