OPTUNE PAX®

Be prepared for dermatologic adverse events (dAEs) with the M3 approach:

Mitigate, **monitor**, and **manage** dAEs

in the treatment of locally advanced pancreatic cancer[1,2]

This brochure does not represent medical advice but guidance based on clinical trial results and real-world experience from other approved indications. Novocure® cannot give medical advice.[3-5]

Indication for Use

Optune Pax® is intended for the treatment of adult patients with locally advanced pancreatic cancer, concomitant with gemcitabine and nab-paclitaxel.

Important Safety Information

Contraindications

Do not use Optune Pax in patients with an electrical implant. Use of Optune Pax together with electrical implants has not been tested and may lead to malfunctioning of the implanted device.

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You play a crucial role in supporting patients during treatment with Optune Pax, concomitantly with gemcitabine and nab-paclitaxel.

This guide to an M3 approach—ie, mitigating, monitoring, and managing dAEs—can be used to support you in partnering with your patients to help them maintain their skin health while using the device.[1,2]

Patient-specific factors such as age, genetics, allergies, and prior treatment may influence their skin health and the risk of dAEs. This, combined with their individual disease experiences, may mean that the conversations with each patient you support will be unique.[6]

dAE=dermatologic adverse event.

Important Safety Information (cont)

Contraindications (cont)

Do not use Optune Pax in patients with a known sensitivity to conductive hydrogels. In patients with this sensitivity, skin contact with the gel used with Optune Pax may commonly cause increased redness and itching. In rare cases, it may lead to severe allergic reactions that can cause a drop in blood pressure and difficulty breathing.

Warnings and Precautions

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

Do not prescribe Optune Pax for patients who are pregnant, who you think might be pregnant, or who are trying to get pregnant. Women who are able to get pregnant must use birth control when using the device. Safety and effectiveness of Optune Pax in these populations have not been established.

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Dermatologic AEs (dAEs) are to be expected with Optune Pax® but can be managed[1]

- dAEs may occur with Optune Pax because the arrays must be adhered directly to the skin to function properly and deliver electric fields[2,3,6]

  Some other potential causes include[2,3,6]:
  - Sensitivity to ingredients in the conductive hydrogel
  - Pressure and sideways pulling of the skin (shearing forces)
  - Moisture-related stresses (eg, sweating) linked to prolonged contact with transducer arrays and adhesive
  - Other risk factors inherent to the patient (ie, preexisting conditions, concomitant treatments, scars, or other dermatological skin conditions)

In the PANOVA-3 clinical trial for locally advanced pancreatic cancer

- dAEs under the transducer arrays were experienced by 76.3% of patients (n=209/274)[1,7]
  - Most events were mild to moderate, with 21 patients (7.7%) reporting a grade 3+ event
- The most common device-related AE not related to skin toxicity was fatigue, reported in 14 participants (5.1%)[1]
- There were no device-related AEs that led to death[1]

Device-related dAEs with Optune Pax + gemcitabine and nab-paclitaxel[8*]

Preferred term	All grades n (%)	Grade ≥3 n (%)
Dermatitis	76 (27.7%)	8 (2.9%)
Rash	48 (17.5%)	4 (1.5%)
Pruritus	41 (15%)	0
Rash maculo-papular	33 (12%)	3 (1.1%)
Erythema	29 (10.6%)	0
Skin irritation	25 (9.1%)	2 (0.7%)
Skin reaction	17 (6.2%)	1 (0.4%)
Skin ulcer	14 (5.1%)	1 (0.4%)
Blister	10 (3.6%)	0
Skin injury	8 (2.9%)	0
Thermal burn	6 (2.2%)	0

*≥2% of patients in any group and all grade 3+ adverse events.
AE=adverse event.

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Mitigate dAEs to help maximize time on therapy

To reduce the incidence and severity of device-related dAEs, advise your patient to adopt proactive skin care, emphasizing prevention and early identification.

Preventive skin care for treatment-related reactions under the transducer arrays

Advise patients and caregivers to[1]:

Cleanse skin daily with lukewarm water and mild, fragrance-free soap or bodywash. Dry without rubbing skin with bath towels, and moisturize regularly.

