A guide to scalp care and proper transducer array placement

Steve is on Optune. Vali is his wife.
What is Optune® approved to treat?
Optune is a wearable, portable, FDA-approved device indicated to treat a type of brain cancer called glioblastoma multiforme (GBM) in adult patients 22 years of age or older.

**Newly diagnosed GBM**
If you have newly diagnosed GBM, Optune is used together with a chemotherapy called temozolomide (TMZ) if:
- Your cancer is confirmed by your healthcare professional **AND**
- You have had surgery to remove as much of the tumor as possible

**Recurrent GBM**
If your tumor has come back, Optune can be used alone as an alternative to standard medical therapy if:
- You have tried surgery and radiation and they did not work or are no longer working **AND**
- You have tried chemotherapy and your GBM has been confirmed by your healthcare professional

Who should not use Optune?
Optune is not for everyone. Talk to your doctor if you have:
- An implanted medical device (programmable shunt), skull defect (missing bone with no replacement), or bullet fragment. Optune has not been tested in people with implanted electronic devices, which may cause the devices not to work properly, and Optune has not been tested in people with skull defects or bullet fragments, which may cause Optune not to work properly
- A known sensitivity to conductive hydrogels (the gel on the arrays placed on the scalp like the ones used on EKGs). When Optune comes into contact with the skin, it may cause more redness and itching or may rarely cause a life-threatening allergic reaction

**Do not use Optune if you are pregnant or are planning to become pregnant.**
It is not known if Optune is safe or effective during pregnancy.

What should I know before using Optune?
Optune should only be used after receiving training from qualified personnel, such as your doctor, a nurse, or other medical staff who have completed a training course given by Novocure™, the maker of Optune.
- Do not use any parts that did not come with the Optune Treatment Kit sent to you by Novocure or given to you by your doctor
- Do not get the device or transducer arrays wet
- 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

What are the possible side effects of Optune?
Most common side effects of Optune when used together with chemotherapy (temozolomide, or TMZ) were low blood platelet count, nausea, constipation, vomiting, tiredness, scalp irritation from the device, headache, seizure, and depression.
The most common side effects when using Optune alone were scalp irritation (redness and itchiness) and headache. Other side effects were malaise, muscle twitching, fall and skin ulcers.
Talk to your doctor if you have any of these side effects or questions.

Please visit Optune.com/Safety for Optune Instructions For Use (IFU) for complete information regarding the device’s indications, contraindications, warnings, and precautions.
The importance of maximizing your time on Optune

Optune is a wearable and portable, FDA-approved treatment of glioblastoma (GBM). For patients with newly diagnosed GBM, Optune is used together with the chemotherapy temozolomide (TMZ). For patients with recurrent GBM, Optune is used alone.

Optune is designed to be worn continuously throughout the day and night. With Optune, it is important to maximize the amount of time you receive treatment each day. Optune should be worn for at least 75% of the time (18 hours per day) to get the best response from treatment.

One of the most common side effects when using Optune was scalp irritation (redness and itchiness) beneath the transducer arrays. Do not use Optune if you have a known sensitivity to conductive hydrogels (the gel on the arrays placed on the scalp like the ones used on EKGs). This may cause more redness or itchiness, or may rarely cause a life-threatening allergic reaction. Please see the Important Safety Information on pages 2-3 for additional adverse events.

Proper scalp care plays an important role in preventing skin irritation

Proper scalp care can help reduce the risk of developing a skin irritation while receiving Optune. While these steps detailed here are intended to help you minimize your risk of skin irritation and maximize your time on Optune, make sure you speak with your doctor to determine what treatment for skin irritation is right for you. This information is not intended to take the place of your doctor’s advice.

