

# Darzalex Faspro™ (dartumumab and hyaluronidase-fihj)

## What is Darzalex Faspro?

Darzalex Faspro is a subcutaneous injection that has been approved to treat AL amyloidosis in combination with cyclophosphamide, bortezomib, and dexamethasone (CyBorD). Darzalex was initially formulated and approved in 2012 as an intravenous infusion for the treatment of multiple myeloma. In 2020, Darzalex Faspro, the subcutaneous version of the treatment was approved for multiple myeloma and has recently been approved for AL amyloidosis patients as well. AL Amyloidosis is caused by the misfolding and subsequent build-up of light-chains, which stem from abnormal plasma cells in the bone marrow. This build-up of amyloid in tissues and organs stops them from working properly.

## How does Darzalex Faspro work?

Darzalex Faspro is an immunotherapy that works with your body to fight disease. It is a CD38-directed cytolytic antibody, along with hyaluronidase, a drug delivery technology. The Darzalex binds to the CD38 protein, a protein found on the surface of many immune cells, like plasma cells in the bone marrow. Darzalex Faspro prevents the abnormal plasma cells from creating excess light chains.

## How is Darzalex Faspro administered?

Darzalex Faspro is a subcutaneous injection, meaning it is injected beneath the skin. It is advised the injection be given to the patient's abdomen over 3-5 minutes by a medical professional. Drugs to minimize reactions are also given before the injection.

## Clinical trial evidence for Darzalex Faspro

The approval of Darzalex Faspro is based on data from the phase 3 ANDROMEDA trial which demonstrated the superiority of subcutaneous daratumumab formulation plus cyclophosphamide, bortezomib, and dexamethasone (CyBorD) over CyBorD alone. Results showed that the subcutaneous daratumumab combination resulted in deeper and more rapid hematologic responses, meeting the primary end point of the trial. The study included 388 patients with newly diagnosed AL amyloidosis with measurable hematologic disease and one or more organs affected.

## Side effects of Darzalex Faspro

Like all drugs, Darzalex Faspro can cause side effects. The most commonly observed side effects in clinical trials were lymphopenia, pneumonia, diarrhea, cardiac failure, neutropenia, syncope, and peripheral edema.

## Availability of Darzalex Faspro

Darzalex Faspro was approved by the FDA for the treatment of AL amyloidosis in the United States.

Insurance coverage of Darzalex Faspro will vary depending on the particular plan. If insurance does not provide enough coverage, there are additional programs that can be looked in to. This includes Janssen's patient prescription assistance program, Janssen CarePath. You can learn more about this program on Janssen's website through the following link: <https://www.darzalex.com/patient-financial-support/janssen-carepath-program>

## More information

For more information you can visit us at [www.arci.org](http://www.arci.org). If you have further questions you can contact us by phone at 617-467-5170 or by email at [arc@arci.org](mailto:arc@arci.org).