

Summary Public Assessment Report
non-generics

Fludrocortisone acetate Hualan 0.1 mg tablets
Fludrocortisone acetate

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Fludrocortisone acetate Hualan 0.1 mg tablets (hereinafter Fludrocortisone acetate Hualan)

Fludrocortisone acetate, 0.1 mg, tablets

This is a summary of the public assessment report (PAR) for Fludrocortisone acetate Hualan. It explains how Fludrocortisone acetate Hualan was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Fludrocortisone acetate Hualan.

For practical information about using Fludrocortisone acetate Hualan, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fludrocortisone acetate Hualan and what is it used for?

Fludrocortisone acetate Hualan is a medicine with ‘well-established use’. This means that the medicinal use of the active substance of Fludrocortisone acetate Hualan is well established in the European Union for at least ten years, with recognised efficacy and an acceptable level of safety.

Fludrocortisone acetate Hualan is used in children above the age of three, adolescents and adults to replace the hormones that are normally produced by glands attached to your kidneys. These hormones will not be produced by your body if you suffer from a condition called Addison’s disease. It is also used to treat a condition called ‘salt losing adrenogenital syndrome’ which is a different form of hormone imbalance.

How does Fludrocortisone acetate Hualan work?

Fludrocortisone acetate Hualan belongs to a group of medicines called steroids. Their full name is *corticosteroids*. These corticosteroids occur naturally in the body and help to maintain health and well-being. Boosting your body with extra corticosteroids (such as Fludrocortisone acetate Hualan) is an effective way to treat various illnesses involving inflammation (swelling) in the body. Fludrocortisone acetate Hualan reduces this inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

How is Fludrocortisone acetate Hualan used?

The pharmaceutical form of Fludrocortisone acetate Hualan is tablet, and the route of administration is oral.

To treat Addison's disease the usual daily dose range is: 0.05 mg (one-half tablet) to 0.3 mg (3 tablets) to be taken once a day. Patients on long term treatment may require the addition of a different type of steroid tablet during times of illness or stress.

To treat adrenal hyperplasia (salt wasting) the usual daily dose range is: 0.1 mg (one tablet) to 0.2 mg (2 tablets).

Use in children above the age of three years and adolescents:

Half a tablet (0.05 mg) to one tablet (0.1 mg) daily for adrenal hyperplasia.

Half a tablet (0.05 mg) to two tablets (0.2 mg) daily for primary adrenal insufficiency.

The dose is adjusted according to the age, weight and severity of the disease of your child and will always be monitored by your doctor.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Fludrocortisone acetate Hualan have been shown in studies?

As fludrocortisone is a well-known substance, and its use in the treatment of Addison's disease and adrenal hyperplasia is well established, the applicant presented data from the scientific literature. The literature provided confirmed the efficacy and safety of fludrocortisone in the treatment of both diseases.

What are the possible side effects from Fludrocortisone acetate Hualan

The most common side effects with Fludrocortisone acetate Hualan (which may affect more than 1 in 10 people) are

- Hypokalemia (low potassium level in the blood)
- Heart failure
- Hypertension

For the full list of all side effects reported with Fludrocortisone acetate Hualan, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Fludrocortisone acetate Hualan approved?

The State Institute for Drug Control decided that Fludrocortisone acetate Hualan's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Fludrocortisone acetate Hualan?

A risk management plan has been developed to ensure that Fludrocortisone acetate Hualan is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Fludrocortisone acetate Hualan, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Fludrocortisone acetate Hualan

The marketing authorisation for Fludrocortisone acetate Hualan was granted on 31 December 2024.

The full PAR for Fludrocortisone acetate Hualan can be found on the [website](#). For more information about treatment with Fludrocortisone acetate Hualan, read the package leaflet ([link](#)) or contact your doctor or pharmacist.

This summary was last updated in 03-2025.