SCALP PREPARATION

In order to ensure good array-to-scalp contact, proper scalp shaving and washing are important. You or your caregiver should:

- Shave your scalp closely with the electric dry razor provided in your starter kit. Test the closeness of the shave by running a gauze pad moistened with 70% isopropyl alcohol across your scalp. If there is noticeable friction, a closer shave is required
- Wash your scalp with a mild fragrance-free shampoo or dandruff shampoo after shaving to clean your scalp and reduce oiliness
- Wipe your skin with 70% isopropyl alcohol to remove additional oil from your scalp.

If you are experiencing a skin irritation, be sure to avoid contact with the affected area

- Ensure that your head is completely dry before applying a new set of transducer arrays

Between applications of transducer arrays, use mineral (baby) oil before shaving to remove any adhesive residue from your scalp if needed.

INFECTION PREVENTION

Although the transducer arrays are provided in individual sterile packages to minimize infection risk, you and/or your caregiver can take additional steps to further reduce the risk of infection.

- Always wash your hands prior to application and removal of transducer arrays
- Wash your scalp between transducer array exchanges
- Clean the electric razor per manufacturer’s guidelines after every shave
Proper transducer array placement helps reduce the risk of skin irritation

Changing your transducer arrays and moving their position slightly from the previous location on your head can help reduce your risk of skin irritation. If you develop skin irritation, please contact your doctor.

**CHANGING YOUR TRANSDUCER ARRAYS**

Change the transducer arrays at least 2 times per week (every 4 days at most). More frequent transducer array exchanges are recommended if:

- The weather has been warmer, causing you to sweat more
- Your hair grows quickly
- You’ve performed intense physical activity, causing you to sweat more
- You’re experiencing discomfort, intense itching, or excessive oiliness on your scalp
- The hydrogel layer over the ceramic discs becomes soft or “gooey” because of excessive moisture on your scalp

Additionally, some medications may increase the risk of skin irritation or affect healing. Contact your doctor to answer any questions you may have about your medications.

To view a brief demonstration of applying transducer arrays, visit Optune.com.

**NOTE:** Please contact Novocure™ to arrange for proper disposal of used transducer arrays. Do not throw them in the trash.

Selected Important Safety Information

- Do not use Optune if you have an implanted medical device (programmable shunt), skull defect (missing bone with no replacement), or bullet fragment. Optune has not been tested in people with implanted electronic devices, which may cause the devices not to work properly, and Optune has not been tested in people with skull defects or bullet fragments, which may cause Optune not to work properly.

The transducer arrays are attached to a medical adhesive patch to keep them in place on the scalp and in continuous direct contact with the skin. Proper application requires rotating the placement of the transducer arrays by approximately 0.75 inches every time you exchange them.

Examples of shifting transducer arrays at each array exchange

- Slightly relocate the transducer arrays each time you exchange them, so contact sites vary. Reference your transducer array layout map for placement.
  - Shift the transducer arrays approximately 0.75 inches from the last location
  - The ceramic discs leave a slight indentation on the surface of your scalp, allowing you or your caregiver to easily see where to position the new set of arrays
  - The transducer arrays work in pairs, so they should be shifted together (see example diagram)
  
- On your next transducer array exchange, shift them back to the previous position

Avoid placing any of the ceramic discs over surgical scars, craniotomy hardware, or anything on your scalp that feels hard or bumpy to your fingertips.
What to do if you develop a skin irritation on your scalp

**It is important to be able to recognize skin irritation symptoms, so you can seek proper treatment**

If you experience swelling, redness, excessive itching, or other skin-related symptoms, contact your healthcare provider for treatment options. By practicing good scalp care habits and properly changing transducer arrays while receiving Optune, you may reduce your risk of developing skin irritation on your scalp. Although skin irritation may sometimes occur, it can typically be treated with topical ointments without discontinuing Optune.

Speak with your doctor to determine what treatment for skin irritation is right for you. This information is not intended to take the place of your doctor’s advice.

For more information about Optune, please visit or call:

Optune.com
nCompass™ support at 1-855-281-9301 (toll free)

**Selected Important Safety Information**

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**References:**


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