Luveris 75 IU לובריס 75

powder and solvent for solution for injection

רופא/ה, רוקח/ת וצוות רפואי נכבדים,

אנו מבקשים להודיעכם כי העלון לרופא ולצרכן של התכשיר **Luveris 75 IU** עודכנו בעקבות עדכון ההתוויה ומשטר המינון של התכשיר.

<u>ההתוויה המאושרת:</u>

Luveris in association with a follicle stimulating hormone (FSH) preparation is indicated for the stimulation of follicular development in adult women with severe luteinising hormone (LH) and FSH deficiency.

<u>השינויים שאושרו הינם</u> (טקסט שנוסף מופיע עם <u>קו תחתון</u>, טקסט שנמחק מופיע עם ~~קו חוצה~~):

Therapeutic indications

Luveris in association with a follicle stimulating hormone (FSH) preparation is ~~recommended~~ <u>indicated</u> for the stimulation of follicular development in adult women with severe luteinising hormone (LH) and FSH deficiency. ~~In clinical trials these patients were defined by an endogenous serum LH level <1.2 IU/L~~.

Posology and method of administration
Treatment with Luveris should be initiated under the supervision of a physician experienced in the treatment of fertility disorders.

Posology
In LH and FSH deficient women, the objective of Luveris therapy in association with FSH is to <u>promote follicular development followed by final maturation</u> ~~develop a single mature Graafian follicle from which the oocyte will be liberated~~ after the administration of human chorionic gonadotropin (hCG). Luveris should be given as a course of daily injections simultaneously with FSH. ~~Since~~ <u>If</u> the~~se~~ patient~~s~~ ~~are~~ <u>is</u> amenorrhoeic and ~~have~~ <u>has</u> low endogenous estrogen secretion, treatment can commence at any time.
Luveris should be administered concomitantly with follitropin alfa.
A recommended regimen commences at 75 IU of lutropin alfa (i.e. one vial of Luveris) daily with 75 to 150 IU FSH. Treatment should be tailored to the individual patient's response as assessed by measuring follicle size by ultrasound and estrogen response.
In clinical trials, Luveris has been shown to increase the ovarian sensitivity to follitropin alfa. If an FSH dose increase is deemed appropriate, dose adaptation should preferably be after 7- to 14-day intervals and preferably by 37.5 IU to 75 IU increments. It may be acceptable to extend the duration of stimulation in any one cycle to up to 5 weeks.
When an optimal response is obtained, a single injection of 250 micrograms of r-hCG or 5,000 IU to

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10,000 IU hCG should be administered 24 to 48 hours after the last Luveris and FSH injections. The patient is recommended to have coitus on the day of, and on the day following, hCG administration.
Alternatively, intrauterine insemination or another medically assisted reproduction procedure ~~(IUI)~~ may be performed based on the physician's judgment of the clinical case.
Luteal phase support may be considered since lack of substances with luteotrophic activity (LH/hCG) after ovulation may lead to premature failure of the corpus luteum.
If an excessive response is obtained, treatment should be stopped and hCG withheld. Treatment should recommence in the next cycle at a dose of FSH lower than that of the previous cycle (see section 4.4).
[…]

שינויים אלו בוצעו בעלון לרופא ובעלון לצרכן.
בנוסף, בעלון לצרכן בוצעו שינויים נוספים על פי נהלי משרד הבריאות.
למידע המלא יש לעיין בעלון לרופא ולצרכן כפי שאושרו על ידי משרד הבריאות.

העלון לרופא ולצרכן מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום: מרק סרונו בע"מ, רח' הקישון 18 , יבנה 81220 , טל' 09-9510737

בברכה,

אורית פוקס
רוקחת ממונה