

2 FORMS OF CONTRACEPTION MUST BE USED; 1 FROM EACH COLUMN

BARRIER METHODS

Male condom
(with spermicide, if
available) **OR**
Diaphragm with
spermicide

HIGHLY EFFECTIVE FORMS OF CONTRACEPTION

- AND**
- Intrauterine device (IUD) **OR**
 - Tubal sterilisation **OR**
 - Vasectomy



The information in this reminder card is intended for healthcare professionals.
This Safety Reminder Card, format and content was checked and approved by the Ministry of Health in November 2017.

Odomzo 200 mg (sonidegib) capsules Reminder Card for healthcare providers



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Odomzo may cause embryo-fetal death or severe birth defects when administered to a pregnant woman. Hedgehog pathway inhibitors, such as Odomzo, have been demonstrated to be embryotoxic and/or teratogenic in animals. Odomzo must not be used during pregnancy.

Please refer to the SmPC (Summary of Product Characteristics) or contact Taro International Ltd. Odomzo is contraindicated in women who are pregnant or breastfeeding.

Please refer to the SmPC (Summary of Product Characteristics) for comprehensive safety information.

Remind patients taking Odomzo (sonidegib) capsules of the following:

- **Do not** become pregnant
- **Do not** breastfeed
- **Do not** donate semen
- **Do not** have unprotected sexual intercourse, even if you are a woman who has undergone a tubal ligation **OR** a man who has undergone a vasectomy
- **Women of childbearing potential should always use pregnancy prevention measures**, such as abstaining from sexual intercourse **OR** using 2 recommended methods of contraception
- Female patients must take a pregnancy test within 7 days before starting Odomzo treatment and monthly during treatment

Also remember to tell your patients to:

- **Keep medicine out of sight and reach of children**
- **Never give capsules** to anyone who is not a healthcare provider
- **Dispose of any unused capsules at the end of treatment** in accordance with local requirements (if applicable, e.g., by returning the capsules to their pharmacist or physician)
- **Refrain from donating blood while on treatment**, and for 20 months after the final dose