EMA/597493/2015
EMEA/H/C/003759

EPAR summary for the public

Intuniv

guanfacine

This is a summary of the European public assessment report (EPAR) for Intuniv. 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 Intuniv.

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

What is Intuniv and what is it used for?

Intuniv is used to treat attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6 to 17 years when stimulant medicines are not appropriate or do not control their symptoms well enough.

Intuniv is used as part of a comprehensive treatment programme that typically involves psychological, educational and other interventions.

The active substance in Intuniv is guanfacine.

How is Intuniv used?

Intuniv treatment must be started by a doctor specialised in childhood or adolescent behavioural problems. Before starting treatment, the doctor should carry out checks to see whether the patient is at risk of side effects of the medicine (particularly sleepiness, effects on heart rate and blood pressure, and weight gain).

The dose of Intuniv requires careful adjustments, taking account side effects and benefits seen in the patient. Weekly monitoring is required at the start of treatment and the patient should continue to be monitored at least every 3 months for the first year.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The medicine is available as tablets (1, 2, 3 and 4 mg). The recommended starting dose for all patients is 1 mg taken by mouth once a day. For information on dose adjustments and checks to be carried out by the doctor, see the summary of product characteristics (SmPC).

The medicine can only be obtained with a prescription

How does Intuniv work?

The way Intuniv works in ADHD is not established. It is thought that the active substance, guanfacine, might influence the way signals are transmitted between cells in areas of the brain called the prefrontal cortex and basal ganglia by attaching to certain receptors that are heavily concentrated in these areas.

What benefits of Intuniv have been shown in studies?

Several studies have shown Intuniv improving ADHD symptom scores (ADHD-RS-IV) in children and adolescents.

In a study of 337 children aged 6 to 17 years, the reduction in ADHD symptoms with Intuniv treatment after 10 to 13 weeks was 24 points compared with a reduction of 15 points seen with placebo (a dummy treatment) and 19 points seen with atomoxetine (an ADHD medicine). In another study of 312 adolescents aged 13 to 17, the reduction in ADHD scores at 13 weeks was 25 points with Intuniv and 19 points with placebo. Two other short-term studies involving 631 patients also showed Intuniv at various doses improving ADHD scores more than placebo.

Intuniv was also evaluated in terms of treatment failures (based either on worsening of ADHD symptoms or patients stopping treatment). In a long-term maintenance study in 301 children and adolescents aged 6 to 17 years treatment failures occurred in 49% of patients taking Intuniv compared with 65% of those taking placebo.

What are the risks associated with Intuniv?

The most common side effects with Intuniv are sleepiness (in nearly half of all patients), headache (in more than a quarter), tiredness (in about 1 patient in 5), and upper abdominal pain and sedation (both in around 1 in 10). Sleepiness usually begins at the start of treatment and lasts for 2 to 3 weeks.

More serious side effects are less common and include: low blood pressure and weight gain (both in around 1 patient in 30), slow heart rate (1 in 60) and fainting (in less than 1 in 100).

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

Why is Intuniv approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) noted that stimulant medicines are first line treatments for ADHD and that these medicines provide a larger and more consistent improvement in ADHD symptoms as part of a comprehensive treatment programme. However, given the benefits seen with Intuniv, the Committee concluded that the medicine can be used as an alternative in patients who cannot take stimulants or in patients in whom stimulants do not control their symptoms well enough.

The most important safety risks are slow heart rate, low blood pressure, fainting, sleepiness and sedation. The CHMP has recommended several measures, including regular monitoring to manage these risks.

The CHMP therefore concluded that the benefits of Intuniv outweigh the risks recommended that it be approved for authorisation in the EU.

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

A risk management plan has been developed to ensure that Intuniv 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 Intuniv, including the appropriate precautions to be followed by healthcare professionals and patients.

The company that markets Intuniv must also provide nationally agreed educational material for healthcare professionals before launching the medicine on the market. The education material should include information on side effects, a checklist to identify children at risk, and a checklist and chart for monitoring children during treatment.

Further information can be found in the summary of the risk management plan.

Other information about Intuniv

The European Commission granted a marketing authorisation valid throughout the European Union for Intuniv on 17 September 2015.

The full EPAR and risk management plan summary for Intuniv 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 Intuniv, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in September 2015.