EMA/68608/2021
EMEA/H/C/005398

Vazkepa (*icosapent ethyl*)

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

What is Vazkepa and what is it used for?

Vazkepa is a medicine for reducing the risk of cardiovascular events such as heart attack, stroke and other problems caused by blocked blood circulation. It is for use as add-on treatment in adults being treated with a statin medicine who have high levels of triglycerides (a type of fat) in their blood.

Vazkepa is to be used in patients either with a cardiovascular disease (a condition that affects the heart or circulation) or with diabetes and another condition that increases the risk of cardiovascular events.

Vazkepa contains the active substance icosapent ethyl.

How is Vazkepa used?

Vazkepa can only be obtained with a prescription. It is available as capsules, each containing 998 mg of icosapent ethyl.

The recommended dose is two capsules twice daily, with or after a meal.

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

How does Vazkepa work?

It is not clear exactly how icosapent ethyl, the active substance in Vazkepa works, but it is likely to have an anti-inflammatory effect, reduce levels of harmful triglyceride-rich proteins and have protective antioxidant effect. As a result, the medicine is likely to reduce the build-up of fatty deposits in blood vessels and so prevent them becoming blocked.

What benefits of Vazkepa have been shown in studies?

A study involving over 8,000 patients, who either had cardiovascular disease or were at high risk of it, found Vazkepa effective at reducing cardiovascular events. Such events included heart attack, stroke, blockages or interruption in blood supply to the heart muscle, and death from cardiovascular events. All patients in the study had raised triglyceride levels and were being treated with a statin.

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Cardiovascular events occurred in 17% (705 out of 4,089) of patients taking Vazkepa compared with 22% (901 out of 4,090) of patients who received placebo (a dummy treatment).

What are the risks associated with Vazkepa?

The most common side effects with Vazkepa (which may affect up to 1 in 10 people) are bleeding, peripheral oedema (swelling in the feet and arms because of fluid build-up), atrial fibrillation (when the upper chambers of the heart do not pump blood effectively), constipation, bone and muscle pain, gout and rash.

Patients must not take Vazkepa if they are allergic to soya or to any of the ingredients of the medicine.

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

Why is Vazkepa authorised in the EU?

Vazkepa was found effective at reducing cardiovascular events in patients at high risk of such events, who were taking a statin and had high levels of triglycerides. The side effects of Vazkepa were considered manageable.

The European Medicines Agency therefore decided that Vazkepa'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 Vazkepa?

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

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

Other information about Vazkepa

Vazkepa received a marketing authorisation valid throughout the EU on 26 March 2021.

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

This overview was last updated in 03-2021.