23 July 2015
EMA/CHMP/450088/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Intuniv

guanfacine

On 23 July 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Intuniv, intended for the treatment of attention deficit hyperactivity disorder (ADHD). The applicant for this medicinal product is Shire Pharmaceuticals Ireland Ltd.

Intuniv will be available as 1 mg, 2 mg, 3 mg and 4 mg prolonged-release tablets. The active substance of Intuniv is guanfacine, a selective alpha$_{2A}$-adrenergic receptor agonist (ATC code: C02AC02) which is expected to work by modulating the brain signalling pathways that are believed to be responsible for the symptoms associated with ADHD.

The benefits with Intuniv are its ability to reduce the behavioural symptoms of ADHD, mainly hyperactivity, impulsivity and/or short attention span, and distractibility. The most common side effects are somnolence, headache, fatigue, abdominal pain and sedation. Serious adverse reactions commonly reported include hypotension, weight increase, bradycardia and syncope.

The full indication is:

“Treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6 to 17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective. Intuniv must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.” Treatment must be initiated under the supervision of an appropriate specialist in childhood and/or adolescent behavioural disorders.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact