

PATIENT PACKAGE INSERT

TUDRIQEV™ (TOO-drih-kev) (vusolimogene oderparepvec-wtpg) suspension for intratumor injection

TUDRIQEV Is:

- Used with nivolumab to treat adults with advanced melanoma who have previously received an anti-PD-1-based regimen.

Important Safety Information

Warnings:

- Avoid touching or scratching the injection sites and dressing to prevent the transfer of TUDRIQEV. You or your caregiver should always wear gloves when replacing or changing your injection site dressings.
- TUDRIQEV may cause a new or a reactivation of the common cold sore (herpes simplex virus, type 1). If you develop a cold sore after treatment with TUDRIQEV, contact your doctor to provide a swab for testing. You may also call TUDRIQEV Medical Information for guidance at 1-877-375-0095.
- Injections of TUDRIQEV into tumors in your liver, lung or other organs may cause injury that requires further monitoring or treatment.

Serious side effects:

TUDRIQEV may cause serious side effects. Call your healthcare provider right away if you develop any of the following signs and symptoms:

- Joint pain
- Headache, vision changes, dizziness or tiredness, which may be signs of inflammation of the pituitary gland
- Abdominal pain, cramping, diarrhea, nausea
- Fever

Drug Interactions

Tell your doctor if you have received antiviral medicine such as acyclovir. TUDRIQEV might not be effective if given within 72 hours of these medicines.

Special Population

Both men and women should use effective birth control during treatment and for 90 days after the last TUDRIQEV injection. Talk to your healthcare provider for more information.

Tell your health care provider:

- If you are breastfeeding or plan to breastfeed. You should not breastfeed during your treatment and for 90 days after your last injection of TUDRIQEV.
- If you are pregnant or plan to become pregnant. For women, your healthcare provider should advise you to take a pregnancy test before starting your TUDRIQEV treatment.
- If you become pregnant during your TUDRIQEV treatment.
- About all the medications you take including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Common Side Effects:

The most common side effects of TUDRIQEV with nivolumab treatment include:

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| • Tiredness | • Fever |
| • Chills | • Nausea |
| • Diarrhea | • Injection Site Reactions (redness, pain, or swelling) |
| • Infection | • Flu-like illness or symptoms |
| • Joint or muscle pain | |

These are not all of the possible side effects of TUDRIQEV. Call your health care provider if you have side effects that worsen or do not go away. You may also report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Directions for Use

TUDRIQEV is given by your healthcare provider and is not self-administered. After injection, keep the injection site(s) covered for at least 48 hours.

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