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Kayshild (*semaglutide*)

A plain-language overview of Kayshild and why it is authorised in the EU

What is Kayshild and what is it used for?

Kayshild is a medicine used together with diet and physical activity to treat adults with non-cirrhotic metabolic dysfunction-associated steatohepatitis (MASH). MASH (also known as NASH, non-alcoholic steatohepatitis) is a disease caused by fat building up in the liver, resulting in inflammation and damage to the liver. Kayshild is used in adults with moderate or advanced scarring of the liver (liver fibrosis stage F2 or F3).

Kayshild contains the active substance semaglutide.

How is Kayshild used?

Kayshild can only be obtained with a prescription and is available as a solution for injection in prefilled pens. It is injected once a week, under the skin of the abdomen (belly), upper arm or thigh. Treatment will start at a low dose that is gradually increased every 4 weeks for the first 16 weeks until you reach the recommended dose.

For more information about using Kayshild, see the package leaflet or contact your healthcare provider.

How does Kayshild work?

The active substance in Kayshild, semaglutide, acts in the same way as GLP-1 (a natural hormone in the body). By mimicking GLP-1, semaglutide acts on receptors in the brain that control hunger, helping people feel less hungry and fuller after meals, which leads to reduced food intake and weight loss. At the same time, semaglutide improves how the body controls blood sugar levels, allowing it to be used more effectively. This helps to improve the metabolic health problems that underly MASH, such as overweight or obesity, type 2 diabetes, high blood sugar or fat levels.

Semaglutide also lowers the build-up of fat in the liver and reduces inflammation caused by the disease.

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What benefits of Kayshild have been shown in studies?

The benefits of Kayshild were evaluated in an ongoing study involving people with MASH with moderate to advanced liver scarring. People were given either Kayshild or placebo (a dummy treatment), alongside dietary changes and exercise. After 72 weeks of treatment, a liver biopsy was taken to evaluate the effects of treatment on liver tissue. The main measures of effectiveness were resolution of MASH (meaning that there was little or no ongoing inflammation or cell damage in the liver) with no worsening of liver scarring, as well as an improvement in liver scarring with no worsening of MASH.

The results showed that after 72 weeks of treatment, around 63% of those treated with Kayshild (336 out of 534) had no MASH and no worsening of liver scarring, compared with 34% of people given placebo (91 out of 266). Furthermore, 37% of people treated with Kayshild (197 out of 534) had an improvement in liver scarring and no worsening of their MASH. In comparison, this outcome was seen in around 22% of those given placebo (59 out of 266).

What are the side effects and restrictions with Kayshild?

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

The most common side effects with Kayshild (which may affect more than 1 in 10 people) include side effects affecting the stomach and gut such as nausea (feeling sick), diarrhoea, constipation and vomiting, and feeling tired.

Why is Kayshild authorised in the EU?

MASH with moderate to advanced liver scarring is a serious condition with limited treatment options. If left untreated it can get worse over time, potentially leading to permanent liver damage, liver failure requiring transplantation and liver cancer.

Kayshild was more effective than placebo at resolving MASH and preventing liver scarring from getting worse in adults with MASH and moderate to advanced liver scarring. The data also showed that Kayshild was more effective at improving liver scarring and preventing MASH from getting worse in these people. These findings are based on data from liver biopsies, which were used as a substitute for long-term measures of effectiveness such as preventing advanced liver disease, liver transplantation or improving survival. However, the main study is ongoing, and the company is therefore expected to provide more data on long-term benefits. Although long-term safety data on the use of Kayshild in people with MASH are not yet available, the medicine's safety profile is comparable to that of other semaglutide medicines authorised in the EU for other uses and is considered acceptable.

Kayshild has been given conditional authorisation for use in the EU. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Kayshild. It must submit further results from the ongoing study in adults with MASH and moderate to advanced liver scarring. Every year, the Agency will review any new information that becomes available.

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

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

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

Other information about Kayshild

Kayshild received a conditional marketing authorisation valid throughout the EU on 26 March 2026.

Further information on Kayshild, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/kayshild

For information about the availability of this medicine in your country, contact your national competent authority.

This overview was last updated in 04-2026.