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First oral GLP-1 treatment for weight management

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Wegovy tablets offer an alternative to subcutaneous injections

News Human Medicines

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EMA has recommended an extension to the marketing authorisation for Wegovy (semaglutide) in the EU to add an oral formulation for weight management. Wegovy tablets can be used, together with diet and physical activity, in adults with obesity, or in those who are overweight and have at least one weight-related comorbidity. This is the first glucagon-like peptide (GLP-1) receptor agonist for weight management developed for oral use.

Wegovy tablets will only be available with a prescription. The medicine is taken once daily on an empty stomach, after at least 8 hours of fasting; people should wait 30 minutes before eating, drinking or taking other medicines. The tablets offer an oral alternative to weekly subcutaneous injections that may be more convenient for some patients.

Although Wegovy subcutaneous injections are authorised for patients from the age of 12 years, the tablets are only intended for adults. As with the injections, the tablets are intended to be used together with diet and physical activity in people with

obesity, or in those who are overweight and have at least one weight-related comorbidity, such as type 2 diabetes, hypertension, high cholesterol, cardiovascular disease or obstructive sleep apnoea.

The safety and efficacy of Wegovy tablets were studied in a phase 3 clinical trial involving 307 adults who had obesity, or were overweight and had at least one comorbidity. People took Wegovy or placebo, in addition to a reduced-calorie diet and increased physical activity for 64 weeks. The primary endpoints were the change in body weight from baseline and the proportion of participants who lost at least 5% of their body weight at the end of treatment.

People who took Wegovy tablets lost on average 13.61% of their body weight, compared with 2.18% in the placebo group. In addition, 76.3% of people taking Wegovy tablets lost at least 5% of their body weight, compared with 30.5% of those on placebo.

The most common side effects with Wegovy tablets were gastrointestinal disorders, including nausea, diarrhoea, constipation, abdominal pain, dyspepsia and vomiting. These side effects mainly occurred at the start of treatment. The safety profile of daily Wegovy tablets was similar to weekly Wegovy injections.

The opinion adopted by the CHMP is an intermediary step on Wegovy tablets' path to patient access. The opinion will now be sent to the European Commission for the adoption of a decision on the extension of the EU marketing authorisation. Once the extension has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential use of this medicine in the context of the national health system of that country.

Note

- The marketing authorisation holder for Wegovy is Novo Nordisk A/S.

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