

Almotriptan (Axert[®]/Almogran[®])* approved by the FDA for the treatment of migraine in adolescents

- **Axert[®]/Almogran[®] (almotriptan) is the first of its class to be approved for treatment of migraine in adolescents by the Food and Drug Administration (FDA).**
- **Axert[®]/Almogran[®] (almotriptan) was approved in adults, in USA, in 2001.**
- **It is estimated that up to 10% of adolescents are affected by migraine³.**

Barcelona, 3rd June 2009.- Almirall announces that the USA regulatory authorities (FDA), have approved a new indication for the use of almotriptan (Axert[®]/Almogran[®]) for the acute treatment of migraine headache in adolescent patients (age 12 to 17 years). Almotriptan, a product coming from Almirall R&D, obtained the initial approval in USA in 2001 for the same indication in adults and it is currently being marketed through a licence-out agreement by Ortho-McNeil Janssen Pharmaceuticals, Inc. (a Johnson & Johnson company) in the USA and Canada.

Axert[®]/Almogran[®] (almotriptan) is the first triptan to be approved for treatment of migraine in adolescents by the FDA. This is an important milestone for Almirall and its partner as it demonstrates their commitment to bring medication to those adolescents who suffer from migraines and who, until now, had no FDA-approved migraine-specific treatment option.

This approval is expected to reinforce the positive evolution of almotriptan in the USA market. Additionally based on completion of the studies that support this approval, a patent extension of 6 months has been granted in the USA, until November 2015.

About almotriptan

Almotriptan (marketed in the USA as Axert[®] and in Europe as Almogran[®]) works on specific 5-HT (serotonin) receptors (the 5-HT_{1B/1D}) leading to a reduction in the transmission of pain impulses and normalisation of the vascular changes associated with migraine. Migraine is believed to involve, basically, an interaction between the trigeminal nerve and the vascular system. The nerve junctions of the trigeminal nerve contain serotonin, a mediator of blood vessel constriction.

More than 42 clinical studies with almotriptan involving over 18,000 patients support the efficacy and safety of this product. Recently, the 'Act when Mild' study was published in *Cephalalgia*¹, and it demonstrates that early treatment with almotriptan significantly reduced the mean duration of a migraine attack, in patients who took almotriptan when pain was still mild, vs those who took it after pain had become moderate to severe. Also, it showed that a significant number of patients were pain-free at two hours (53% for mild basal pain patients vs 37.5% for moderate-to-severe basal pain patients).

Almotriptan, a product from Almirall's R&D, was the first Spanish pharmaceutical product approved by the FDA, and it is available in 15 countries including USA, Canada and across Europe. The product is also marketed in South Korea, since January 2009, by Yuhan.

About migraine

Migraine is a common chronic neurological/neurovascular disorder. Sufferers have recurrent disabling attacks of severe headache, autonomic dysfunction and, in a proportion of patients, an aura. Diagnosis

* Axert[®] is a trademark of Laboratorios Almirall, S.A. used for the marketing of almotriptan in the USA and Canada. Almogran[®] is a trademark of Laboratorios Almirall, S.A. used for the marketing of almotriptan outside those countries.

is based on clinical history. Migraine has several subtypes being “common migraine” (no aura) twice as common as classic migraine (with aura). It affects about 14% of people in Europe; 16.6% women and 7.45% men².

The cause of migraine is unknown, but it is thought to involve interaction between the circulatory and nervous systems (in particular the trigeminal nerve) and genetic inheritance is involved.

Migraine may begin at any age, although the onset is usually before the age of 30, with the highest incidence between the ages of 20 and 30. It's estimated that up to 10% of adolescents are affected by migraine and that up to 2.75 million school days are missed annually because of migraine attacks in children and adolescents.³ As difficult as Migraine can be for adults, for children and adolescents, it can be even more difficult. Migraine attacks often cause them to not do as well academically, not be able to participate in extracurricular activities, and miss out on social events and relationships with their peers.

The diagnosis of migraine is based on the clinical history. Key indicators include: one-sided headache, severe throbbing type of pain, pain made worse by physical activity, nausea, vomiting, photophobia and /or phonophobia. A number of factors do provoke migraine attacks in some patients, these include: stress, sleep disturbances, not eating, physical exertion, food (especially those with tyramines -some cheeses-, chocolate, milk products), alcohol, and changes in menstrual cycle in women.

About Almirall

Almirall is an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, it researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing.

The therapeutic areas on which Almirall focuses its research resources are related to the treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), rheumatoid arthritis, multiple sclerosis, psoriasis and dermatology.

Almirall's products are currently present in over 70 countries while it has direct presence in Europe and Latin America through 11 affiliates.

For further information please visit the website at: www.almirall.com

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¹ P Goadsby, et al. Early vs non-early intervention in acute “Act when Mild (AwM)”. A double-blind, placebo controlled study on almotriptan. *Cephalalgia* 2008;28:383-91

² Hartmaier SL, et al. Development of a brief 24-hour adolescent migraine functioning questionnaire. *Headache* 2001; 41: 150-156.

³ L. J. Stovner, J.-A. Zwart, K. Hagen et al. Epidemiology of headache in Europe. *European Journal of Neurology* 2006, 13:333–45