EMA/153788/2025
EMEA/H/C/006248

Attrogy (*diflunisal*)

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

What is Attrogy and what is it used for?

Attrogy is a medicine used to treat polyneuropathy (nerve damage) caused by hereditary transthyretin-mediated amyloidosis (hATTR), a disease in which abnormal proteins called amyloids build up in tissues around the body including around the nerves.

Attrogy is used in adults in the first two stages of the nerve damage (stage 1, when the patient has weakness in the legs but is able to walk unaided, and stage 2, when the patient can walk but needs help).

Attrogy contains the active substance diflunisal.

How is Attrogy used?

Attrogy can only be obtained with a prescription and is available as tablets to be taken by mouth. The recommended dose is one tablet twice a day with food.

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

How does Attrogy work?

In patients with hATTR amyloidosis, a protein called transthyretin which circulates in the blood is defective and breaks easily. The broken protein forms amyloid deposits in tissues and organs around the body, including around nerves, where it interferes with the normal organ function.

The active substance in Attrogy, diflunisal, belongs to the class of non-steroidal anti-inflammatory medicines and is also a stabiliser of transthyretin. Diflunisal attaches to transthyretin and prevents it from breaking up, thereby stopping the formation of amyloid deposits and slowing down the progression of the nerve disease.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

What benefits of Attrogy have been shown in studies?

In a main study involving 130 patients with hATTR and stage 1 or 2 nerve damage, Attrogy was shown to be more effective than placebo (a dummy treatment) at slowing the nerve damage progression caused by the disease.

The main measure of effectiveness was the change in the patients' symptoms of nerve damage, as measured by a standard scale called mNIS+7, where a higher score indicates greater nerve damage. After 24 months of treatment, the average mNIS+7 score was 8.2 in patients taking Attrogy compared with 26.2 points in those taking placebo.

What are the risks associated with Attrogy?

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

The most common side effects with Attrogy (which may affect up to 1 in 10 people) include indigestion and heart burn.

Attrogy must not be used in patients who have had an acute (sudden) asthmatic attacks, urticaria (itchy rash), rhinitis (stuffy and runny nose) or angioedema (rapid swelling under the skin) caused by acetylsalicylic acid (also known as aspirin) or other related medicines called non-steroidal anti-inflammatory medicines. It must also not be used in patients who have bleeding in the gut, severely reduced kidney or liver function or severe heart failure. It must also not be used in the third trimester of pregnancy and in breast-feeding mothers.

Why is Attrogy authorised in the EU?

Despite some limitations in the data such as the high number of patients who left the study because they needed a liver transplant, Attrogy was more effective than placebo in delaying nerve damage in patients with hATTR. In terms of safety, most side effects were mild or moderate in severity. The European Medicines Agency therefore decided that Attrogy'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 Attrogy?

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

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

Other information about Attrogy

Attrogy received a marketing authorisation valid throughout the EU on 17 July 2025.

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

This overview was last updated in 08-2025.