

# Datroway

**Pronunciation:** *DAT-roe-way*

**Generic name:** datopotamab deruxtecan-dlnk

**Dosage form:** injection (100 mg powder single-dose vial)

**Drug class:** Miscellaneous antineoplastics

Medically reviewed by Melisa Puckey, BPharm. Last updated on Jan 20, 2025.

## What is Datroway?

**Datroway (datopotamab deruxtecan) infusion is used to treat metastatic HR Positive, HER2-negative breast cancer to help slow cancer progression.** It can be used in patients who have already had certain treatments, whose cancer can not be removed by surgery (unresectable), or has spread (metastatic disease).

- Datroway is a Trop-2-directed antibody and topoisomerase inhibitor antibody-drug conjugate.
- Datroway is given as an infusion into a vein (IV infusion) once every 3 weeks and will usually take half an hour after your first dose.

Datroway FDA approval was granted on January 17, 2025, after positive results from the TROPION-Breast01 clinical trial (NCT05104866) which show a statistically significant increase in progression-free survival (PFS), which is how long it takes before cancer gets worse or progresses after treatment.

## What is Datroway used for?

Datroway is used to treat used to treat breast cancer in adults whose cancer is:

- hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer
- It is unable to be removed by surgery (unresectable) or has spread to other parts of the body (metastatic) and
- The patient has already received endocrine-based therapy (hormone therapy) and chemotherapy treatment for unresectable or metastatic cancer.

## What is HR Positive, HER2-negative breast cancer?

When you have a biopsy for breast cancer it is tested to find out what type of cancer it is. This is important to determine what treatment will be most successful. Datroway is used to treat metastatic HR

Positive, HER2 negative breast cancer, in patients who have already tried chemotherapy and endocrine-based therapy.

**HER2-negative breast cancer** is when cancer cells do NOT contain high levels of human epidermal growth factor receptor 2 (HER2). HER2 is a protein that controls cell growth. If your breast cancer is HER2-negative, it means your cancer may grow more slowly and is less likely to spread or come back, when compared to HER2-positive cancer.

**Hormone receptor-positive (HR-positive) breast cancer** cells have either estrogen receptors (called ER-positive) or progesterone receptors (called PR-positive) or both types of receptors. Estrogen and progesterone receptors help control growth but in HR-positive cancer, there are more receptors to which estrogen or/and progesterone can bind which increases cancer growth. HR-positive breast cancers can be treated with hormone therapy drugs that lower estrogen levels or block estrogen receptors. Datroway is used when hormone therapy has already been used.

**Advanced or metastatic breast cancer.** Breast cancer can be described as advanced when it has spread locally to tissue near the breast or described as metastatic when breast cancer has spread to other parts of the body like the bones, liver, or lungs.

## How does Datroway work?

Datroway is an antibody-drug conjugate (ADC) which is a medicine that has **3 sections**,

- a monoclonal antibody (mAb) that binds to proteins called TROP2 (trophoblast cell surface antigen 2) on the cancer cells
- the anticancer molecule called DXd
- a linker that joins the MAB and anticancer molecule.

Datroway works by the mAb section binding to TROP2 proteins on cancer cells, it then passes into the cells where the anticancer small molecule (DXd) is released, causing the cancer cells to die.

Datroway mechanism of action is Trop-2-directed antibody-drug conjugate.

## Datroway side effects

### Common Datroway side effects

The most common side effects of Datroway include:

- mouth ulcers and sores 59% (stomatitis)
- nausea 56%
- tiredness 44% (fatigue)
- hair loss 38% (alopecia)

- constipation 34%
- dry eye 27%
- keratitis 25%
- vomiting 24%
- rash 19%
- low appetite 16%
- COVID 16%
- cough 15%
- diarrhea 11%
- abdominal pain 11%
- lung problems (15%)
- laboratory Abnormality

The above side effects occurred in 10% or more of patients in the TROPION-Breast01 clinical trial.

Other common Datroway side effects that affected less than 10% of patients included infusion-related reactions (including bronchospasm), interstitial lung disease (ILD)/pneumonitis, headache, itchy skin, dry skin, dry mouth, conjunctivitis, blepharitis, meibomian gland dysfunction, blurred vision, increased tears, light sensitivity (photosensitivity), visual problems, skin pigmentation, and loss of eyelashes or eyebrows.

Datroway may cause changes in laboratory tests including a decrease in leukocytes, lymphocytes hemoglobin, neutrophils, and calcium, with an increase in AST, ALT, and alkaline phosphatase. These changes in laboratory results affected 20% or more patients in the clinical trial.

## Serious Datroway side effects

Datroway can cause common and serious side effects including eye problems, mouth ulcers and sores (stomatitis), and lung problems.

**Lung problems.** If you have any symptoms of lung problems including cough, shortness of breath, trouble breathing, fever, wheezing or chest tightness, or any other new or worsening breathing problems tell your doctor immediately. Lung problems may be severe, life-threatening, or may lead to death

**Mouth ulcers and sores.** Side effects of mouth ulcers and sores are common and can be severe. Tell your doctor immediately if you develop mouth pain, ulcers, sores swelling, or redness, during treatment

with Datroway.

**Eye problems.** Side effects of eye problems are common and can also be severe. Tell your doctor right away if you develop any new or worsening eye problems during treatment with this medicine. This includes symptoms of dry eyes, eye pain, eye redness, eye swelling, eye irritation, increased tears, feeling like something is in your eyes, discharge from your eyes, eye crusting, photo sensitivity, blurred vision, or vision changes. You should **not** wear contact lenses during treatment with Datroway unless your eye specialist tells you to. You should have your eyes checked by an eye specialist before, during treatment, and at the end of treatment with this medicine.


