J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

נובמבר 2021

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא ובעלון לצרכן של התכשיר:

ZAVESCA® 100mg Capsules

ההתוויה המאושרת בישראל:

Zavesca is indicated for the oral treatment of mild to moderate type 1 Gaucher disease. Zavesca may be used only in the treatment of patients for whom enzyme replacement therapy is unsuitable.

Zavesca is indicated for the treatment of progressive neurological manifestations in adult patients and paediatric patients with Niemann-Pick type C disease.

להלן עיקרי העידכונים בעלון לרופא ובעלון לצרכן.

עלון לצרכן

עידכוני ניסוח ללא שינוי במהות המידע.

עלון לרופא

4.1 Fertility, Pregnancy and lactation

Pregnancy

There are no adequate data from the use of miglustat in pregnant women. Studies in animals have shown ~~reproductive toxicity~~ maternal and embryo-foetal toxicity, including decreased embryo-foetal survival (see section 5.3). The potential risk for humans is unknown. Miglustat crosses the placenta and should not be used during pregnancy.

Fertility

Studies in the rat have shown that miglustat adversely affects sperm parameters (motility and morphology) thereby reducing fertility (see sections 4.4 and 5.3).

~~Until further information is available, it is advised that before seeking to conceive, male patients should cease Zavesca and maintain reliable contraceptive methods for 3 months thereafter.~~

Contraception in males and females

Contraceptive measures should be used by women of childbearing potential. Reliable contraceptive methods should be maintained while male patients are taking Zavesca and for 3 months following discontinuation ~~Male patients should maintain reliable contraceptive methods while taking Zavesca~~ (see sections 4.4 and 5.3).

J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

4.4. Special warnings and precautions for use

Effects on spermatogenesis

Reliable contraceptive methods should be maintained while male patients are taking Zavesca and for 3 months following discontinuation. ~~Male patients should maintain reliable contraceptive methods while taking Zavesca.~~Zavesca should be discontinued and reliable contraception be used for the next 3 months before attempting to conceive (see section 4.6 and 5.3). Studies in the rat have shown that miglustat adversely affects spermatogenesis and sperm parameters, and reduces fertility (see sections 4.6 and 5.3). ~~Until further information is available, before seeking to conceive, male patients should cease Zavesca and maintain reliable contraceptive methods for a further 3 months.~~

4.6 Fertility, Pregnancy and lactation

Pregnancy

There are no adequate data from the use of miglustat in pregnant women. Studies in animals have shown ~~reproductive toxicity, including dystocia~~ maternal and embryo-foetal toxicity, including decreased embryo-foetal survival (see section 5.3).
The potential risk for humans is unknown. Miglustat crosses the placenta and should not be used during pregnancy.

Fertility

Studies in the rat have shown that miglustat adversely affects sperm parameters (motility and morphology) thereby reducing fertility (see sections 4.4 and 5.3). ~~Until further information is available, it is advised that before seeking to conceive, male patients should cease Zavesca and maintain reliable contraceptive methods for 3 months thereafter~~.

Contraception in males and females

Contraceptive measures should be used by women of childbearing potential. Reliable contraceptive methods should be maintained while male patients are taking Zavesca and for 3 months following discontinuation ~~Male patients should maintain reliable contraceptive methods while taking Zavesca~~ (see sections 4.4 and 5.3).

5.3 Preclinical safety data

.
.

Repeated dose toxicity studies in rats showed ~~effects on the seminiferous epithelium of the testes~~ seminiferous degeneration and atrophy. Other studies revealed changes in sperm parameters (sperm concentration, motility and morphology) consistent with an observed reduction in fertility. These effects occurred at ~~exposure levels~~ dose levels adjusted for body surface area similar

J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
tel +972-9-959-1111
fax +972-9-958-3636

to those in patients but showed reversibility. Miglustat ~~affected~~ decreased embryo/foetal survival in rats and rabbits. Prolonged parturition ~~dystocia~~ was reported; post-implantation losses were increased and an increased incidence of vascular anomalies occurred in rabbits. These effects may be partly related to maternal toxicity.

העלון לרופא והעלון לצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/drugs/index.html#/byDrug
כמו כן, ניתן לקבל עותק מודפס על ידי פנייה לבעל הרישום לטלפון 09-9591111

בברכה,
רונית עקירב
רוקחת ממונה