EMA/136423/2024
EMEA/H/C/006009

Agilus (*dantrolene*)

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

What is Agilus and what is it used for?

Agilus is a medicine used to treat malignant hyperthermia (rapid rise in body temperature caused by uncontrolled muscle contractions) in adults and children. Malignant hyperthermia is a serious reaction to certain medicines used for general anaesthesia during surgery or other medical procedures.

Agilus contains the active substance dantrolene and is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but there are certain differences between the two. Agilus contains a higher amount of the active substance than the reference medicine, and also contains different excipients (ingredients) that make the powder easier to dissolve. The reference medicine for Agilus is Dantrium IV.

How is Agilus used?

The medicine can only be obtained with a prescription. It is available as a powder to be made up into a solution for injection into a vein.

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

How does Agilus work?

Malignant hyperthermia involves a very high body temperature and uncontrolled muscle contractions. The active substance in Agilus, dantrolene, attaches to a receptor (target) called the ryanodine receptor, which is involved in the contraction of skeletal muscles (muscles involved in movement) by releasing calcium in the skeletal muscle cells. By binding to this receptor, dantrolene blocks calcium release, thereby helping the muscles to relax and improving the symptoms of malignant hyperthermia.

What benefits of Agilus have been shown in studies?

As for every medicine, the company provided studies on the quality of Agilus, as well as published literature on the safety of the new excipients. The company also carried out a study that showed that Agilus is 'bioequivalent' to the reference medicine, Dantrium IV. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

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

Because dantrolene is a well-established substance that has been used for many decades in the EU, the company provided data from the scientific literature on the benefits and risks of dantrolene in the treatment of malignant hyperthermia in adults and children.

What are the risks associated with Agilus?

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

The most common side effect with Agilus is skeletal muscle weakness, which is linked to the way the medicine works. The frequency of this side effect is not known because not enough data are available.

Why is Agilus authorised in the EU?

Malignant hyperthermia is a rare but serious condition that requires rapid treatment. Agilus has been shown to be bioequivalent to another medicine authorised for the condition, but it contains different excipients which allow it to be prepared and given more quickly and in a lower volume of fluid. There is some uncertainty about the possible negative effect of one of the excipients, hydroxypropyl beta-cyclodextrin (HP-β-CD), on hearing. However, the European Medicines Agency noted that the few cases of hearing loss reported in patients who were treated with HP-β-CD for a different condition were mostly mild and short-lasting.

The Agency therefore decided that Agilus'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 Agilus?

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

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

Other information about Agilus

Agilus received a marketing authorisation valid throughout the EU on 29 May 2024.

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

This overview was last updated in 05-2024.