

# Prophylaxis, Monitoring & Management of Dato-DXd associated Adverse Events

## Key clinical takeaways



**Datopotamab deruxtecan (Dato-DXd) shows clinically meaningful activity** in previously treated advanced solid tumours (including NSCLC and HR+/HER2- breast cancer)



**Proactive prophylaxis** across all AEs and education is critical



**Mucositis/stomatitis, nausea, and ocular events are key**, mostly low-grade toxicities, to be aware of



**Structured, multidisciplinary monitoring enables safe delivery**, including early detection and management of uncommon but serious AEs such as interstitial lung disease (ILD)



### OCULAR SURFACE EVENTS

**PROPHYLAXIS** Have patients start **preservative-free** artificial tears 4 times daily and avoid **contact lenses**.

**MONITORING** Refer patients to an eye care professional (optometrist or ophthalmologist) for an **ophthalmic exam** at treatment initiation, annually while on treatment, at end of treatment, and as clinically indicated. **Monitor patients** for ocular adverse reactions during treatment (ie, redness, pain, teary eyes, blurred vision). If present, promptly **refer patients to an eye care professional**.

**MANAGEMENT** Continue **preservative-free artificial tears 4 times daily throughout treatment** in addition to corticosteroid drops at the discretion of an ophthalmologist or eye care professional. Depending on grade, consider delay and reduce the dose or discontinue.



### ORAL MUCOSITIS/STOMATITIS

**PROPHYLAXIS** Develop an oral care plan that includes a **corticosteroid-containing mouthwash** (eg, dexamethasone oral solution 0.1 mg/mL or alternative corticosteroid mouthwash advocated by institutional/local guidelines) and **good oral hygiene**. In the absence of a prophylactic steroid-containing mouthwash, daily use of inert, bland mouth rinses e.g., with a non-alcoholic and/or bicarbonate-containing mouthwash, 6 to 8 times a day) is recommended. Consider **prophylactic cryotherapy** (ie, ice chips or ice water held in the mouth throughout the infusion).

**MONITORING** Perform **regular oral exams** to detect sensitivity, inflammation, tenderness, and/or sores throughout treatment.

**MANAGEMENT** If oral mucositis/stomatitis occurs, **optimise prophylactic and supportive medications**, provide pain management with lidocaine-based mouthwash, treat sores with clobetasol gel; depending on grade, consider dose delay or reduction if clinically indicated.

