

Press Release

Alcohol-related Disorders: Ethypharm is Granted Marketing Authorisation for Its Drug Baclocur®

Saint Cloud, France – October 23rd 2018

World first

The National Agency for the Safety of Medicines and Healthcare Products (ANSM) has just granted Ethypharm marketing authorisation for its drug Baclocur® in France, a range of baclofen tablets in doses of 10, 20 and 40 mg. For more than 15 years, the use of baclofen in alcohol-related disorders has been the subject of numerous scientific publications across the world (Europe, USA, Australia, Israel, etc.). France is the first country to grant marketing authorisation to a baclofen preparation aimed at reducing alcohol consumption. Baclocur® is intended for use by alcohol-dependent adult patients with high-risk alcohol consumption. It should be prescribed by a doctor, preferably an addiction specialist, after other drug therapies have failed and used within the context of psychosocial support focused on compliance and reducing consumption. The maximum authorised daily dose is 80 mg per day.

Available in 2019

Baclocur® should be available in the second half of 2019, after obtaining approval from the authorities and the opinion of the Transparency Commission from the French National Authority for Health, followed by a reimbursement price from the Economic Committee for Health Products. Then alcohol-dependent patients who would benefit from treatment with baclofen will be given Baclocur®, the only form of baclofen authorised for this indication. From the time when Baclocur® is launched on the market, Ethypharm will guarantee that its real-life use will be monitored. Systems for pharmacovigilance (CRPV), addictovigilance (CEIP-A) and toxicovigilance (CAP-TV) can also better observe baclofen's use within the scope of a marketing authorisation and a well-defined indication and thanks to a more easily identifiable drug.

Evaluation of Baclocur® in alcohol-related disorders

The application for marketing authorisation submitted by Ethypharm was subject to a special evaluation procedure, during which various stakeholders were able to express their opinions; these included patient associations and representatives of all the expert societies in the field of addiction treatment (French Federation for the Study of Addiction, French Society for the Study of Alcohol, Addiction Federation and MG Addiction, amongst others). On completion of the multidisciplinary evaluation, the ANSM granted marketing authorisation to Ethypharm for its drug Baclocur®.

Burden of the disease in France

Alcohol is the cause of almost 400,000 hospital admissions and 50,000 deaths every year, including 15,000 due to cancer. By providing Baclocur®, Ethypharm would like to help to reduce the burden caused by alcohol alongside other social measures, such as reinforcing the ban on the sale of alcohol to minors, increasing tax on alcohol, preventative actions and training in early identification and brief intervention.

Faced with the scourge of alcohol, the marketing authorisation granted to Baclocur® again demonstrates the urgent need for strong action by all stakeholders (health authorities, healthcare professionals, expert societies and patient associations) in order to care for the tens of thousands of



patients with alcohol problems and to continue to support them with the various pharmacological and non-pharmacological treatment options available.

Ethypharm, a company committed to the development and provision of drugs to treat addictions

Baclocur[®] is the third Ethypharm drug to obtain marketing authorisation in the field of addictions in a year in France. This marketing authorisation follows the authorisations for Orobupré[®], a substitute opioid drug that will be available in the next few days and Prenoxad[®], a naloxone intramuscular kit and antidote to opioid overdoses.

This marketing authorisation is the fruit of development work since 2011 and confirms Ethypharm's involvement in the field of addictions where medical needs and patients' needs are still not sufficiently covered.

About Ethypharm

Ethypharm is a European-based specialty pharmaceutical company with global reach and a committed player in the treatment of pain and addiction.

Ethypharm also develops and markets complex generics and essential medicines that help reduce healthcare costs, particularly in the field of emergency care and oncology.

The Company employs 1400 people mainly in Europe, and its drugs are marketed in more than 80 countries.

Our ambition is to become the European leader for the treatment of pain and addiction, and to help patients around the world gain access to high quality, essential and affordable medicines.

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