Avoid alcohol- and petroleum-based products and products containing fragrances, solvents, or harsh disinfectants.

Minimize sun exposure and apply appropriate sun protection when outdoors and not wearing arrays.

Wear loose-fitting, breathable clothing to help avoid excessive sweating around the arrays. Avoid materials that can irritate the skin (eg, coarse wool)

Consider prescribing routine prophylaxis using water- or silicone-based products (eg, dimethicone-based films or nonpetroleum-based wipes) and skin barrier films.

Note: It's important to understand key risk factors—such as preexisting conditions, surgical scars and hardware, and concomitant treatments like ICIs or targeted therapies—and to intervene early to help decrease the risk and severity of dAEs.[3]

dAE=dermatologic adverse event; ICI=immune checkpoint inhibitor.

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Important guidelines for proper array management

Your patient's dedicated Device Support Specialist is expected to show your patient how to place the arrays at their initial start appointment, so removing arrays should be your patient's first step. In the case of patients initially applying arrays for the first time, they can skip the removal guidelines and begin with proper placement.[1,2]

Emphasize the following to patients and caregivers:

Removing the arrays from the skin[2]

- You will need to change the arrays at least two times per week (every 3–4 days)
- In general, remove the arrays without pulling or rubbing the skin
- Unplug the arrays from the Optune Pax® device and leave the device outside the bathroom
- Thoroughly wet the arrays until they are fully saturated using lukewarm water while showering
- Apply even tension, and slowly and gently peel back the arrays from the skin
- Mineral (baby) oil or medical-grade, silicone-based, and alcohol-free adhesive or ostomy remover may be applied to help
- If you are using a skin barrier film, it must be removed and reapplied when replacing transducer arrays
- Check for signs of skin damage or excess irritation. Encourage patients to report and keep a photograph diary of any skin problems[6]

Preparing the skin and placing the arrays[2]

- Wash hands thoroughly before preparing the skin
- Shave the abdomen using a clean, electric shaver. Do not use razor blades
  - Repeat shaving as needed when you replace the arrays
- Wash your abdomen with a mild, fragrance-free soap and pat the skin dry
- Apply any topical skin product advised by your doctor (eg, moisturizing lotion, skin barrier film, corticosteroid, antibiotic cream)
  - Wait at least 20 minutes (or per the manufacturer's instructions) to ensure absorption
  - Remove excess residues and ensure skin is completely dry before array placement
- Place the arrays according to the array layout provided by your doctor
  - Shift arrays 2 cm (¾ inch) from their original position, and move arrays back at subsequent changes
  - Ensure that pairs of arrays are moved together
- Press the entire edge of each transducer array to your skin
- You may need to ask a friend or family member to help place the transducer array(s) on your back
- Avoid placing the arrays over surgical hardware (eg, screws or shunts), scars, or open wounds
- Wear breathable clothing to help avoid excessive sweating around the arrays

Note: Encourage your patients to notify you at the earliest signs of a skin issue, such as itching, redness, or inflammation.[2]

dAE=dermatologic adverse event.

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Monitor symptoms and intervene with the necessary action

Recommended treatment of skin AEs during Optune Pax® use[1]

Grade 1

Description
- Asymptomatic or mild skin changes (eg, erythema, dryness, pruritus)
- No functional impact

Recommended management
- Initiate or optimize use of water-based moisturizers
- Add barrier film or dimethicone-based protectant, if needed
- Low-potency topical corticosteroids, if needed (eg, hydrocortisone 1%)
- Preference for nonocclusive, alcohol-free, fragrance-free products

TTFields guidance
- Continue TTFields therapy uninterrupted

Dermatology referral
- Not required unless symptoms persist or diagnosis is unclear

Grade 2

Description
- Symptomatic erythema, localized erosions, or pruritus interfering with daily activities

Recommended management
- Moderate-potency corticosteroids (eg, triamcinolone 0.1%)
- Topical antibiotics for suspected secondary infection
- Antihistamines or antipruritic, as needed

