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Datroway (*datopotamab deruxtecan*)

An overview of Datroway and why it is authorised in the EU

What is Datroway and what is it used for?

Datroway is a cancer medicine used in adults to treat breast cancer when the cancer cells have receptors (targets) for certain hormones on their surface (HR-positive) and do not have large quantities of a protein called HER2 on their surface (HER2-negative). It is used in patients who have had endocrine therapy (hormone treatment) as well as one additional cancer treatment when their cancer cannot be removed by surgery (unresectable) or has spread to other parts of the body (metastatic).

Datroway contains the active substances datopotamab deruxtecan.

How is Datroway used?

Datroway can only be obtained with a prescription by a doctor and is given under the supervision of a healthcare professional experienced in the use of cancer medicines.

Datroway is given by infusion (drip) into a vein. The dose to be given depends on the patient's bodyweight and the infusion is repeated every 3 weeks. Patients who tolerate the first 90-minute infusion can receive subsequent infusions over 30 minutes. Patients may remain on treatment unless the disease gets worse or unless they no longer tolerate treatment.

Patients are monitored for any reactions during the infusion and for at least 30 minutes afterwards. Infusion-related reactions can be severe and, to reduce their risk, patients should be given other medicines before treatment with Datroway. If the patient develops infusion-related reactions, the doctor may slow down or interrupt the infusion.

For more information about using Datroway, see the package leaflet or contact your doctor or pharmacist.

How does Datroway work?

The active substance in Datroway, datopotamab deruxtecan, is made up of two components that are linked together:

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- datopotamab is a monoclonal antibody (a type of protein) that has been designed to target breast cancer cells in the body. It does this by attaching to a protein called TROP2 that is present at high levels on the surface of breast cancer cells;
- deruxtecan becomes active once datopotamab has attached to TROP2 and enters the cancer cell. Deruxtecan kills the cancer cell by blocking an enzyme (protein) called topoisomerase I which is involved in making new cancer cells.

What benefits of Datroway have been shown in studies?

In one main study involving 732 patients with HR-positive, HER2-negative breast cancer that was metastatic or that could not be removed by surgery, Datroway was compared with chemotherapy chosen by the doctor for each patient. Patients had received at least one previous chemotherapy treatment. Patients given Datroway lived for an average of 6.9 months before their disease got worse (progression-free survival), compared with 4.9 months for patients given chemotherapy. Patients given Datroway lived for an average of 18.6 months compared with 18.3 months for patients given chemotherapy.

What are the risks associated with Datroway?

For the full list of side effects and restrictions with Datroway, see the package leaflet.

The most common side effects with Datroway (which may affect more than 1 in 10 people) include stomatitis (inflammation of the lining of the mouth), nausea (feeling sick), tiredness, alopecia (hair loss), constipation, vomiting, dry eye, keratitis (inflammation of the cornea), COVID-19, anaemia (low levels of red blood cells), decreased appetite, increase in liver enzymes called aspartate aminotransferase and alanine aminotransferase, rash, diarrhoea, and neutropenia (low levels of neutrophils, a type of white blood cell).

Some side effects can be serious. The most frequently reported serious side effects with Datroway (which may affect up to 1 in 10 people) include COVID-19, urinary tract infection (infection of the parts of the body that collect and pass out urine), interstitial lung disease (disorders causing scarring in the lungs), pneumonitis (inflammation in the lungs) and sepsis (when bacteria and their toxins circulate in the blood leading to organ damage).

Why is Datroway authorised in the EU?

Despite recent medical advances, there is still a need for better treatments for HR-positive, HER2-negative, metastatic breast cancer. Datroway has been shown to delay the progression of the disease compared to standard treatment, especially for patients who have already undergone multiple treatments. However, Datroway was not compared to two commonly used chemotherapy drugs which means that the real-life benefits might differ from those seen in the study. In terms of safety, Datroway can cause side effects affecting the gut, eyes, skin and tissues. However, these can be managed using routine clinical practice guidelines.

The European Medicines Agency decided that Datroway’s benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Datroway?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Datroway have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Datroway are continuously monitored. Suspected side effects reported with Datroway are carefully evaluated and any necessary action taken to protect patients.

Other information about Datroway

Datroway received a marketing authorisation valid throughout the EU on 4 April 2025.

Further information on Datroway can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/datroway

This overview was last updated in 04-2025.