For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

HIGHLY PURIFIED CHORIONIC GONADOTROPHIN INJECTION B.P. (HUMAN CHORIONIC GONADOTROPHIN INJECTION)

karma-HCG (FREEZE DRIED)

for i.m. / s.c. Injection

DESCRIPTION:

Vials of karma-HCG injection contains highly purified Human Chorionic Gonadotrophin (HCG) as a white, freeze-dried, sterile and pyrogen-free powder. Three strengths are available: Each vial of karma-HCG contains Chorionic Gonadotrophin B.P. (Human) 2000, 5000 & 10000 IU.

ADDED SUBSTANCES:

Disodium Hydrogen Phosphate B.P., Sodium Dihydrogen Phosphate B.P. and Mannitol B.P.

One IU of Chorionic Gonadotrophin is defined as the activity contained in 1.279 mg of the 2nd International Standard Preparation. Each vial of karma-HCG is accoompanied by a solvent ampoule containing 1 ml of isotonic, sterile and pyrogen free Sodium Chloride Injection B.P.

PROPERTIES:

Chorionic Gonadotrophin (HCG) is a hormonal substance obtained from urine of pregnant women. Its action is predominantly luteinizing.

INDICATIONS:

Anovulatory infertility

In the female, karma-HCG Inj. is used in the treatment of anovulatory infertility. where its administration would form part of recognized treatment regimen involving the prior stimulation of follicular maturation and endometrial proliferation e.q. with Menotrophin Injection (karma-HMG)

Hypogonadotrophin hypogonadism and cryptochidism:

In the male, karma-HCG Inj. stimulates the interstitial cells of the testes and consequently the secretion of androgens and the development of secondary sexual characteristics. With concomitant Menotrophin Inj. therapy, karma-HCG Inj. stimulates the induction and maintenance of spermatogenesis.

DOSAGE & ADMINISTRATION:

karma-HCG is given by intramuscular injection only. The injection should be reconstituted with Sodium Chloride Injection B.P. provided, immediately prior to use.

Anovulatory infertility:

karma-HCG Inj. 10000 I.U. is administered in mid-cycle, following treatment with Menotrophin Inj. (karma-HCG) according to a recognised scheme. Details of Menotrophin Inj. dosage and monitoring are available on request.

Hypogonadotrophic hypogonadism: karma-HCG Inj. 2000 I.U. twice weekly concomitant with Menotrophin Inj. (1 vial three times a week) if

necessary for a minimum period of four months.

Cryptochidism:

1000 I.U. on alternate days for several weeks.

CONTRA-INDICATION AND WARNINGS:

Stimulation of ovulation with karma-HCG may lead to superovulation and the hyperstimulation syndrome. Oestrogen assays will detect the excessive response so that karma-HCG Inj. may be withheld in that particular treatment cycle. In the male, high dosages of karma-HCG Inj. may lead to oedema and in such cases dosages should be considerably reduced.

If signs of sexual precocity are observed a reduced dosage regimen should be instituted.

STORAGE:

Vials of karma-HCG Inj. should be stored between 2°C-8°C. Do not freeze. Protect from light. Reconstituted solution should be used immediately after preparation, any unused portion should be discarded.

PRESENTATION:

RESERVATION.

Karma-HCG Inj. 2000 IU / 5000 IU / 10000 IU packed as a single vial and is accompanied by one ampoule of 1ml Sodium Chloride Injection B.P. as solvent.

SHELF LIFE:

Sealed and unopened containers, when stored as recommended have a shelf life of 36 months from date of manufacturing.

Keep out of reach of children.

Manufactured by:

BISV

BioScience GmbH

Germany

karma
Pharmatech GmbH

Germany