



27 לאפריל 2020

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

PUREGON SOLUTION FOR INJECTION :הנדון:

פיורגון תמיסה להזרקה

Dosage form: Solution for injection

Composition: Follitropin beta 833 IU/1 ml

חברת מרק שארפ ודוהם ישראל (MSD) מבקשת ליידע על עידכון העלון לרופא של פיורגון תמיסה להזרקה.

להלן לשון ההתוויה המאושרת לתכשיר:

In the female: Puregon is indicated for the treatment of female infertility in the following clinical situations:

- Anovulation (including polycystic ovarian syndrome, PCOS) in women who have been unresponsive to treatment with clomifene citrate.
- Controlled ovarian hyperstimulation to include the development of multiple follicles in medically assisted reproduction programs [e.g. *in vitro* fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)].

In the male:

- Deficient spermatogenesis due to hypogonadotropic hypogonadism.

עדכונים מהותיים בעלון לרופא:

טקסט מהותי שהתווסף מודגש בקו תחתון.

4.4 Special warnings and precautions for use

...

Follow current clinical practice for reducing the risk of OHSS during Assisted Reproductive Technology (ART). Adherence to the recommended Puregon dose and treatment regimen and careful monitoring of ovarian response is important to reduce the risk of OHSS. To ~~reduce~~ monitor the risk of OHSS, ultrasonographic assessment of follicular development should be performed prior to treatment and at regular intervals during treatment; . the The concurrent determination of serum oestradiol levels may also be useful. In ART there is an increased risk of OHSS with 18 or more follicles of 11 mm or more in diameter. ~~When there are 30 or more follicles in total it is advised to withhold hCG administration.~~

~~Depending on the ovarian response, the following measurements can be considered to reduce OHSS:~~

- ~~–withhold further stimulation with a gonadotropin for a maximum of 3 days (coasting);~~
- ~~–withhold hCG and cancel the treatment cycle;~~
- ~~–administer a dose lower than 10,000 IU of urinary hCG for triggering final oocyte maturation, e.g. 5,000 IU urinary hCG or 250 micrograms rec-hCG (which is equivalent to approximately 6,500 IU of urinary hCG);~~
- ~~–cancel the fresh embryo transfer and cryopreserve embryos;~~
- ~~–avoid administration of hCG for luteal phase support.~~

If OHSS develops, standard and appropriate management of OHSS should be implemented and followed.

...

בעלון לרופא היו עדכונים נוספים שאינם מהותיים ואינם נכללים בהודעה זו.
העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום,
חברת MSD, בטלפון 09-9533333.
PUREGON SOLUTION FOR INJECTION מופצת יל ידי חברת נובולוג בע"מ.
בברכה,

מיכל סרפר

רוקחת ממונה

חברת MSD ישראל

References:

Israeli approved PC revised in April 2020