MEDISON

We are **Always Ahead** | We **Grow as One** | We **Care**

2023 מרץ

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

הריני להודיעכם כי העלונים לרופא ולצרכן של התכשיר עודכנו:

Zejula 100 mg **זג'ולה 100 מ"ג**

כמוסות קשות

מרכיב פעיל : **niraparib (as tosylate monohydrate) 100 mg**

התוויות מאושרות :

Zejula is indicated:

- as monotherapy for the maintenance treatment of adult patients with advanced epithelial (FIGO Stages III and IV) high-grade ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

- as monotherapy for the maintenance treatment of adult patients with platinum sensitive relapsed high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum based chemotherapy.

להלן העדכונים בעלון לרופא המהווים החמרות (מסומנים בצהוב):

4.4 Special warnings and precautions for use

[…]

Myelodysplastic syndrome/acute myeloid leukaemia

Cases of myelodysplastic syndrome/acute myeloid leukemia (MDS/AML), including cases with fatal outcome, have been observed in patients treated with Zejula monotherapy or combination therapy in clinical trials and postmarketing (see section 4.8).

[…]

For suspected MDS/AML or prolonged haematological toxicities, the patient should be referred to a haematologist for further evaluation.

[…]

Pregnancy/contraception

Zejula should not be used during pregnancy or in women of childbearing potential not willing to use highly effective contraception during therapy and for 6 months after receiving the last dose of Zejula (see section 4.6).

[…]

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/Contraception in females

[…] Women of childbearing potential must use highly effective contraception during therapy and for 6 months after receiving the last dose of Zejula .

[…]

4.8 Undesirable effects

[…]

System Organ Class	**Frequency of all CTCAE* grades**	**Frequency of CTCAE* grade 3 or 4**
[…]		
Neoplasms benign, malignant and unspecified (including cysts and polyps)	**Common** Myelodysplastic syndrome/ acute myeloid leukaemia**	**Common** Myelodysplastic syndrome/ acute myeloid leukaemia**
[…]		

Medison Pharma Ltd.
10 Hashiloach St., P.O.B 7090, Petach-Tikva 4917002 Israel
Tel. +972. 3. 925. 0250, Fax. +972. 3. 922. 5740
medisonpharma.com

[…]
Myelodysplastic syndrome/Acute myeloid leukaemia
In clinical studies, MDS/AML occurred in 1% patients treated with Zejula, with 41% of cases having a fatal outcome. The incidence was higher in patients with relapsed ovarian cancer who had received 2 or more lines of prior platinum chemotherapy and with *gBRCA*mut following 75 months survival follow-up. All patients had potential contributing factors for the development of MDS/AML, having received previous chemotherapy with platinum agents. Many had also received other DNA damaging agents and radiotherapy. The majority of reports were in g*BRCA*mut carriers. Some of the patients had a history of previous cancer or of bone marrow suppression.

In the PRIMA study, the incidence of MDS/AML was 0.8% in patients receiving Zejula and 0.4% in patients received placebo.

In the NOVA study in patients with relapsed ovarian cancer who had received at least two prior lines of platinum chemotherapy, the overall incidence of MDS/AML was 3.8% in patients receiving Zejula and 1.7% in patients receiving placebo at a follow-up of 75 months. In g*BRCA*mut and non-g*BRCA*mut cohorts, the incidence of MDS/AML was 7.4% and 1.7% in patients receiving Zejula and 3.1% and 0.9% in patients receiving placebo, respectively.

להלן העדכונים בעלון לצרכן המהווים החמרות (מסומנים בצהוב):

2. לפני השימוש בתרופה
[...]
היריון והנקה
היריון
[...]
אם את יכולה להרות, עלייך להשתמש באמצעי מניעה בעל יעילות גבוהה במהלך הטיפול בזג'ולה, ועלייך להמשיך להשתמש באמצעי מניעה בעל יעילות גבוהה למשך 6 חודשים לאחר נטילת המנה האחרונה של התרופה. [...]

4. תופעות לוואי
[...]
תופעות לוואי שכיחות (תופעות שמופיעות ב- 1-10 משתמשות מתוך 100)
[...]
- ספירות תאי דם נמוכות כתוצאה מבעיה במח העצם או סרטן דם המתחיל ממח העצם 'תסמונת מיאלודיספלסטית' (MDS - myelodysplastic syndrome) או 'לוקמיה מיאלואידית חריפה' (- AML acute myeloid leukaemia).

[...]

העלון לרופא והעלון לצרכן נמצאים בקישור, וכן מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בברכה,

מדיסון פארמה בע"מ