Optune®
System Description[1]

Indication

- Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma (GBM)
- Optune with temozolomide (TMZ) is indicated for the treatment of adult patients with **newly diagnosed, supratentorial GBM** following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy
- For the treatment of recurrent GBM, Optune is indicated following **histologically- or radiologically-confirmed recurrence in the supratentorial region** of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted

1. Shoulder bag and strap
2. Connection cable and box
3. Electric field generator (the device)
4. Plug-in power supply
5. Transducer arrays
6. Portable battery case
7. Charger for portable batteries
8. Portable batteries

Optune Components[2]

Optune consists of 3 main components:

- Device (electric field generator) and portable batteries
- Two sets of transducer arrays
- The device shoulder bag and portable battery case

The following items are also included in the Optune treatment kit:

- Charger for portable batteries
- Connection cable and box
- Plug-in power supply

How Optune Works

- Optune is a portable, noninvasive, antimitotic cancer treatment for GBM that uses Tumor Treating Fields (TTFields) at 200 KHz. TTFields are electric fields delivered in 2 directions to disrupt cancer cell division
- TTFields **specifically target and disrupt division of GBM cells**, inhibiting tumor growth and possibly causing affected cancer cells to die while sparing normal, healthy cells

How Optune Is Used

- Transducer arrays are applied to the clean, shaved scalp and need to be replaced at least twice per week (every 4 days at most) to help minimize the risk of skin irritation[2,3]
- Portable for use during normal daily activities
  - Note: Patients should avoid activities that may result in Optune or the transducer arrays becoming wet, as this may cause damage[2]
- It is recommended that Optune is turned on at least 75% of the time (≥18 hours a day) in order to obtain optimal outcomes
- Patients should refer to the *Skin Care Guidelines* for specific information regarding taking care of their skin and array placement instructions

Visit Optune.com/HCP for more information

OPTUNE®

Indications For Use

Optune is intended as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM).

Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery, and completion of radiation therapy together with concomitant standard of care chemotherapy.

For the treatment of recurrent GBM, Optune is indicated following histologically-or radiologically-confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. The device is intended to be used as a monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted.

Important Safety Information

Contraindications

Do not use Optune in patients with an active implanted medical device, a skull defect (such as, missing bone with no replacement), or bullet fragments. Use of Optune together with implanted electronic devices has not been tested and may theoretically lead to malfunctioning of the implanted device. Use of Optune together with skull defects or bullet fragments has not been tested and may possibly lead to tissue damage or render Optune ineffective.

Do not use Optune in patients that are known to be sensitive to conductive hydrogels. In this case, skin contact with the gel used with Optune may commonly cause increased redness and itching, and rarely may even lead to severe allergic reactions such as shock and respiratory failure.

Warnings and Precautions

Optune can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure (the device manufacturer).

Do not prescribe Optune for patients that are pregnant, you think might be pregnant or are trying to get pregnant, as the safety and effectiveness of Optune in these populations have not been established.

The most common (≥10%) adverse events involving Optune in combination with temozolomide were thrombocytopenia, nausea, constipation, vomiting, fatigue, medical device site reaction, headache, convulsions, and depression.

The most common (≥10%) adverse events seen with Optune monotherapy were medical device site reaction and headache.

The following adverse reactions were considered related to Optune when used as monotherapy: medical device site reaction, headache, malaise, muscle twitching, fall and skin ulcer.

Use of Optune in patients with an inactive implanted medical device in the brain has not been studied for safety and effectiveness, and use of Optune in these patients could lead to tissue damage or lower the chance of Optune being effective.

If the patient has an underlying serious skin condition on the scalp, evaluate whether this may prevent or temporarily interfere with Optune treatment.

Please go to www.optune.com/Content/pdfs/Optune_IFU_8.5x11.pdf to see the Optune IFU for complete information regarding the device's indications, contraindications, warnings and precautions.

References: **1.** Optune. Instructions for Use. Novocure; 2019. **2.** Optune. Patient Information and Operation Manual. Novocure; 2019. **3.** Lacouture ME, et al. *Front Oncol.* 2020;10:1045.

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