

MEDICATION GUIDE

DATROWAY® (DAT-roe-way)
(datopotamab deruxtecan-dlnk)
for injection, for intravenous use

What is the most important information I should know about DATROWAY?

DATROWAY can cause serious side effects, including:

- **Lung problems that may be severe, life-threatening, or that may lead to death.** If you develop lung problems your healthcare provider may treat you with corticosteroid medicines. Tell your healthcare provider right away if you get any of the following signs and symptoms:
 - cough
 - trouble breathing or shortness of breath
 - fever
 - other new or worsening breathing symptoms such as chest tightness or wheezing
- **Eye problems.** Eye problems are common with DATROWAY and can also be severe. Tell your healthcare provider right away if you develop any new or worsening eye problems during treatment with DATROWAY, including 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, sensitivity to light, blurred vision, or vision changes.
 - You should use preservative-free lubricating eye drops at least 4 times a day and as needed.
 - Do not wear contact lenses during treatment with DATROWAY unless your eye specialist tells you to.
 - Your healthcare provider will send you to an eye specialist to check your eyes when you start your treatment with DATROWAY, every three 21-day treatment cycles (about every 9 weeks), at the end of treatment, and as needed for any new or worsening signs and symptoms of eye problems.
- **Mouth ulcers and sores.** Mouth ulcers and sores are common with DATROWAY and can also be severe. Tell your healthcare provider right away if you develop mouth pain, swelling, redness, ulcers, or sores during treatment with DATROWAY.
 - Your healthcare provider will prescribe a steroid-containing mouthwash to use 4 times a day and as needed during treatment with DATROWAY.
 - You should hold ice chips or ice water in your mouth during your DATROWAY infusions.

Your healthcare provider will check you for these side effects during your treatment with DATROWAY. Your healthcare provider may reduce your dose, delay treatment, or completely stop treatment with DATROWAY if you have severe side effects.

- **Harm to your unborn baby.** Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with DATROWAY.
 - If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with DATROWAY.
 - **Females** who are able to become pregnant should use effective birth control (contraception) during treatment with DATROWAY and for 7 months after the last dose.
 - **Males** who have female partners that are able to become pregnant should use effective birth control (contraception) during treatment with DATROWAY and for 4 months after the last dose.

See “**What are the possible side effects of DATROWAY?**” for more information about side effects.

What is DATROWAY?

DATROWAY is a prescription medicine used to treat adults who have:

- non-small cell lung cancer (NSCLC) that has certain mutations in a gene called epidermal growth factor receptor (EGFR):
 - that has spread to areas outside of the lung (locally advanced) or has spread to other parts of the body (metastatic), **and**
 - who have received prior EGFR-directed medicine and platinum-based chemotherapy.
- triple-negative breast cancer (TNBC):
 - that cannot be removed by surgery (unresectable) or has spread to other parts of the body (metastatic), **and**
 - who cannot receive PD-1 or PD-L1 inhibitor therapy.
- hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer:
 - that cannot be removed by surgery (unresectable) or has spread to other parts of the body (metastatic), **and**
 - who have received prior endocrine-based therapy and chemotherapy treatment for unresectable or metastatic disease.

It is not known if DATROWAY is safe and effective in children.

Before receiving DATROWAY, tell your healthcare provider about all of your medical conditions, including if you:

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

- have liver problems.
- are breastfeeding or plan to breastfeed. It is not known if DATROWAY passes into your breast milk. Do not breastfeed during treatment with DATROWAY and for 1 month after the last dose.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive DATROWAY?

- You will receive DATROWAY into your vein through an intravenous (IV) line by your healthcare provider.
- DATROWAY is usually given 1 time every three weeks (21-day treatment cycle).
- You will receive your first infusion over 90 minutes. If you do not have problems with your first infusion, you may receive your next infusions over 30 minutes.
- You will be monitored for side effects for at least 1 hour after your first 2 infusions. If you do not have problems after your second infusion, you will be monitored for at least 30 minutes after each following infusion.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will give you medicines before your infusion to help prevent nausea, vomiting, and infusion-related reactions.
- Your healthcare provider may slow down or temporarily stop your infusion of DATROWAY if you have an infusion-related reaction, or permanently stop DATROWAY if you have severe infusion reactions, including severe allergic reactions.
- 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 are the possible side effects of DATROWAY?

DATROWAY can cause serious side effects, including:

- **See "What is the most important information I should know about DATROWAY?"**

The most common side effects of DATROWAY when used in adults with EGFR-mutated NSCLC include:

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| • nausea | • increased blood levels of liver enzymes |
| • hair loss | • increased levels of enzyme called lactate dehydrogenase in the blood |
| • tiredness | • muscle and joint pain |
| • decreased red blood cell counts | • decreased appetite |
| • decreased white blood cell counts | • rash |
| • constipation | |
| • increased blood levels of calcium | |

The most common side effects of DATROWAY when used in adults with TNBC include:

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| • increased levels of digestive enzyme (amylase) in the blood | • increased blood levels of liver enzymes |
| • nausea | • dry eye |
| • hair loss | • an eye problem called keratitis. See "What is the most important information I should know about DATROWAY?" |
| • decreased red blood cell counts | • decreased protein levels (albumin) in the blood |
| • decreased white blood cell counts | • vomiting |
| • constipation | • muscle and joint pain |
| • decreased blood levels of calcium | • decreased blood levels of sodium |
| • tiredness | • increased blood levels of alkaline phosphatase |

The most common side effects of DATROWAY when used in adults with HR-positive HER2-negative breast cancer include:

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|-------------------------------------|--|
| • nausea | • constipation |
| • tiredness | • dry eye |
| • decreased white blood cell counts | • vomiting |
| • decreased blood levels of calcium | • increased blood levels of liver enzymes |
| • hair loss | • an eye problem called keratitis |
| • decreased red blood cell counts | • increased blood levels of alkaline phosphatase |

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.

These are not all of the possible side effects of DATROWAY.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of DATROWAY.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about DATROWAY that is written for health professionals.

What are the ingredients in DATROWAY?

Active ingredient: datopotamab deruxtecan-dlnk

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

Manufactured by: Daiichi Sankyo, Inc., Basking Ridge, NJ 07920
U.S. License No. 2128

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For more information, call 1-877-437-7763 or go to <https://www.DATROWAY.com>.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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