



Odomzo 200 mg (sonidegib) capsules: Important information to minimise the risk of teratogenicity

צוות רפואי נכבד,

חברת תרו, בשיתוף משרד הבריאות, מביאה לידיעתכם מידע בטיחותי חשוב לגבי ההשפעות הטרטוגניות של אודומזו 200 מ"ג ואת התכנית למניעת היריון אשר יש ליישמה על מנת להקטין את הסיכון.

להלן עיקרי הדברים:

- אודומזו עלולה לגרום למוות עוברי או למומים קשים ביילוד ואין להשתמש בתרופה במשך ההיריון.
- בנשים המסוגלות להרות נדרשת בדיקת היריון עד 7 ימים לפני תחילת הטיפול ואחת לחודש במשך הטיפול באודומזו.
- נשים המסוגלות להרות חייבות להשתמש בשתי שיטות של אמצעי מניעה מומלצים במשך הטיפול באודומזו ובמשך 20 חודשים אחרי המנה האחרונה, אלא אם כן הן נמנעות מיחסי מין.
- מטופלים גברים חייבים להשתמש בקונדום (עם קוטל זרע, במידת האפשר) בעת קיום יחסי מין עם בת זוג במשך הטיפול באודומזו ובמשך 6 חודשים לאחר סיום הטיפול.
- ודא שכל המטופלים:
 - מיודעים באופן מספק לגבי ההשפעות הטרטוגניות של אודומזו.
 - מקבלים את 'חוברת המידע למטופל' אשר כוללת את ה'כרטיס למטופל'.

תרו אינטרנשיונל בע"מ

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Dear Healthcare Professional,

This letter is sent in agreement with the Israeli Ministry of Health to inform you of important safety information regarding the teratogenic effects of Odomzo 200 mg and the Pregnancy Prevention Programme (PPP), which must be implemented to minimise this risk.

SUMMARY

- Odomzo 200 mg may cause embryo-foetal death or severe birth defects and must not be used during pregnancy.
- Pregnancy testing is required in women of childbearing potential within 7 days before and monthly during treatment with Odomzo.
- Women of childbearing potential must use two methods of recommended contraception during Odomzo therapy and for 20 months after the final dose unless they abstain from sexual intercourse.
- Male patients must use a condom (with spermicide, if available) when having sex with a female partner while taking Odomzo and for 6 months after ending treatment.
- Ensure that all patients:
 - Are appropriately informed regarding the teratogenic effects of Odomzo.
 - Receive the Patient Information Brochure which includes the Patient Reminder Card.

Further Information

Odomzo is indicated for the treatment of adult patients with locally advanced basal cell carcinoma who are not amenable to curative surgery or radiotherapy. Hedgehog pathway inhibitors such as Odomzo have been demonstrated to be embryotoxic and/or teratogenic in multiple animal species and can cause severe malformations. Therefore a PPP (which includes this communication, educational materials and the product information) has been developed to reinforce the warnings about the expected teratogenic risk of Odomzo, provide advice on contraception, pregnancy testing and other measures to minimise this risk.

Women of child bearing potential (WCBP)

Please refer to the Summary of Product Characteristics for the definition of a WCBP.

Pregnancy testing

Pregnancy status must be established within 7 days prior to the initiation of Odomzo treatment and monthly during treatment by means of a test performed by a healthcare professional. Patients who present with amenorrhoea during treatment should continue monthly pregnancy testing. Pregnancy tests should have a minimum sensitivity of 25 mIU/ml as per local availability. In the event of pregnancy, treatment must not be initiated. In case of pregnancy occurring during treatment, Odomzo must be stopped immediately.

Methods of contraception

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Women of childbearing potential must use two methods of recommended contraception, a highly effective method (tubal sterilisation, IUD or vasectomy) and a barrier method (male condom or diaphragm, with spermicide if available). These contraceptive measures must be used during Odomzo therapy and for 20 months after the final dose unless they abstain from sexual intercourse.

Prescribing and dispensing

The initial prescription and dispensing of Odomzo should occur within 7 days of a negative pregnancy test. Prescriptions of Odomzo should be limited to 30 days of treatment, with continuation of treatment requiring a new prescription.

In case of pregnancy or missed menstrual periods

A patient who becomes pregnant, misses a menstrual period, or suspects for any reason that she may be pregnant must notify her treating healthcare professional immediately. Persistent lack of menses during treatment should be assumed to indicate a pregnancy until medically evaluated and confirmed. In cases of pregnancy or suspicion of pregnancy, treatment must be stopped immediately.

Breastfeeding

Women must not breastfeed while taking Odomzo or for 20 months after ending treatment.

Men

Male patients, even those who have had a vasectomy, must use a condom (with spermicide, if available) when having sex with a female partner while taking Odomzo and for 6 months after ending treatment. Male patients should not donate semen while taking Odomzo and for at least 6 months after ending treatment.

All patients

All patients must not donate blood while taking Odomzo and for at least 20 months after the final dose.

Additional precautions

Patients must be advised that Odomzo should not be given to another person, and that they must dispose of any unused capsules at the end of treatment in accordance with local requirements (e.g. by returning the capsules to their pharmacist or physician).

Educational material and SmPC (Summary of Product Characteristics)

Further detailed information about the measures that must be taken to minimise the risk of teratogenicity can be found in the SmPC (Summary of Product Characteristics) and educational materials, which comprise an educational brochure for healthcare professionals and patients. Please ensure that you carefully read these materials before prescribing Odomzo.

Call for reporting

Healthcare professionals should report any pregnancy and also all adverse events suspected to be associated with the use of Odomzo to Taro International Ltd (drug.safety@taro.co.il).

Any suspected adverse events should be reported to the Ministry of Health according to the

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National Regulation by using an online form

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

Sincerely yours,
Taro International Ltd.

Enclosures

1. Odomzo (sonidegib) Healthcare Professional Education Brochure with integrated Reminder Card.
2. Odomzo (sonidegib) Patient Education Brochure with integrated Reminder Card.

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