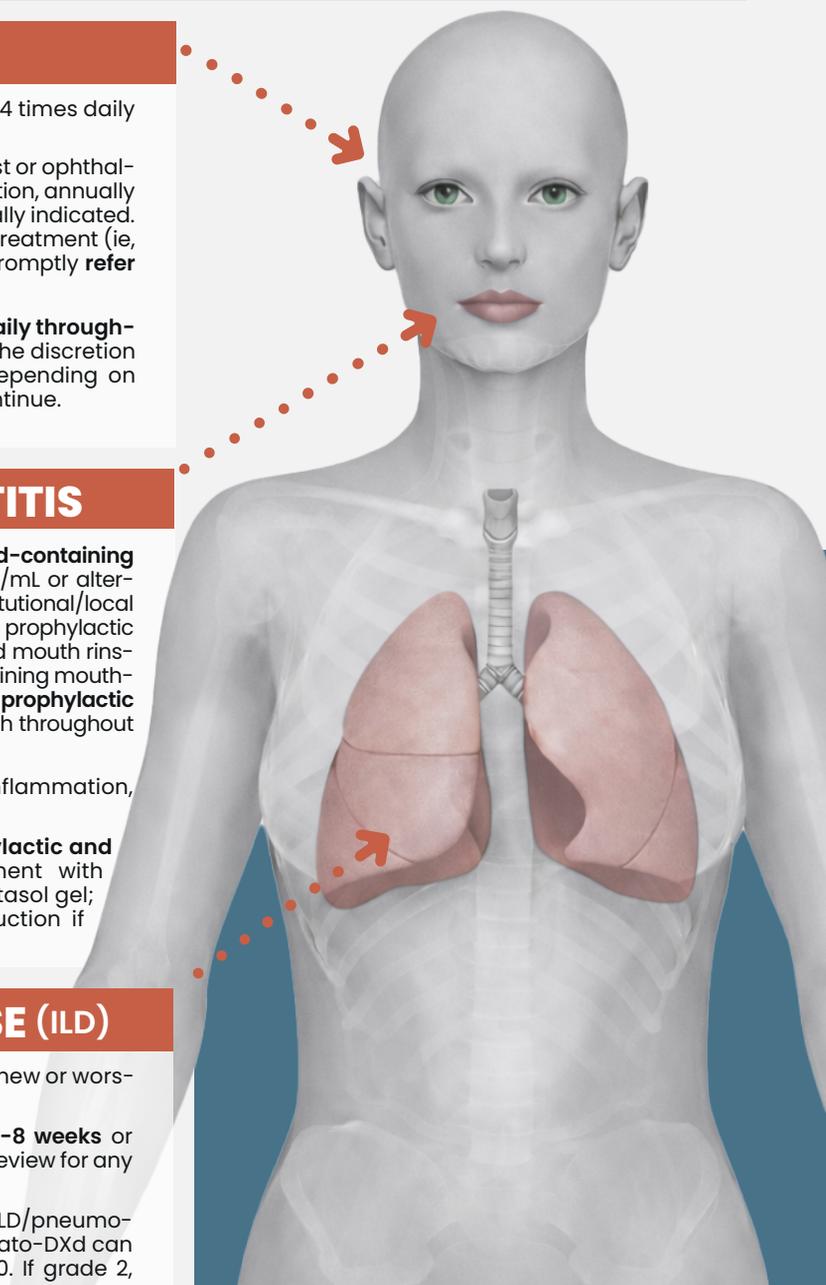


### INTERSTITIAL LUNG DISEASE (ILD)

**PATIENT COUNSELLING** Educate patients to **report immediately** if they have new or worsening shortness of breath, chest pain, or cough.

**MONITORING** Perform **contrast-enhanced chest CT scan every 6-8 weeks** or according to institutional guidelines, and thoroughly review for any signs of ILD.

**MANAGEMENT** Administration of Dato-DXd must be delayed for any ILD/pneumonitis events regardless of grade. For Grade 1 events, Dato-DXd can be restarted only if the event is resolved to Grade 0. If grade 2, discontinue Dato-DXd.



AE, adverse event; CT, computed tomography; Dato-DXd, datopotamab deruxtecan; HER2-, human epidermal growth factor receptor 2 negative; HR+, hormone receptor positive; ILD, interstitial lung disease; NSCLC, non-small cell lung cancer

**References:** Lisberg A, et al. *Oncologist* 2025; 30:oyaf225. doi: 10.1093/oncolo/oyaf225; Meric-Bernstam F, et al. *Oncologist* 2025; 30:oyaf031. doi: 10.1093/oncolo/oyaf031

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## Ocular surface events (Dry eye/Keratitis)



### PROPHYLAXIS



- It should be strongly recommended that subjects/participants avoid the use of contact lenses starting on the day of the first Dato-DXd dose and to use artificial tears (preferably preservative-free) 4 times/day as a preventative measure and up to 8 times/day if clinically needed



### MONITOR



- Refer patients to an eye care professional (optometrist or ophthalmologist) for an **ophthalmic exam** at treatment initiation, annually while on treatment, at end of treatment, and as clinically indicated
- **Monitor patients for ocular adverse reactions** during treatment (i.e. redness, pain, teary eyes, blurred vision). If present, promptly **refer patients to an eye care professional**



### MANAGE<sup>a</sup>



#### GRADE 1:

- Consider obtaining an **ophthalmologic assessment**
- Ensure use of **artificial tears** daily (or increase frequency to 8 times daily)

