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Sogroya (*somapacitan*)

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

What is Sogroya and what is it used for?

Sogroya is used as replacement therapy in adults with growth hormone deficiency (lack of growth hormone).

Growth hormone deficiency is rare, and Sogroya was designated an 'orphan medicine' (a medicine used in rare diseases) on 24 August 2018. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3182068.

Sogroya contains the active substance somapacitan.

How is Sogroya used?

Sogroya is injected once a week using a pre-filled pen. It is injected under the skin in the belly or the thigh, and the site changed from one week to another. The starting dose depends on the patient's age and on whether they have already used daily growth hormone replacement therapy. Women taking oral oestrogen (contraceptive pill or hormonal replacement therapy) may need a higher dose of Sogroya. The dose must then be adjusted for each patient based on individual response to treatment. If an acceptable response is not achieved within 12 months, other treatments should be considered.

The medicine can only be obtained with a prescription and treatment should be started and monitored by doctors who are qualified and experienced in the diagnosis and management of adults with growth hormone deficiency (such as endocrinologists).

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

How does Sogroya work?

The active substance in Sogroya, somapacitan, acts in the same way as human growth hormone. Once injected into the patient, Sogroya attaches to a protein in the blood called albumin, which makes it remain in the body for longer. This allows the medicine to be given once a week, compared with other growth hormone replacement therapies which are given daily.

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What benefits of Sogroya have been shown in studies?

One main study involving 300 adults with growth hormone deficiency showed that Sogroya was more effective than placebo (a dummy treatment) at lowering the amount of truncal body fat (fat around the stomach and abdomen) after 34 weeks of treatment. The study also showed that weekly treatment with Sogroya had a comparable effect on truncal body fat to daily injections of somatropin (another medicine for growth hormone deficiency).

What are the risks associated with Sogroya?

The most common side effect with Sogroya (which may affect more than 1 in 10 people) is headache. Peripheral oedema (swelling, especially of the ankles and feet) and adrenocortical insufficiency (when the adrenal glands do not produce enough steroid hormones, primarily cortisol) may affect up to 1 in 10 people. For the full list of side effects of Sogroya, see the package leaflet.

Sogroya must not be used if the patient has an active tumour. In patients with brain tumours, tumours must be inactive and cancer therapy must have been completed before starting Sogroya. Treatment should be stopped if the tumour grows. Sogroya must also not be used in patients with acute serious illness suffering from complications after open heart surgery, abdominal surgery, multiple accidental trauma, acute respiratory failure or similar conditions. For the full list of restrictions, see the package leaflet.

Why is Sogroya authorised in the EU?

Sogroya was shown to be effective at lowering truncal fat percentage and improving other body composition parameters, such as lean body mass, compared with placebo. Its effects are considered clinically relevant and comparable with those of daily somatropin injection. The short-term safety profile of Sogroya appears similar to that of other growth hormone-containing medicinal products, and additional data on the long-term safety will be provided from future studies.

The European Medicines Agency decided that Sogroya'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 Sogroya?

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

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

Other information about Sogroya

Sogroya received a marketing authorisation valid throughout the EU on 31 March 2021.

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

This overview was last updated in 03-2021.