TTFields guidance
- Continue TTFields therapy if tolerable
- Consider brief treatment break (2–7 days) for recovery

Dermatology referral
- Recommended if symptoms do not resolve or diagnosis is uncertain

Grade 3

Description
- Skin ulceration, bleeding, or widespread erosions

Recommended management
- Wound care with hydrogels or hydrocolloid dressings
- Topical and/or systemic antibiotics, based on culture
- Short-course, systemic corticosteriods if topical therapy is inadequate

TTFields guidance
- Interrupt treatment with TTFields
- Resume once lesion is re-epithelialized and resolves to Grade ≤1

Dermatology referral
- Strongly recommended. Seek dermatologist or wound care specialist

Grade 4

Description
- Full thickness ulceration, systemic infection, or necrosis

Recommended management
- Hospital-based wound care
- IV antibiotics
- Multidisciplinary care, including dermatology and infectious disease

TTFields guidance
- Discontinue TTFields therapy temporarily or permanently based on clinical judgement
- Reinitiate only after full resolution and multidisciplinary approval

Dermatology referral
- Mandatory multidisciplinary referral

AE=adverse event; IV=intravenous; TTFields=Tumor Treating Fields.

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Dermatitis and rash[3]

Symptoms

1. Contact dermatitis:
   - Skin rash (red, itchy papules)
2. Irritant dermatitis:
   - Skin redness (itchy, painful)
   - Mild edema
   - Local, at area of irritant

Potential causes

1. Contact: Allergy to specific exogenous allergens, such as adhesive tape and/or hydrogel, that come into contact with the skin, causing an inflammatory reaction
2. Irritant: Nonspecific inflammation caused by chemical irritation from hydrogel, moisture, and/or alcohol

Suggested interventions

- Immediate removal of the irritant/allergen
- Array removal from irritation site
- Mild-to-moderate strength topical steroid creams or solutions
- Consider trimming adhesive or tubular elastic bandage retainer if reaction exists to tape or adhesive
- If blistering, apply cold, moist compress (20 minutes; 3 times/day)
- Consider systemic corticosteroids/treatment breaks if condition persists

Pruritus[3]

Symptoms

- Dry skin (xerosis)
- Itchy skin (pruritus)

Potential causes

- Genetic predisposition
- Cold/dry climate
- Loss of water/oil
- Medications
- May be related to contact dermatitis

Suggested interventions

- Limit skin contact with alcohol-based products
- Topical corticosteroids (eg, betamethasone, clobetasol, water-based fluocinonide) may be prescribed if inflammation is present
- Refrigeration of topical products to aid in the antipruritic effect[6]
- For severe cases, consider treatment interruption until resolution of dAE; restart with prophylactic measures[9]

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Hyperhidrosis[3]

Symptoms

- Excessive sweating

Potential causes

- Genetic predisposition
- Hot/humid climate
- Intense activity
- Medications

Suggested interventions

- Aluminum zirconium, antiperspirant or topical glycopyrrolate at every array exchange
- Avoid using ointments and medications that may cause sweating
- Anti-sweat, breathable sportswear or loosely woven materials are advised[6]

Skin ulcer[3]

Symptoms

- Open skin defects, bleeding, or oozing
- Complete loss of epidermis, portions of dermis, fat, or muscle

Potential causes

- Ischemic injury and/or decreased perfusion produced by array pressure
- Trauma from shaving and/or array application or removal
  - May develop from inflammation or maceration due to sweat, rupture of vesicles, bullae from infection, or epidermal necrosis

Suggested interventions

- Transducer array removal from site of ulcer—consider re-placement to avoid area of breakdown/skin issue
- Wound dressing with gauzes, hydrogels, or hydrocolloids
- Treat with topical antibiotics
- Consider wound culture
- Keep clear of excess discharge and dead skin (severe cases may require surgical debridement)
- Return to clinic in 2 weeks; if condition persists, consider oral antibiotic/treatment break

> **Suggested interventions based on "Prevention and Management of Dermatologic Adverse Events Associated With Tumor Treating Fields in Patients With Glioblastoma" from Lacouture, et al.**