#### GRADE 2:

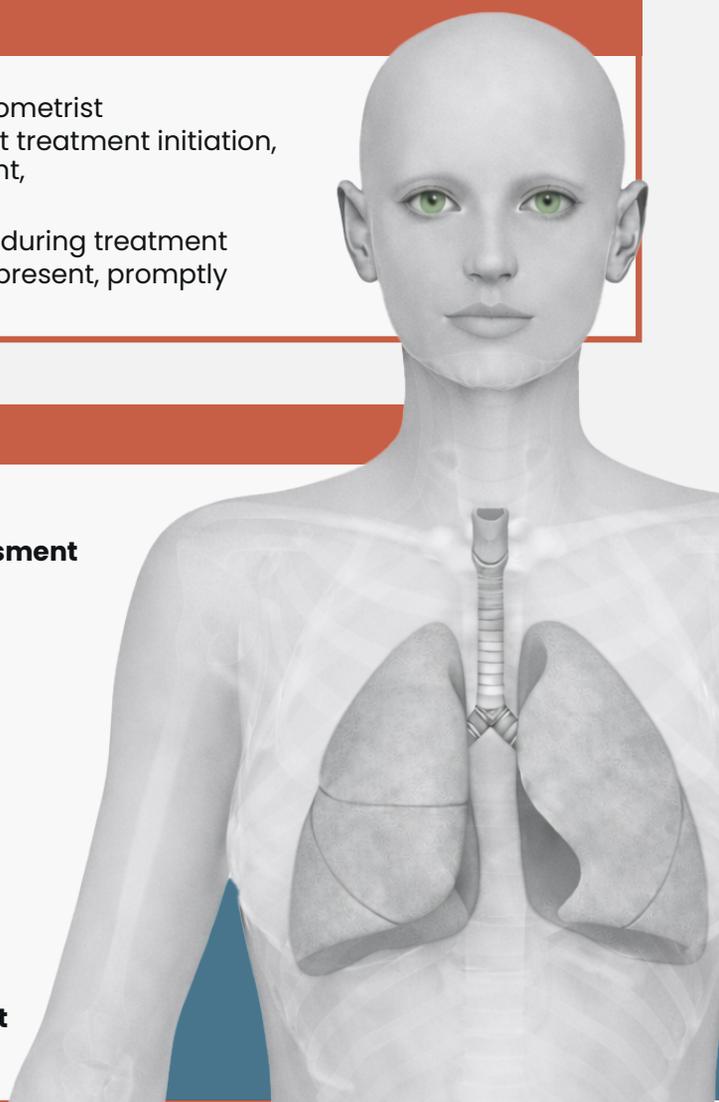
- Obtain an **ophthalmologic assessment**
- **Delay dose** until resolved to grade  $\leq 1$ , then maintain dose

#### GRADE 3:

- Obtain an **ophthalmologic assessment**
- **Delay dose** until resolved to grade  $\leq 1$ , then reduce dose by 1 level

#### GRADE 4:

- Obtain an urgent **ophthalmologic assessment**
- Discontinue **Dato-DXd**



Dato-DXd dose reduction schedule: starting dose = 6.0 mg/kg; 1<sup>st</sup> reduction = 4.0 mg/kg; 2<sup>nd</sup> reduction = 3.0 mg/kg; 3<sup>rd</sup> reduction (for patients with lung cancer only) = 2.0 mg/kg; if further dose reduction required = discontinue treatment

<sup>a</sup>NCI CTCAE version 5.0 grading

Dato-DXd, datopotamab deruxtecan; NCI CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events

References: Lisberg A, et al. Oncologist 2025; 30:oyaf225. doi: 10.1093/oncolo/oyaf225; Meric-Bernstam F, et al. Oncologist 2025; 30:oyaf031. doi: 10.1093/oncolo/oyaf031

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# Prophylaxis, Monitoring & Management of Dato-DXd associated Adverse Events

