

Patient Card - Odomzo 200 mg

Do not use Odomzo if:

- ☑ you are pregnant or think you may be pregnant
- ☑ you are breastfeeding or planning to breastfeed
- ☑ you are not abstaining from sexual intercourse **or**, if you are a woman, you are not using 2 recommended methods of contraception.

If you are currently being treated with Odomzo or were treated with it in the past 20 months (20 months for female patients and 6 months for male patients), and you think that you or your partner (if the patient is a male) has become pregnant, stop using the medicine immediately and contact your doctor.

Any Odomzo patient who is sexually active during or after treatment must carefully follow this contraception advice:

- If you are a woman, you must completely abstain from sexual intercourse **or** use 2 recommended methods of contraception for 20 months after taking the final dose.
- If you are a man, you must use a condom during sexual intercourse, even if you have had a vasectomy, for 6 months after taking the final dose.

Female patients must take a pregnancy test within 7 days before starting Odomzo treatment and once a month during treatment.

You must use 2 methods of contraception. Use one method of contraception from each of the columns below.		
Barrier methods		a highly effective contraception method
 male condom (with spermicide, if available) or a diaphragm with spermicide 	together with	 intra-uterine device (IUD) or tubal sterilization or vasectomy

- Odomzo 200 mg may cause severe birth defects
- This medicine may lead to the death of your unborn baby or newborn
- You or your partner must not become pregnant while taking this medicine
- If you are a woman, consult your doctor if you are breastfeeding or if you become pregnant during treatment or during the 20 months following your final dose
- If you are a man, consult your doctor if your partner becomes pregnant during treatment or during the 6 months following your final dose
- Women and men must follow the contraception instructions described in this brochure

After treatment

- Return any unused capsules to the pharmacist at the end of the treatment.
- Do not donate blood while on treatment with Odomzo and for 20 months after taking your final dose.

Side effects of Odomzo

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- The patient package insert contains a complete list of all the known side effects of this medicine. It is important to be familiar with the side effects that you may experience during treatment. Tell your doctor if you experience any side effect.
- You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
 https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il
 or to Taro International by email at drug.safety@taro.co.il

Keep this card in a highly visible place to remind you of the precautions to take while taking Odomzo.

The format and content of this safety information card were reviewed and approved by the Ministry of Health in November 2017.