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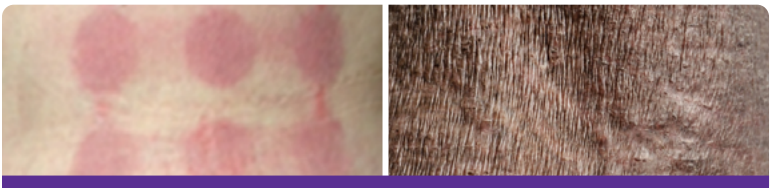
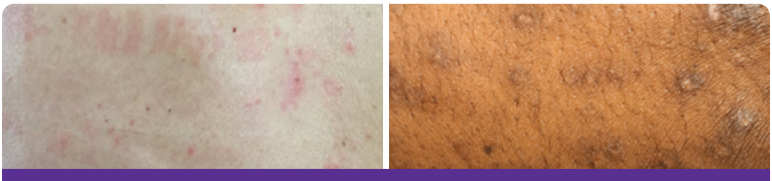
Identifying skin changes early is essential to help minimize dAE severity[1,3,6]

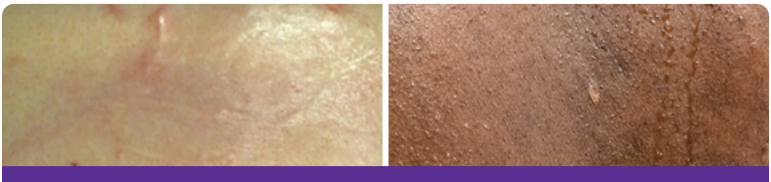
Use these photos to help recognize dAEs and see suggested interventions for each on pages 7–8.



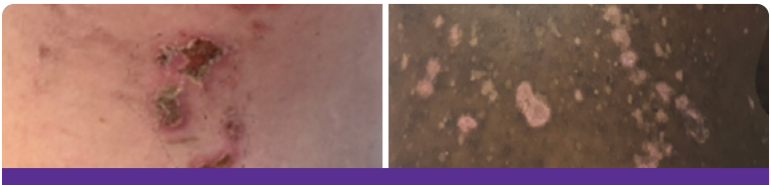
Dermatitis



Pruritus



Hyperhidrosis



Skin ulcer

The images on the left are from an open-access article distributed under the terms of the Creative Commons Attribution License (CC BY) and illustrate dAEs related to Optune® Treatments. The images on the right depict the general presentation of these adverse events and are not specific to Optune Treatments.

Pictured are patients who may have high-grade dAEs. If skin conditions continue, consider referral to a dermatologist. Refer patients to a dermatologist based on the recommendations by grade on page 6 and your independent clinical judgment.[3]

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Depending on symptom severity, topical agents for dAE management may be appropriate[1,3,6]

Consider prescribing:

- Topical corticosteroids, nonsteroidal immunomodulators, antibiotics
- Routine prophylaxis using water- or silicone-based skin barrier products (eg, dimethicone-based films or nonpetroleum-based barrier wipes)

Guidelines to share with patients who use topical agents[2,3]

- Topical agents—including medications and skin barriers—should be applied at each array change to skin that is clean and dry
  - For sensitive skin or hyperhidrosis (excessive sweating), skin barriers are recommended to help reduce moisture and offer skin protection
- For optimal TTFields delivery, apply topical agents to the skin in a thin layer
  - Use compatible formulations with the Optune Pax® device—ie, water-based creams, gels, lotions, soaps, foams, wipes, and sprays
- See "Preparing the skin and placing the arrays" on page 5 for more details on applying topical agents after array removal

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Important Safety Information (cont)

Warnings and Precautions (cont)

The most common (≥10%) adverse events involving Optune Pax concomitant with gemcitabine and nab-paclitaxel were neutropenia, anemia, thrombocytopenia, leukopenia, diarrhea, nausea, vomiting, abdominal pain, constipation, fatigue, peripheral edema, pyrexia, pain, COVID-19, infection, respiratory tract infection, urinary tract infection, pneumonia, hepatic enzyme increased, anorexia, hypokalemia, hypoalbuminemia, hyperglycemia, musculoskeletal pain, peripheral neuropathy, taste disorder, dizziness, sleep disorder, dyspnea, alopecia, skin-related disorders, and hypotension.

