



# The Odomzo 200 mg Pregnancy Prevention Program

## **Important information for patients who are taking Odomzo<sup>®</sup> about preventing pregnancy and contraception methods**

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

This brochure gives you a summary of important safety information and instructions about taking Odomzo. Read it carefully and keep it in case you need to read it again. Please also read the patient package insert inside the medicine package for important information about taking this medicine. If there is anything that you do not understand or if you have any more questions, please consult your doctor or pharmacist.

## **Important things to know about Odomzo**

### **What is Odomzo?**

Odomzo is an anticancer medicine that contains the active ingredient sonidegib. Odomzo is used to treat adults with a type of skin cancer called advanced basal cell carcinoma. Odomzo is given in cases where the cancer has spread to areas nearby (locally advanced). Odomzo is available by prescription only. Please contact your doctor if you have any questions before starting treatment.

### **How does Odomzo work?**

Odomzo is an anticancer medicine that affects the activity of one of the key proteins involved in this type of skin cancer. This action may slow down or stop the growth of the cancer cells, or may kill them. As a result, your skin cancer may improve.

### **Odomzo and the risk of fetal death and birth defects**

Anticancer medicines like Odomzo may cause death of the unborn baby or severe defects in the unborn baby if you become pregnant during treatment or within 20 months after your final dose.



Studies in animals show that defects may include:

- Missing and/or fused fingers
- Head and face abnormalities (such as a cleft palate)

## **Before you start Odomzo treatment**

If you are a woman and it is possible for you to become pregnant, you must **take a pregnancy test** under supervision of a healthcare professional **within 7 days before starting treatment with Odomzo**.

## **During and after treatment**

Odomzo may harm your unborn or newborn baby. **It is important to carefully follow the instructions below during the course of this treatment and after it is completed.**

**If you are a woman** who is taking Odomzo or it is not yet **20 months after taking your final dose**:

- ☒ Do not become pregnant
- ☒ Do not breastfeed
- ☒ Do not donate blood
- ☒ Use the contraception methods recommended in this brochure even if your periods have stopped before you started treatment
- ☒ Prevent pregnancy by completely abstaining from sexual intercourse or by using effective contraception methods
- ☒ Talk to your doctor about which contraception methods are best for you
- ☒ Stop this treatment and tell your doctor immediately if your period is late or you suspect you might be pregnant

## **Recommended methods of contraception for women who are taking Odomzo**

If you are a woman and it is possible for you to become pregnant, it is very important that you understand the importance of preventing pregnancy and of using suitable contraception. If you are not abstaining from sexual intercourse (complete abstinence) during the course of this treatment (and for 20 months after your final dose), you must use 2 of the recommended methods of contraception at the same time, of the ones listed in the table below. One of the two must be a barrier method.

You must use 2 methods of contraception. Use one method of contraception from <b>each of the columns</b> below.		
Barrier methods	together with	a highly effective contraception method
<ul style="list-style-type: none"><li>• male condom (with spermicide, if available) <b>or</b></li><li>• diaphragm with spermicide</li></ul>		<ul style="list-style-type: none"><li>• Intra-uterine device (IUD) <b>or</b></li><li>• Tubal sterilization <b>or</b></li><li>• Vasectomy</li></ul>
Consult your doctor if you are not sure what contraception method to use or if you need more information.		



**If you are a man who is taking Odomzo or it is not yet 6 months after taking your final dose:**

- ☒ Do not donate semen
- ☒ Use a condom when having sexual intercourse with a woman even if you have had a vasectomy
- ☒ Consult your doctor immediately if you suspect your partner may have become pregnant

**Recommended for all patients**

- ☒ Return the unused capsules to the pharmacist at the end of treatment with Odomzo
- ☒ Keep this medicine out of the sight and reach of children
- ☒ Do not give this medicine to anyone
- ☒ Do not donate blood

**If you suspect pregnancy**

Stop this treatment immediately and tell your doctor if your period is late, you have unusual bleeding between periods, you suspect a pregnancy or you are pregnant.

**Do not use Odomzo if:**

- ☒ you are pregnant or think you may be pregnant
- ☒ you are breastfeeding or planning to breastfeed
- ☒ you are not using pregnancy prevention measures by completely abstaining from sex **or**, for women who can get pregnant, by using effective methods of contraception (see the table **Recommended methods of contraception for women who are taking Odomzo**)

**Return any unused capsules to the pharmacist at the end of your treatment.**

***Women***

Continue following the instructions for Odomzo while you are taking Odomzo and for 20 months after taking your final dose.

***Men***

Continue following the instructions for Odomzo while you are taking Odomzo and for 6 months after taking your final dose.

**Side effects of Odomzo**

- 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](http://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](mailto:drug.safety@taro.co.il)

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