EMA/196211/2022
EMEA/H/C/005839

Amifampridine Serb (*amifampridine*)

An overview of Amifampridine Serb and why it is authorised in the EU

What is Amifampridine Serb and what is it used for?

Amifampridine Serb is a medicine used to treat the symptoms of Lambert-Eaton myasthenic syndrome (LEMS) in adults. LEMS is a disease in which patients have muscle weakness because of a failure of the nerves to transmit electrical impulses to the muscles.

Amifampridine Serb contains the active substance amifampridine and is a 'generic medicine'. This means that Amifampridine Serb contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Firdapse. For more information on generic medicines, see the question-and-answer document here.

How is Amifampridine Serb used?

Amifampridine Serb can only be obtained with a prescription and treatment with this medicine should only be started under the supervision of a doctor experienced in treating LEMS.

The recommended starting dose of Amifampridine Serb is 15 mg per day, which can be increased by 5 mg every four to five days up to a maximum of 60 mg per day. Amifampridine Serb is taken in divided doses, three or four times a day, and a single dose should not be more than 20 mg. Amifampridine Serb should be taken with food.

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

How does Amifampridine Serb work?

For muscles to contract, nerves have to transmit electrical impulses to the muscles through a chemical messenger called acetylcholine. Acetylcholine is released from the nerve endings during a period of 'depolarisation'. The active substance in Amifampridine Serb, amifampridine, is a potassium channel blocker, which prevents charged potassium particles from leaving the nerve cells. This prolongs the period of depolarisation, allowing more time for the nerves to release acetylcholine and so stimulate the muscles to contract.

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

How has Amifampridine Serb been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Firdapse, and do not need to be repeated for Amifampridine Serb.

As for every medicine, the company provided data on the quality of Amifampridine Serb. There was no need for 'bioequivalence' studies to investigate whether Amifampridine Serb is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because the composition of Amifampridine Serb is the same as the reference medicine and the active substance in both products is expected to be absorbed in the same way.

What are the benefits and risks of Amifampridine Serb?

Because Amifampridine Serb is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Amifampridine Serb authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Amifampridine Serb has been shown to be comparable to Firdapse. Therefore, the Agency's view was that, as for Firdapse, the benefits of Amifampridine Serb outweigh the identified risks and it can be authorised for use in the EU.

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

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

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

Other information about Amifampridine Serb

Amifampridine Serb received a marketing authorisation valid throughout the EU on <date of issue of the Marketing Authorisation>.

Further information on Amifampridine Serb can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/amifampridine-serb. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in MM-YYYY.