

Datopotamab deruxtecan-dlnk (Datroway®)

Pronounce: DA-toe-POE-tah-mab-DER-ux -EE-kan

Classification: Trop-2-directed antibody and topoisomerase inhibitor conjugate

About Datopotamab deruxtecan-dlnk (Datroway®)

Datopotamab deruxtecan-dlnk is an antibody-drug conjugate (an antibody with a cell-killing medication attached to it) directed against a protein called Trop-2 (trophoblast cell surface antigen 2), found on the surface of some cancer cells. Antibodies, which are normally found in the body, are developed by the immune system to destroy foreign material (such as a germ). Datopotamab deruxtecan-dlnk is a manmade antibody that causes the immune system to attack cancer cells that have the Trop-2 protein on them. Along with this antibody, Datopotamab deruxtecan-dlnk has a medication attached to it called a topoisomerase I inhibitor. Topoisomerase inhibitors work against certain enzymes, called topoisomerase I, to stop cancer cells from replicating their DNA, which leads to cell death.

How to Take Datopotamab deruxtecan-dlnk

Datopotamab deruxtecan-dlnk is given by intravenous (IV, into a vein) infusion. The dosage and schedule are determined by the person's size and type of cancer.

Tell your care team about all the medications you take, including prescription and over-the-counter medications, vitamins, and herbal supplements. Prior to each dose, you will be given acetaminophen and diphenhydramine to minimize the risk of having an infusion reaction. Let your nurse or provider know right away if you feel any different during the infusion, and are experiencing things like chills, fever, nausea, shortness of breath, itching, flushing, swelling of face, lip, or tongue, or tightness in your chest or throat.

Possible Side Effects of Datopotamab deruxtecan-dlnk

There are a number of things you can do to manage the side effects of Datopotamab deruxtecan-dlnk. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Mouth Ulcers (Mucositis)

Certain cancer treatments can cause sores or soreness in your mouth and/or throat. Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Your treatment team may prescribe a steroid mouthwash to use during this treatment to help prevent mouth sores. You also may be instructed to hold ice chips or ice water in your mouth throughout the infusion to reduce the risk of mouth sores.

Performing regular mouth care can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2
 level teaspoons of baking soda or 1 level teaspoon of salt in an eight ounce glass of warm water) is
 recommended 4 times daily.

- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage nausea and vomiting. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy/fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines, or ginger ale to lessen symptoms.

Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

Eye Concerns

While receiving this medication, some patients may develop irritation or damage to the cornea (clear part covers the eyeball), changes in your eyesight, and watery or dry eyes. You will need an eye exam before starting this medication and annually while you are receiving this medication.

To prevent dry eyes and irritation, use lubricating eye drops at least four times daily and as needed. It is recommended to avoid using contact lenses during treatment with datopotamab deruxtecan-dlnk.

Notify your healthcare team if you develop any eye pain, swelling or redness of the eye, any vision changes, including blurriness, seeing floaters, and sensitivity to light.

Low White Blood Cell Count (Leukopenia, Lymphopenia, Neutropenia)

White blood cells (WBC) are important for fighting infection. While receiving treatment, your WBC count can drop, putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal.

Tips to preventing infection:

- Washing hands, both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bathe daily and perform frequent mouth care.
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with has any vaccinations.

Electrolyte Abnormalities

This medication can affect the normal levels of potassium in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

Loss or Thinning of Scalp and Body Hair (Alopecia)

Your hair may become thin, brittle, or may fall out. This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats, and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

Low Red Blood Cell Count (Anemia)

Your red blood cells are responsible for carrying oxygen to the tissues in your body. When the red cell count is low, you may feel tired or weak. You should let your oncology care team know if you experience any shortness of breath, difficulty breathing or pain in your chest. If the count gets too low, you may receive a blood transfusion.

Constipation

There are several things you can do to prevent or relieve constipation. Include fiber in your diet (fruits and vegetables), drink 8-10 glasses of non-alcoholic fluids a day, and keep active. A stool softener once or twice a day may prevent constipation. If you do not have a bowel movement for 2-3 days, you should contact your healthcare team for suggestions to relieve the constipation.

Liver Toxicity

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have pain in your abdomen, as these can be signs of liver toxicity.

Important but Less Common Side Effects

• Lung Changes and Pneumonitis: Patients can develop an inflammation of the lungs (called pneumonitis) or interstitial lung disease while taking this medication. Notify your healthcare provider right away if you develop any new or worsening symptoms, including shortness of breath, trouble breathing, cough or fever.

Reproductive Concerns

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 7 months for women and 4 months for men after treatment, even if your menstrual cycle stops or you believe you are not producing sperm. You may want to consider sperm banking or egg harvesting if you may wish to have a child in the future. Discuss these options with your oncology team. You should not breastfeed while receiving this medication and for 1 month after the last dose.

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