## Stomatitis and Mucositis Management with Dato-DXd



### PROPHYLAXIS

Initiate daily oral care plan prior to administration of first Dato-DXd dose



- **Gentle brushing** of teeth after meals and at bedtime using a soft toothbrush and a bland fluoride-containing toothpaste



- **Daily use of a corticosteroid-containing mouthwash**, e.g., dexamethasone oral solution 0.1 mg/mL (10 mL, 4 times daily, swish for 1-2 minutes then spit out), or a similar mouthwash regimen using an alternative steroid advocated by institutional/local clinical practice guidelines is highly recommended; an oral nystatin suspension, or other topical antifungal agents, may be considered ≥15 minutes after the steroid-containing mouthwash.



- **Consider cryotherapy** (ie, ice chips or ice water held in mouth) during infusions
- **Education on the importance of oral hygiene**, hydration and lubrication of the oral mucosa and adherence to oral care plan



### MONITOR



- **Stomatitis** often occurs earlier during the course of Dato-DXd therapy but can occur at anytime throughout treatment
- Regular oral exams by oncology care team to **detect mucositis** early
- **Oral sensitivity, inflammation and tenderness** of the oral mucosa can occur without the appearance of sores



### MANAGE<sup>a</sup>

#### SUPPORTIVE CARE



- **Increase frequency of mouthwash** to up to every hour, if necessary
- **Use steroid-containing mouthwash** as soon as oral pain, inflammation, or ulceration develops



- **Provide pain management** (lidocaine-based mouthwash, topical clobetasol gel)



- **Consider referral to a dentist**, oral surgeon, oral medicine expert, or dermatologist for severe or persistent events

#### DOSE MODIFICATIONS



**GRADE 1:** Maintain dose, optimise prophylactic and supportive medications

**GRADE 2:** Consider a dose delay or reduction if not resolved

**GRADE 3:**

- **If prophylaxis and supportive medications have not yet been optimised**, delay dose until resolved to grade ≤1 or baseline, optimise medications, and then maintain dose
- **If prophylaxis and supportive medications have already been optimised**, delay dose until resolved to grade ≤1 or baseline, then reduce the dose by 1 level

**GRADE 4:** Discontinue Dato-DXd

Dato-DXd dose reduction schedule: starting dose = 6.0 mg/kg; 1<sup>st</sup> reduction = 4.0 mg/kg; 2<sup>nd</sup> reduction = 3.0 mg/kg; 3<sup>rd</sup> reduction (for patients with lung cancer only) = 2.0 mg/kg; if further dose reduction required = discontinue treatment

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# Prophylaxis, Monitoring & Management of Dato-DXd associated Adverse Events

## Interstitial Lung Disease (ILD)



### MONITOR



- Patients should be **monitored for new or worsening signs and symptoms of ILD/pneumonitis** during treatment with Dato-DXd
- **Educate patients to report immediately** if they have new or worsening shortness of breath, chest pain or cough (don't self-treat with OTC cough medications)



### CONFIRM



- **Perform contrast-enhanced chest CT scan every 6–8 weeks** or according to institutional guidelines, and thoroughly review for any signs of ILD
- **Evaluations should include:**
  - High-resolution CT • Pulmonologist consultation (infectious disease consultation as clinically indicated)
  - Bronchoscopy and BAL if clinically indicated and feasible
  - Pulmonary function tests (including FVC and CO diffusing capacity) and pulse oximetry (SpO<sub>2</sub>)
  - Clinical laboratory tests (arterial blood gases if clinically indicated, blood culture, blood cell count, differential WBC, CRP, COVID-19 test)



### MANAGE<sup>a</sup>

#### GRADE 1:

- Consider a consultation with a **pulmonologist**
- Monitor and closely **follow-up in 2–7 days** for onset of clinical symptoms and SpO<sub>2</sub>
- Consider follow-up **imaging in 1–2 weeks** (or as clinically indicated)
- Consider starting **systemic corticosteroids** (e.g., at least 0.5 mg/kg/day prednisone or equivalent) until improvement, followed by gradual taper over at least 4 weeks
- **Pause Dato-DXd** until resolved to grade 0, then:
  - **If resolved in ≤28 days** from day of onset, maintain dose
  - **If resolved in >28 days** from day of onset, reduce dose by one level

