

אוקטובר 2020

רופא/ה, רוקח/ת נכבד/ה,

**הנדון: Dacarbazine medac 200 mg - דקרביזין מדאק 200 מ"ג**  
**Dacarbazine medac 500 mg - דקרביזין מדאק 500 מ"ג**  
**Dacarbazine medac 1000 mg - דקרביזין מדאק 1000 מ"ג**

מרכיב פעיל:

Dacarbazine medac 200 mg: 200 mg dacarbazine  
(as dacarbazine citrate, formed in situ)

Dacarbazine medac 500 mg: 500 mg dacarbazine  
(as dacarbazine citrate, formed in situ)

Dacarbazine medac 1000 mg: 1000 mg dacarbazine  
(as dacarbazine citrate, formed in situ)

צורת מינון:

Dacarbazine medac 200 mg: Powder for solution for injection/ infusion.  
Dacarbazine medac 500 mg / 1000 mg: Powder for solution for infusion.

התוויות מאושרות:

Dacarbazine is indicated for the treatment of patients with metastasised malignant melanoma .

Further indication for dacarbazine as part of a combination chemotherapy in advanced Hodgkin's disease, as a second line.

חברת צמל ביו-פארמה בע"מ מבקשת להודיעכם על העדכונים הבאים בעלון לרופא של התכשיר.  
בהודעה זו מצוינים השינויים המהווים החמרה בלבד. החמרה מסומנת באמצעות קו תחתני, שמשמעותו תוספת מידע הקשור להחמרה, או מחיקה שמשמעותה הסרת מידע הקשור להחמרה.

**החמרות בעלון לרופא:**

## 4.2 Posology and Method of Administration

### *Duration of therapy*

The treating physician should individually decide about the duration of therapy taking into account the type and stage of the underlying disease, the combination therapy administered and the response to and adverse effects of dacarbazine. In advanced Hodgkin's disease, a

usual recommendation is to administer 6 cycles of ABVD combination therapy. In metastasized malignant melanoma and in advanced tissue sarcoma, the duration of treatment depends on the efficacy and tolerability in the individual patient.

## 4.4 Special warnings and precautions for use

Concomitant use with phenytoin should be avoided because reduced absorption of phenytoin from the gastrointestinal tract may predispose the patient to convulsions (see section 4.5).

.....Administration of live vaccines to patients who are immunocompromised as a result of treatment with chemotherapeutics such as dacarbazine can cause serious and potentially fatal infections. Immunisation with live vaccines should therefore be avoided during dacarbazine therapy. It is generally advised to use live virus vaccines with caution after stopping chemotherapy and to take the patient's immune status into account, depending also on the disease and other therapies. Vaccination with live vaccines should be administered no sooner than 3 months after the completion of chemotherapy. Inactivated vaccines can be used if available.

Concomitant use of fotemustine can cause acute pulmonary toxicity (adult respiratory distress syndrome), which may lead to a fatal outcome. Fotemustine and dacarbazine should not be used concomitantly.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Immunisation with live vaccines should be avoided during therapy with dacarbazine due to the risk of serious and potentially fatal infections. It is advised to use live virus vaccines with caution after stopping chemotherapy and vaccinate not sooner than 3 months after the last dose of chemotherapy. It is recommended to use an inactivated vaccine if available (see also section 4.4).

Risk of thrombosis is increased in malignant diseases...If the patient is to receive oral anticoagulants, the frequency of INR monitoring must be increased due to large interindividual variability in coagulation and due to possible interaction between anticoagulants and cytostatics.

Concomitant use with phenytoin may cause reduced absorption of phenytoin from the gastrointestinal tract and may predispose the patient to convulsions (see section 4.4).

Concomitant use of cyclosporine (and in some cases tacrolimus) must be considered carefully because these agents may cause excessive immunosuppression and lymphoproliferation.

Concomitant use of fotemustine can cause acute pulmonary toxicity (adult respiratory distress syndrome). Fotemustine and dacarbazine should not be used concomitantly.

#### **4.6 Fertility, pregnancy and lactation**

Women of child-bearing potential have to use effective contraception during treatment.

#### **4.8 Undesirable effects**

Hepatobiliary disorders

Rare

...Budd-Chiari syndrome (with potentially fatal outcome)

Investigations

Rare

...blood lactate dehydrogenase (LDH) increased, blood creatinine increased, blood urea increased

העלון המאושר נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום, צמל ביו-פארמה בע"מ, טלפון: 073-7151111.

בברכה,

צמל ביו-פארמה בע"מ