

2021 אוגוסט

רופא/ה נכבד/ה  
חוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא ולצרכן של התכשיר:

Dacogen Powder for concentrate for solution for infusion 143-65-31633-00

הרשום להתוויה:

Dacogen is indicated for treatment of patients with myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia) and Intermediate-1, Intermediate-2 and High-Risk International Prognostic Scoring System groups. Dacogen is indicated for the treatment of adult patients with newly diagnosed de novo or secondary acute myeloid leukemia (AML), according to the World Health Organization (WHO) classification, who are not candidates for standard induction chemotherapy.

להלן השינויים העיקריים שחלו בעלון לרופא:

[...]

#### 4.4 Special Warnings and Special Precautions for Use

[...]

##### Differentiation syndrome

Cases of differentiation syndrome (also known as retinoic acid syndrome) have been reported in patients receiving decitabine. Differentiation syndrome may be fatal (see section 4.8). Treatment with high-dose IV corticosteroids and haemodynamic monitoring should be considered at first onset of symptoms or signs suggestive of differentiation syndrome. Temporary discontinuation of Dacogen should be considered until resolution of symptoms and if resumed, caution is advised.

[...]

#### 4.6 Special Warnings and Special Precautions for Use

**Women of childbearing potential/Contraception in ~~males-men~~ and ~~females-women~~**

DACOGEN can cause fetal harm when administered to pregnant women. ~~Women-Due to the genotoxic potential of decitabine (see section 5.3), women~~ of childbearing potential must use

effective contraceptive measures and avoid becoming pregnant while being treated with Dacogen. ~~The time period and for 6 months following completion of treatment with Dacogen where it is safe to become pregnant is unknown.~~ Men should use effective contraceptive measures and be advised to not father a child while receiving Dacogen, and for 3 months following completion of treatment (see section 5.3).

[...]

#### 4.8 Undesirable Effects

[...]

##### Differentiation syndrome

Cases of differentiation syndrome (also known as retinoic acid syndrome) have been reported in patients receiving decitabine. Differentiation syndrome may be fatal and symptoms and clinical findings include respiratory distress, pulmonary infiltrates, fever, rash, pulmonary oedema, peripheral oedema, rapid weight gain, pleural effusions, pericardial effusions, hypotension and renal dysfunction. Differentiation syndrome may occur with or without concomitant leucocytosis. Capillary leak syndrome and coagulopathy can also occur (see section 4.4).

מצ"ב הקובץ הנקי לאחר השינויים. על מנת לראות את פירוט השינויים ניתן לפנות למאגר המידע שבאתר  
משרד הבריאות בכתובת [.https://data.health.gov.il/drugs/index.html#!/byDrug](https://data.health.gov.il/drugs/index.html#!/byDrug)

העלון לרופא נשלח לפרסום במלואו למאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבלו מודפס  
בפניה אלינו לטלפון 09-9591111.

בברכה,

צפיר כהן

רוקח ממונה