

Optune Lua™

System Description¹

Indication

For the first-line **treatment of unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM)**, the FDA has approved Optune Lua in combination with pemetrexed + cisplatin/carboplatin.

Optune Lua overview

Optune Lua **provides loco-regional delivery of Tumor Treating Fields (TTFields) via transducer arrays** resulting in antimitotic activity at the site of the malignancy.

Optune Lua

Optune Lua consists of 3 main components:

- The device & battery carrying bag
- Device (electric field generator) & battery
- Transducer arrays
 - Customized based on gender, body type, and tumor location

The following components are also included in the Optune Lua treatment kit:

- Portable battery charger
- Connection cable and box

How Optune Lua works

Optune Lua is a noninvasive, antimitotic cancer treatment for MPM that delivers TTFields. TTFields are low-intensity (1-3 V/cm) alternating electric fields tuned to a specific frequency (150 kHz) to disrupt solid tumor cancer cell division.

TTFields **specifically target and disrupt division of MPM cells**, inhibiting tumor growth and possibly causing affected cancer cells to die while sparing normal, healthy cells.

Caution: Federal law restricts this device to sale by or on the order of a physician. Humanitarian Device. Authorized by Federal Law for use in the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma concurrently with pemetrexed and platinum-based chemotherapy.



- 1 The device & battery carrying bag
- 2 Device (electric field generator) & battery
- 3 Transducer arrays

How Optune Lua is used

- Transducer arrays are applied to the torso and need to be replaced at least twice per week (every 3-4 days at most) to help minimize the risk of skin irritation²
- Portable for use during normal daily activities
 - Note: Patients should avoid activities that may result in Optune Lua or the transducer arrays becoming wet, as this may cause damage²
- It is recommended that Optune Lua 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 [OptuneLua.com](https://www.OptuneLua.com) for more information



Indications For Use

Optune Lua™ is indicated for the treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy.

Important Safety Information

Contraindications

Do not use Optune Lua in patients with implantable electronic medical devices such as pacemakers or implantable automatic defibrillators, etc. Use of Optune Lua together with implanted electronic devices has not been tested and may lead to malfunctioning of the implanted device.

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

Warnings and Precautions

Optune Lua can only be prescribed by a healthcare provider that has completed the required certification training provided by Novocure®. The most common ($\geq 10\%$) adverse events involving Optune Lua in combination with chemotherapy were anemia, constipation, nausea, asthenia, chest pain, fatigue, medical device site reaction, pruritus, and cough.

Other potential adverse effects associated with the use of Optune Lua include: treatment related skin toxicity, allergic reaction to the plaster or to the gel, electrode overheating leading to pain and/or local skin burns, infections at sites of electrode contact with the skin, local warmth and tingling sensation beneath the electrodes, muscle twitching, medical device site reaction and skin breakdown/skin ulcer.

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

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

Please see the accompanying Optune Lua Instructions For Use (IFU) for complete information regarding the device's indications, contraindications, warnings, and precautions.

References: 1. Optune Lua Instructions For Use for Unresectable Malignant Pleural Mesothelioma. Novocure 2019. 2. Optune Lua Patient Information and Operation Manual for Unresectable Malignant Pleural Mesothelioma.