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Takhzyro (*lanadelumab*)

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

What is Takhzyro and what is it used for?

Takhzyro is a medicine used to prevent attacks of hereditary angioedema in patients aged 2 years and over.

Patients with angioedema have rapid swelling under the skin in areas such as the face, throat, arms and legs. Attacks of hereditary angioedema can be life threatening when the swelling around the throat presses against the airway.

Hereditary angioedema is rare, and Takhzyro was designated an 'orphan medicine' (a medicine used in rare diseases) on 9 October 2015. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3151551.

Takhzyro contains the active substance lanadelumab.

How is Takhzyro used?

Takhzyro is given as an injection under the skin, preferably in the abdomen (belly), thighs or upper arms. The recommended dose and frequency depends on the patient's age and bodyweight. At the beginning of treatment the dose is usually given every 2 weeks, which the doctor can reduce to once every 4 weeks if the patient remains free of attacks with the two-weekly dose.

Caregivers or patients aged 12 years and above may inject the medicine themselves after they have been properly trained.

Takhzyro can only be obtained with a prescription and should be started under supervision of a doctor experienced in managing hereditary angioedema.

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

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How does Takhzyro work?

Patients with hereditary angioedema have high levels of a substance called 'bradykinin', which causes blood vessels to widen and leak fluid into the surrounding tissue leading to the swelling attacks seen in angioedema.

The active substance in Takhzyro, lanadelumab, works by attaching to and blocking an enzyme in the blood called 'kallikrein', which has several functions, including increasing levels of bradykinin. By blocking the actions of kallikrein, lanadelumab helps to prevent the swelling and related symptoms of angioedema.

What benefits of Takhzyro have been shown in studies?

Takhzyro was found to be effective in reducing the number of angioedema attacks in a main study in 126 adults and children above 12 years of age with hereditary angioedema.

Patients experienced on average 0.3 attacks per month when given Takhzyro injections every 2 weeks and 0.5 attacks when given injections every 4 weeks. This compared with 2 attacks per month for patients on placebo (a dummy treatment).

An additional study was carried out in 21 children with hereditary angioedema aged between 2 and 12 years. Treatment with Takhzyro reduced the number of angioedema attacks from on average 1.84 attacks per month to 0.08 attacks after one year of treatment.

What are the risks associated with Takhzyro?

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

The most common side effects with Takhzyro (which may affect more than 1 patient in 10) include reactions at the site of injection including erythema (redness), bruising and pain.

Why is Takhzyro authorised in the EU?

Takhzyro is effective in preventing angioedema attacks and the fact that it only needs to be given every 2 or 4 weeks was considered an advantage over existing treatments. Overall, the safety profile was considered acceptable.

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

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

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

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

Other information about Takhzyro

Takhzyro received a marketing authorisation valid throughout the EU on 22 November 2018.

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

This overview was last updated in 10-2023.