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EPAR summary for the public

Plenadren

hydrocortisone

This is a summary of the European public assessment report (EPAR) for Plenadren. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Plenadren. For practical information about using Plenadren, patients should read the package leaflet or contact their doctor or pharmacist.

What is Plenadren and what is it used for?

Plenadren is a medicine used to treat adrenal insufficiency in adults. Adrenal insufficiency (including primary insufficiency or Addison's disease) is a condition where the adrenal glands (located just above the kidneys) do not produce enough of a steroid hormone called cortisol (also known as the stress hormone because it is released in response to stress). Symptoms include weight loss, muscle weakness, fatigue, low blood pressure, and sometimes darkening of the skin. Adrenal insufficiency can require life-long treatment to replace the missing cortisol.

Because the number of patients with adrenal insufficiency is low, the disease is considered 'rare', and Plenadren was designated an 'orphan medicine' (a medicine used in rare diseases) on 22 May 2006.

Plenadren contains the active substance hydrocortisone.

How is Plenadren used?

Plenadren can only be obtained with a prescription. It is available as modified-release tablets (5 mg and 20 mg).

The usual daily dose ranges from 20 to 30 mg, once per day early in the morning; tablets should be swallowed whole with a glass of water at least 30 minutes before food. Treatment may need to be individually adjusted according to how the patient responds. In situations of excessive physical or mental stress or illness, patients may need further doses of hydrocortisone. This may be given as Plenadren tablets twice or three times daily or as conventional immediate-release tablets or injections, either alone or in combination with Plenadren.

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How does Plenadren work?

The active substance in Plenadren, hydrocortisone, is the pharmaceutical form of cortisol, the main steroid hormone secreted by the adrenal gland. Hydrocortisone replaces the natural cortisol that is missing in patients with adrenal insufficiency. It has been used in medicines for several decades.

Because it is available as a modified-release tablet, Plenadren releases hydrocortisone over a longer period of time allowing for a once-daily dosing. It is taken early in the morning to mimic the fact that in healthy people the blood level of cortisol increases early in the morning.

What benefits of Plenadren have been shown in studies?

The effects of Plenadren were investigated in one main study involving 64 patients with adrenal insufficiency. Plenadren, given once per day, was compared with conventional hydrocortisone treatment, which is given three times per day. The study looked at the levels of cortisol in the patients' blood during a 24-hour period following three months of treatment. In patients taking Plenadren the cortisol levels achieved were considered to be satisfactory for patients with adrenal insufficiency. The overall amount of cortisol absorbed into the blood was around 20% lower in patients taking Plenadren compared with patients taking conventional hydrocortisone treatment.

What are the risks associated with Plenadren?

The most common side effects with Plenadren (seen in more than 1 patient in 10) are fatigue (tiredness), diarrhoea, vertigo (feeling dizzy) and headache.

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

Why is Plenadren approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that Plenadren achieved satisfactory levels of cortisol during the treatment of patients with adrenal insufficiency. The Committee also noted that with Plenadren there is the convenience of once daily dosing. Although once daily dosing comes with a risk of cortisol levels being too low in the afternoon, this can be managed by adding further doses of hydrocortisone if needed.

The CHMP concluded that the benefits of Plenadren were greater than its risks and recommended that it be granted marketing authorisation.

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

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

Other information about Plenadren

The European Commission granted a marketing authorisation valid throughout the European Union for Plenadren on 3 November 2011.

The full EPAR for Plenadren can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about

treatment with Plenadren, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for Plenadren can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designations.

This summary was last updated in 11-2016.