#### GRADE 2:

- Permanently **discontinue Dato-DXd**
- Consider a consultation with a **pulmonologist**
- Promptly start **systemic corticosteroids** (e.g., at least 1 mg/kg/day prednisone or equivalent) for at least 14 days or until complete resolution
- **Monitor symptoms** closely
- **Re-image** as clinically indicated

- If clinical or diagnostic observations worsen or do not improve in 5 days:
  - Consider **increasing corticosteroid dose** (e.g., 2 mg/kg/day prednisone or equivalent) and switching to IV administration (e.g., methylprednisolone)
  - Reconsider **additional workup** for alternative etiologies
  - **Escalate care** as clinically indicated

#### GRADE 3–4:

- Permanently **discontinue treatment**
- Consider a consultation with a **pulmonologist**
- **Hospitalisation** required
- Promptly initiate **intensive corticosteroid treatment** empiric high-dose methylprednisolone IV treatment (eg, 500–1000 mg/day for 3 days), followed by prednisone ≥1.0 mg/kg/day (or equivalent) for ≥14 days or until complete resolution of clinical symptoms and chest CT findings, followed by gradual taper over ≥4 weeks
- **Re-image** as clinically indicated
- If still no improvement within 3–5 days:
  - Reconsider **additional workup** for alternative etiologies
  - Consider other **immunosuppressants** and/or treat per local practice

Dato-DXd dose reduction schedule: starting dose = 6.0 mg/kg; 1<sup>st</sup> reduction = 4.0 mg/kg; 2<sup>nd</sup> reduction = 3.0 mg/kg; 3<sup>rd</sup> reduction (for patients with lung cancer only) = 2.0 mg/kg; if further dose reduction required = discontinue treatment

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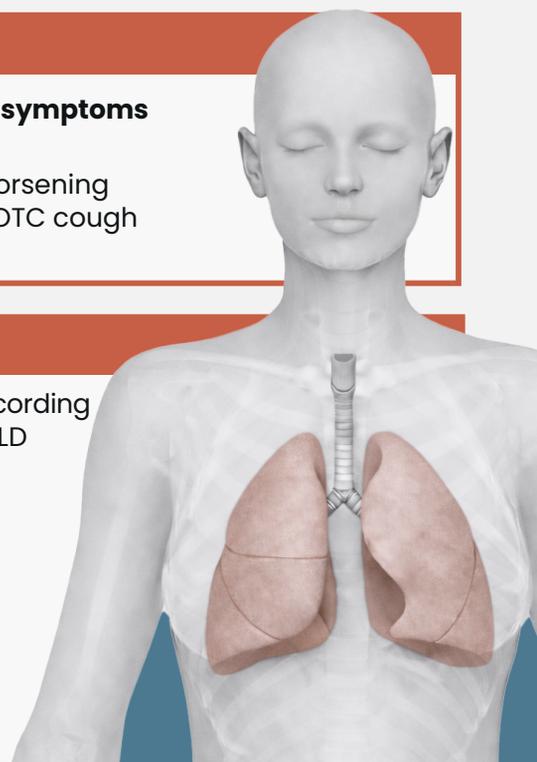
BAL, bronchoalveolar lavage; CO, carbon monoxide; CRP, C-reactive protein; CT, computed tomography; Dato-DXd, datopotamab deruxtecan; FVC, forced vital capacity; ILD, interstitial lung disease; IV, intravenous; NCI CTCAE, National Cancer Institute Common Terminology Criteria for Adverse Events; OTC, over the counter; SpO<sub>2</sub>, pulse oximetry; WBC, white blood cell