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For persistent or severe dAEs, treatment breaks may be needed[1,3]

If dAE symptoms do not improve with proper management, you may decide that treatment interruption is the next right step.

Instructions on treatment interruptions

- Please refer to the table on page 6 regarding recommended treatment interruptions based on dAE severity
- Depending on grade, interrupting for 2–7 days, in addition to topical treatment, may be sufficient. In other cases, a longer interruption may be needed

Skin toxicity associated with treatment with Optune Pax® may be managed with proper skin care and the use of medications without discontinuing therapy[1,2]

- In most cases, skin dAEs were effectively controlled using prophylaxis and topical therapies

8% (23/274) patients in the PANOVA-3 trial discontinued treatment with Optune Pax due to device-related AEs of any cause[1]

dAE=dermatologic adverse event.

Important Safety Information (cont)

Warnings and Precautions (cont)

Optune Pax device-related skin adverse events (≥5%) include dermatitis, rash, pruritus, maculo-papular rash, erythema, skin irritation, skin reaction, and skin ulcer. Other device-related adverse effects associated with the use of Optune Pax include overheating of the array, leading to pain and/or local skin burns, allergic reaction to the adhesive or gel from the transducer arrays, and local warmth and tingling sensation beneath the arrays.

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

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References: 1. Optune Pax for Locally Advanced Pancreatic Cancer. Physician Instructions for Use. Novocure; 2026. **2.** Optune Pax for Locally Advanced Pancreatic Cancer. Patient Information and Operation Manual. Novocure; 2026. **3.** Lacouture ME, Anadkat MJ, Ballo M, et al. Prevention and management of dermatologic adverse events associated with Tumor Treating Fields in patients with glioblastoma. *Front Oncol.* 2020;10:1045. doi: 10.3389/fonc.2020.01045 **4.** Optune Lua for Non-Small Cell Lung Cancer (NSCLC). Physician Instructions for Use. Novocure; 2024. **5.** Optune Gio. Instructions For Use. Novocure; 2023. **6.** Anadkat MJ, Lacouture M, Friedman A, et al. Expert guidance on prophylaxis and treatment of dermatologic adverse events with Tumor Treating Fields (TTFields) therapy in the thoracic region. *Front Oncol.* 2023;12:975473. doi: 10.3389/fonc.2022.975473 **7.** Babiker HM, Picozzi V, Chandana SR, et al. Tumor Treating Fields with gemcitabine and nab-paclitaxel for locally advanced pancreatic adenocarcinoma: randomized, open-label, pivotal phase III PANOVA-3 study. *J Clin Oncol.* 2025;43(21):2350–2360. doi: 10.1200/JCO-25-00746 **8.** Novocure Data on File 2025. [PANOVA-3 Data.] **9.** Anadkat MJ, Lacouture M, Friedman A, et al. Expert guidance on prophylaxis and treatment of dermatologic adverse events with Tumor Treating Fields (TTFields) therapy in the thoracic region. *Front Oncol.* 2023;12(Suppl 1):1.

Maximize time on treatment with the M3 approach for managing dAEs

Mitigating, monitoring, and managing dAEs[1-3,6]

- Monitor patients for skin issues especially closely during the first 25 days of Optune Pax® treatment
- To allow for skin inspection, request patients not wear the arrays to follow-up visits
- Educate patients and caregivers about array changes, hygienic measures, and proper skin care
- Encourage patients to report and keep a photograph diary of any skin problems
- Reinforce patient and caregiver hygiene, adherence to proper array guidelines, and prompt communication
- In case of dAEs, increase frequency of follow-up visits (consider virtual consultation)

For Optune Pax dAEs, follow M3: **mitigate** with preventive care, **monitor** symptoms, and **manage** with proper treatment[1,2]

Support

Contact your Novocure representative or click to visit **OptunePaxHCP.com** for additional resources.

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