## Embryo-Fetal Toxicity

Datroway can cause embryo-fetal harm when administered to a pregnant woman.

**Female patients** of who are able to become pregnant should use effective contraception during treatment with Datroway and for 7 months after the last dose. **Male patients** with female partners of rare able to become pregnant should use effective contraception during treatment and for 4 months after the last dose.

**Fertility** Datroway may cause fertility problems in males and females, which may affect your ability to have children.

This is not a complete list of side effects, and others may occur. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

 [Datroway side effects \(more detail\)](#)

## Related/similar drugs

### Trodelvy

Trodelvy is a targeted anticancer medication used to treat types of breast cancer and bladder ...

#### Reviews & ratings

4 Reviews

### Keytruda

Keytruda is used to treat multiple types of cancer such as melanoma, non-small cell lung cancer ...

#### Reviews & ratings

4.8 / 10

248 Reviews

#### FEATURES

### Verzenio

Verzenio is used to treat positive hormone receptor breast cancer

#### Review

8.0 / 10

## Tips for managing Datroway side effects

### Tips for managing mouth ulcers and sores.

- Your doctor or healthcare provider will prescribe a steroid-containing mouthwash to help reduce mouth problems.

- You should use the mouthwash 4 times a day, and as needed during treatment.
- Your dose may be decreased or treatment discontinued if mouth side effects are severe.
- It will also help if you hold ice chips or ice water in your mouth during your infusions.

### Tips for managing eye issues.

- It is recommended that you use preservative-free lubricating eye drops at least 4 times a day and as needed during treatment.
- Avoid wearing contact lenses.

### Tips for managing lung problems (Interstitial lung disease and pneumonitis)

- Tell your healthcare provider immediately about any changes in your breathing, a fever, or other lung symptoms.
- Your doctor may prescribe prednisolone or another corticosteroid, reduce your dose, or stop treatment if you have lung side effects.

## Warnings

Datroway can cause serious side effects including lung problems, eye problems, mouth ulcers and sores (stomatitis), and embryo-fetal toxicity. See serious side effects for more information.

## Before taking this medicine

Before receiving Datroway, tell your doctor or healthcare provider about all your medical conditions, including if you:

- have any lung or breathing problems
- have eye problems
- use contact lenses.

## Pregnancy

Datroway may cause **harm to your unborn baby**. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with this medicine.

**Female patients** who are able to become pregnant should use effective contraception **during treatment and for 7 months after the last dose**.

**Male patients** with female partners of are able to become pregnant should use effective contraception **during treatment and for 4 months after the last dose**.

**Fertility** Datroway may **cause fertility problems in males and females**, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility

 Datroway pregnancy and breastfeeding warnings (more detail)

## How will I receive this medicine?

- Datroway is given as an infusion into your vein through by your healthcare provider.
- It is usually given once every three weeks (21-day treatment cycle).
- The first infusion is given over 90 minutes, then if that goes well your next infusion are given over 30 minutes.
- During and for 1 hour after your first 2 infusion you will be monitored for side effects and if all goes well you will be monitored for 30 minutes after your next infusions.
- You will be given medicines before your infusion to help prevent nausea, vomiting, and infusion related reactions.
- If you have an infusion-related reaction, your infusion may be slowed down, temporarily stopped. If your reaction is severe enough you may need to permanently stop Datroway.

## Datroway dosing information

- Recommended Datroway dose is 6 mg/kg given as an intravenous infusion once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity.

 Detailed Datroway dosage information

## Missed dose

If you miss a planned dose of DATROWAY, call your healthcare provider right away to schedule an appointment. Do not wait until the next planned treatment cycle.

## What other drugs will affect this medicine?

Other drugs may interact with Datroway, including prescription and over-the-counter medicines, vitamins, and herbal products. Not all possible drug interactions are listed here.

 Datroway drug interactions (more detail)

## Storage

### Vials

- Store vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of reconstitution.

- Do not freeze.

## Reconstituted

- Refrigerate the reconstituted solution in the original vial at 2°C to 8°C (36°F to 46°F) for up to 24 hours from the time of reconstitution.
- Protect the vial from light.
- Do not freeze.
- The product does not contain a preservative.
- Discard unused reconstituted Datroway after 24 hours refrigerated.

## Diluted

- If not used immediately, store at room temperature at up to 25°C (77°F) for up to 4 hours including preparation or in a refrigerator at 2°C to 8°C (36°F to 46°F) for up to 24 hours.
- Do not freeze.

## Ingredients

**Active ingredient:** datopotamab deruxtecan-dlnk

**Inactive ingredients:** L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, and sucrose.

## Company

Datroway Daiichi Sankyo, Inc., Basking Ridge, NJ 07920 U.S. License No. 2128 Marketed by: Daiichi Sankyo, Inc., Basking Ridge, NJ 07920 and AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850.

## Datroway Biosimilars

Biosimilar and interchangeable products are biological products that are highly similar to and have no clinically meaningful differences from the reference product.

## Reference products

These are biological products that have already been approved by the FDA, against which biosimilar products are compared. There is 1 for Datroway.

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### Datroway (datopotamab deruxtecan-dlnk) - Daiichi Sankyo, Inc



Formulation type	Strength
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Single-Dose Vial	100 mg
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## References

1. Trophoblast Cell Surface Antigen 2 (Trop-2) Protein is Highly Expressed in Salivary Gland Carcinomas and Represents a Potential Therapeutic Target
2. Datroway Package Insert
3. National Cancer Institute at the National Institutes of Health: Hormone Therapy for Breast Cancer
4. American Cancer Society Breast Cancer Hormone Receptor Status

## Further information

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.