Optune® Fact Sheet

- Optune is a FDA-approved treatment for glioblastoma (GBM), the most common and deadliest type of primary brain cancer.[1]
- Optune is the first FDA-approved treatment in more than a decade for newly diagnosed GBM.[2]
- Optune is a wearable, portable device that has been shown in clinical trials to safely deliver continuous treatment to the location of GBM tumors.[3]
    - Optune creates low-intensity electric fields, called Tumor Treating Fields, or TTFields, which help slow or stop GBM cancer cells from dividing and may also destroy some of them.
    - TTFields work when cancer cells are dividing and do not disrupt healthy resting cells.
- For patients with newly diagnosed GBM, Optune has proven to extend survival and maintain quality of life.
    - A large clinical trial showed that adding Optune to TMZ provided the greatest opportunity to live longer compared to TMZ alone at 5 years. Survival doubled at 5 years from 5% with TMZ alone to 13% by adding Optune.[4]
        - In a 5-year followup, people on Optune plus TMZ lived longer across all groups analyzed regardless of well-being, age, gender and how much of the tumor was removed.[4]
        - People in the study were also able to maintain their mental, emotional, and physical well-being longer than those on chemotherapy alone for up to one year.[5]
    - Nearly half, or 43%, of people on Optune plus TMZ were alive at 2 years compared with 31% of people on TMZ alone.[4]
- Because TTFields do not enter the bloodstream like a drug, they did not significantly increase chemotherapy related side effects. The most common (≥10%) adverse events seen when using Optune alone were scalp irritation from device use and headache.
- Optune is small and light weighing just 2.7 pounds. This makes Optune wearable and portable so continuous treatment with Optune can be received almost everywhere.
- Optune delivers treatment through 4 adhesive patches called transducer arrays. These arrays are applied to the shaved scalp and are connected to the device and battery.[6]
- Optune received its FDA approval in newly diagnosed GBM in 2015. The FDA previously approved Optune in 2011 for the treatment of recurrent GBM after surgery and radiation options have been exhausted.

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 if you have 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 if you 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

Use Optune only after receiving training from qualified personnel, such as your doctor, a nurse, or other medical personnel who have completed a training course given by Novocure™ (the device manufacturer).

Do not use Optune if you are pregnant, you think you might be pregnant or are trying to get pregnant. It is not known if Optune is safe or effective in these populations.

The most common (≥10%) adverse events involving Optune in combination with temozolomide were low blood platelet count, nausea, constipation, vomiting, fatigue, scalp irritation from device use, headache, convulsions, and depression.

The most common (≥10%) adverse events seen when using Optune alone were scalp irritation from device use and headache.

The following adverse reactions were considered related to Optune when using the device alone: scalp irritation from device use, headache, malaise, muscle twitching, fall and skin ulcer.

All servicing procedures must be performed by qualified and trained personnel.

Do not use any parts that do not come with the Optune Treatment Kit, or that were not sent to you by the device manufacturer or given to you by your doctor.

Do not wet the device or transducer arrays.

If you have an underlying serious skin condition on the scalp, discuss with your doctor whether this may prevent or temporarily interfere with Optune treatment.

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1. Ostrom QT, Gittleman H, Truitt G et al. CBTRUS Statistical Report: Primary Brain and Central Nervous System Tumors Diagnosed in the United States in 2011–2015, Neuro Oncol (2018) 20 (suppl 4): iv1-iv86 doi: 10.1093/neuonc/noy131. 2. Novocure Data on File. OPT-117. 3. Optune Instructions For Use. Novocure 2016. 4. Stupp R, Taillibert S, Kanner A, et al. Effect of tumor-treating fields plus maintenance temozolomide vs maintenance temozolomide alone on survival in patients with glioblastoma: a randomized clinical trial. JAMA Oncology. 2017;318(23):2306-2316. 5. Taphoorn M, Dirven L, Kanner A, et al. Influence of treatment with tumor-treating fields on health-related quality of life of patients with newly diagnosed glioblastoma: a secondary analysis of a randomized clinical trial. 6. JAMA Oncol. 2018 Apr 1;4(4):495-504. doi: 10.1001/jamaoncol.2017.5082.