**References:** Lisberg A, et al. *Oncologist* 2025; 30:oyaf225. doi: 10.1093/oncolo/oyaf225; Meric-Bernstam F, et al. *Oncologist* 2025; 30:oyaf031. doi: 10.1093/oncolo/oyaf031

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# Prophylaxis, Monitoring & Management of Dato-DXd associated Adverse Events

## Dato-DXd Starter Checklist

### Patient Counselling Checklist



#### LUNG CARE COUNSELLING

- Counsel patient to **report immediately** if they have new or worsening shortness of breath, chest pain, cough, or fever



#### ORAL CARE COUNSELLING

- Ensure patients have been **prescribed dexamethasone mouthwash** (0.1 mg/mL) or equivalent
- Counsel patient **to swish and gargle** dexamethasone mouthwash (0.1 mg/mL) **for 1-2 minutes, 4 times daily**, then spit out; avoid eating or drinking for 30 minutes after use
- Ensure patients have a **soft toothbrush**, bland fluoride-containing toothpaste, floss, and tongue scraper
- Counsel patients to **brush teeth after meals**, and floss and tongue scrape daily



#### EYE CARE COUNSELLING

- Ensure patients can obtain **preservative-free artificial tears**
- Counsel patients to use artificial tears **4 times daily**
- Counsel patients to **avoid contact lenses** and practice good skin hygiene around the eyes
- Provide eye care professional contact
- Counsel patients to **report tearing eyes and blurring vision** immediately

Counsel patients to use eye drops and mouthwash simultaneously each day to improve patient adherence

### Dato-DXd Infusion Checklist

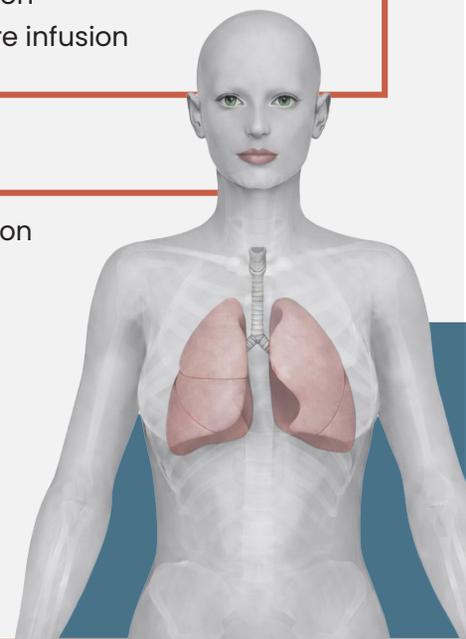


- Ice water, ice chips, or popsicle to hold in mouth** during infusion for stomatitis prevention
- Antiemetic premedication** 30 minutes before infusion for N/V prevention
- Antihistamines and acetaminophen premedication** 30 minutes before infusion for IRR prevention

### Exam Checklist



- Ask patient if they are experiencing any tearing eyes and/or blurring vision **to assess for ocular toxicities**
- Ask patient if they are experiencing any oral sensitivity, inflammation, and/or tenderness and provide an oral exam **to assess stomatitis**
- Ask patient if they are experiencing shortness of breath, chest pain, cough, or fever, measure baseline oxygen saturation, and review contrast-enhanced or high-resolution chest CT scan every 6 weeks or according to institutional guidelines **to assess for ILD**
- Assess for GI toxicities** (N/V and diarrhea)
- Assess all lab workup for abnormalities** of clinical significance (eg, neutropenia, anemia, etc.)
- If any of the above toxicities are present, address based on grade**



CT, computed tomography; Dato-DXd, datopotamab deruxtecan; GI, gastrointestinal; ILD, interstitial lung disease IRR, infusion-related reactions; N/V, nausea and vomiting

References: Lisberg A, et al. Oncologist 2025; 30:oyaf225. doi: 10.1093/oncolo/oyaf225; Meric-Bernstam F, et al. Oncologist 2025; 30:oyaf031. doi: 10.1093/oncolo/oyaf031

