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Somavert (*pegvisomant*)

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

What is Somavert and what is it used for?

Somavert is a medicine used to treat adults with acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults and is caused by the pituitary gland producing excess growth hormone.

Somavert is used in patients who did not respond well to surgery and/or radiation therapy, and to treatment with somatostatin analogues (another type of medicine used in acromegaly).

Somavert contains the active substance pegvisomant.

How is Somavert used?

Somavert can only be obtained with a prescription and treatment should be started by a doctor who has experience in the treatment of acromegaly. Somavert is available as powder and solvent that are mixed together to make up a solution for injection under the skin.

Before starting and during treatment with Somavert, the patient should have tests to measure levels of liver enzymes in the blood. If levels are too high, the doctor may decide not to begin or to stop treatment with Somavert.

The patient first receives a starting dose of 80 mg under medical supervision. Following this, Somavert is given as an injection of 10 mg once a day. The patient or caregiver can inject Somavert after being trained by a doctor or a nurse. The doctor should check the response every four to six weeks and adjust the dose if needed. The maximum dose is 30 mg per day.

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

How does Somavert work?

Acromegaly occurs when the pituitary gland at the base of the brain makes too much growth hormone, generally because of a benign (non-cancerous) tumour. Growth hormone promotes growth during childhood and adolescence. In adults, rather than gaining height, overproduction of growth hormone leads to acromegaly, with overgrowth of bone, swelling of soft tissue (such as the hands and feet),

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heart disease and other disorders. The active substance in Somavert, pegvisomant, is very similar to human growth hormone, but it has been designed so that it blocks the receptors to which growth hormone normally attaches itself. By blocking the receptors, Somavert prevents growth hormone from having an effect, thereby preventing the unwanted growth and other disorders seen in acromegaly.

What benefits of Somavert have been shown in studies?

Somavert has been studied in 112 patients with acromegaly in a 12-week study. Patients received a starting dose of 80 mg Somavert or placebo (a dummy treatment). Afterwards, they received 10, 15 or 20 mg Somavert per day or placebo. The effectiveness was measured by comparing the levels of insulin-like growth factor-I (IGF-I) before and at the end of the study. IGF-I is regulated by human growth hormone and causes growth in the body.

Somavert lowered IGF-I levels at all of the doses tested. IGF-I levels were normal at the end of the study (week 12) in 38.5%, 75% and 82% of patients treated with 10, 15 or 20 mg/day Somavert, respectively, compared with 9.7% of the patients treated with placebo.

What are the risks associated with Somavert?

The most common side effects of Somavert (seen in more than 1 in 10 people) were headache, diarrhoea and joint pain. The majority of side effects were mild to moderate and of limited duration.

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

Why is Somavert authorised in the EU?

The European Medicines Agency decided that Somavert'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 Somavert?

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

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

Other information about Somavert

Somavert received a marketing authorisation valid throughout the EU on 13 November 2002.

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

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