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# Prophylaxis, clinical management, and monitoring of datopotamab deruxtecan-associated oral mucositis/stomatitis

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 Advance access publication 20 March 2025  
 Review Article

OXFORD

## Prophylaxis, clinical management, and monitoring of datopotamab deruxtecan-associated oral mucositis/stomatitis

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**Abstract**  
 Oral mucositis/stomatitis (hereafter stomatitis) is a common dose-limiting toxicity seen with various classes of cancer treatment. Symptoms associated with stomatitis, primarily oral pain, may impact patient quality of life and may lead to dose delay and reduction or treatment discontinuation. Datopotamab deruxtecan (Dato-DXd) is a novel trophoblast cell-surface antigen 2, a protein that is broadly expressed in several types of solid tumors. Dato-DXd demonstrated statistically significant improvement in median progression-free survival (mPFS) over docetaxel in patients with previously treated metastatic non-small cell lung cancer (mNSCLC) and over the investigator's choice of chemotherapy in patients with previously treated post-endocrine therapy hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer (mBC). Dato-DXd also demonstrated a distinct safety profile in both trials. The successful implementation of any new anticancer therapy requires learning how to prevent, monitor, and manage treatment-related adverse events (AE).  
**Methods:** Perspectives were gathered from 4 medical oncologists, 2 nursing professionals, and 1 pharmacist with experience using Dato-DXd in either mNSCLC or mBC across several US practices.  
**Results:** Here, we share practical insights and management and treatment of key AEs from Dato-DXd, including oral mucositis/stomatitis, nausea and vomiting, ocular surface events, and interstitial lung disease garnered from the multidisciplinary team of health care professionals experienced in treating patients with Dato-DXd.  
**Conclusion:** Sharing experiences and institutional approaches from real-world clinical practices and multidisciplinary teams who treat patients with Dato-DXd may help provide a better patient experience and improved outcomes to a broader population of patients.  
**Key words:** stomatitis; oral mucositis; antibody drug conjugate; prophylaxis; management.

### LEAD AUTHOR

Funda Meric-Bernstam

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# Datopotamab deruxtecan-associated select adverse events: clinical practices and institutional protocols on prophylaxis, monitoring, and management

### LEAD AUTHOR

Aaron Lisberg

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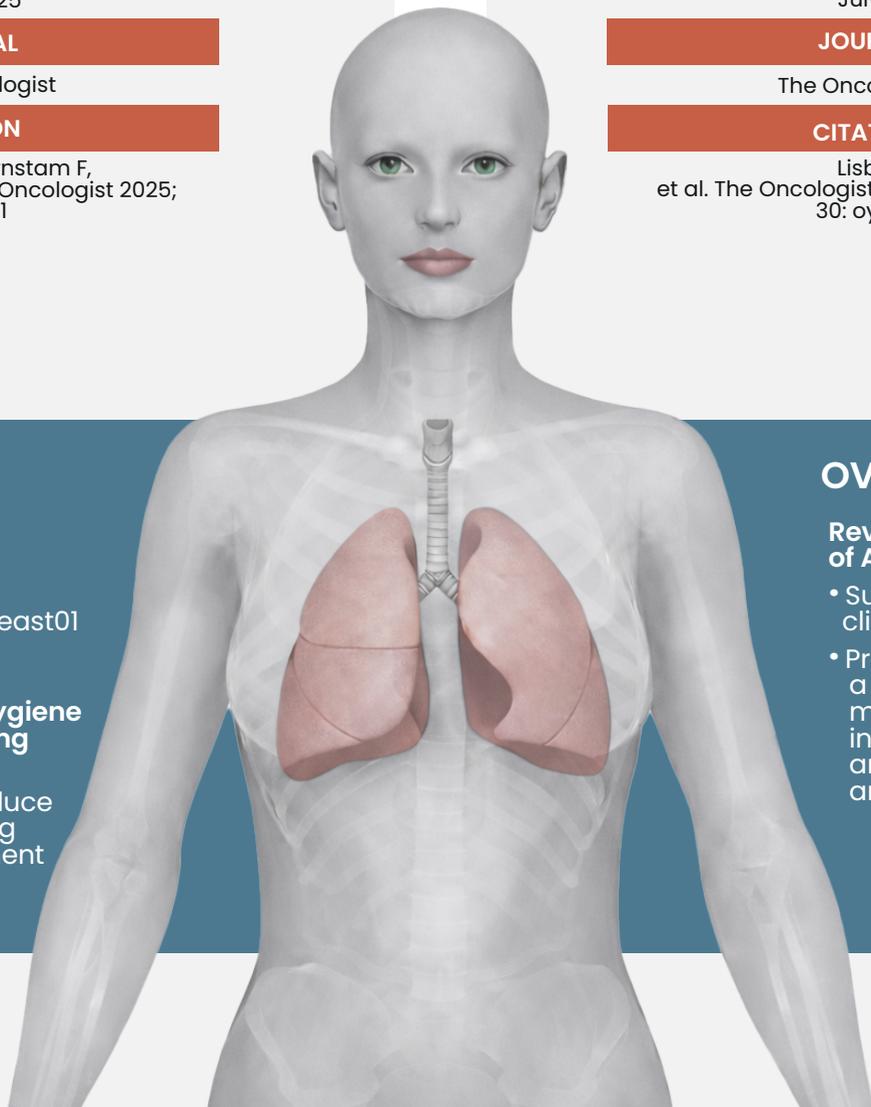
OXFORD

## Datopotamab deruxtecan-associated select adverse events: clinical practices and institutional protocols on prophylaxis, monitoring, and management

Aaron Lisberg<sup>1</sup>, Laura A. Huppert<sup>2</sup>, Balazs Halmos<sup>3</sup>, Blanca Ledezma<sup>4</sup>, Vanessa Soto-Romano<sup>5</sup>, Tiffany A. Trains<sup>6</sup>

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**Abstract**  
**Objective:** Datopotamab deruxtecan (Dato-DXd) is an antibody-drug conjugate comprised of a topoisomerase I inhibitor payload and a monoclonal antibody directed to trophoblast cell-surface antigen 2, a protein that is broadly expressed in several types of solid tumors. Dato-DXd demonstrated statistically significant improvement in median progression-free survival (mPFS) over docetaxel in patients with previously treated metastatic non-small cell lung cancer (mNSCLC) and over the investigator's choice of chemotherapy in patients with previously treated post-endocrine therapy hormone receptor-positive/human epidermal growth factor receptor 2-negative metastatic breast cancer (mBC). Dato-DXd also demonstrated a distinct safety profile in both trials. The successful implementation of any new anticancer therapy requires learning how to prevent, monitor, and manage treatment-related adverse events (AE).  
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**Key words:** breast neoplasm; lung neoplasm; clinical practice patterns; drug-related side effects and adverse reactions; datopotamab deruxtecan.



## OVERVIEW

### Review article focused on stomatitis, associated with Dato-DXd:

- Summarises **stomatitis incidence** observed in TROPION-Lung01, TROPION-Lung05, TROPION-Breast01 and TROPION-PanTumor01 trials
- Prophylactic recommendations include a daily oral care plan with **education for oral hygiene and hydration**, utilisation of a **steroid-containing mouthwash** and **cryotherapy**
- Reviews clinical management strategies to reduce severity and duration of stomatitis, with ongoing studies aiming to better prevention and treatment protocols to optimise patient outcome

## OVERVIEW

### Review article focused on toxicity management of AEs associated with Dato-DXd:

- Summarises AE incidence in Dato-DXd clinical trials
- Provides practical insights from a multidisciplinary HCP team on prophylaxis, monitoring and management of key AEs including oral mucositis/stomatitis, nausea and vomiting, ocular surface events and interstitial lung disease