HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE

OPINION

20 NOVEMBER 2019

baclofen

BACLOCUR scored film-coated tablets

First assessment

Key points

Favourable opinion for reimbursement to reduce alcohol consumption, following the failure of other available medicinal treatments, in adult patients with alcohol dependency and high-risk alcohol consumption (> 60 g/day for men and > 40 g/day for women). This opinion is subject to the collection of efficacy and safety data within a maximum period of 3 years with a view to reevaluation.

Role in the care pathway?

The management of alcohol dependency is the subject of national recommendations issued by the *Société française d'Alcoologie* [French Alcohology Society].

In combination with psychosocial follow-up focusing on treatment compliance and the reduction of alcohol consumption, baclofen is a **treatment option of last resort** to reduce alcohol consumption in adult patients with alcohol dependency and high-risk alcohol consumption (> 60 g/day for men and > 40 g/day for women), not presenting physical symptoms of withdrawal and not requiring immediate abstinence. The potential benefit of the treatment is dictated by the patient's compliance.

In accordance with the SPC, its use must be accompanied by regular medical follow-up, particularly during the dose titration phase. **The maximum daily dosage of baclofen is 80 mg per day**. The SPC also specifies that in the absence of any efficacy after 3 months of treatment, the medicinal product should be progressively discontinued and that there are no data from studies beyond 12 months.

◗ Special recommendations

The Committee deems that BACLOCUR may be prescribed to alcohol-dependent patients at high risk of failure of other medicinal treatments when it appears to be essential to reduce their alcohol consumption in order to improve their health status or prevent their health from deteriorating.

Detailed information concerning the treatment regimen, its benefits and drawbacks - in particular, adverse effects - should be given to patients before any treatment decision is reached. Their attention should be drawn to the need for regular medical follow-up, especially during the titration phase, in order to determine the optimal dosage (tailored to each patient), i.e., the lowest dose enabling an optimal treatment response and acceptable safety, without exceeding the dose of 80 mg per day.

The Committee will reevaluate the medicinal product within a maximum period of 3 years.

COMMITTEE'S CONCLUSIONS

Clinical Benefit

◗ Alcohol dependence is a serious, chronic condition that is potentially life-threatening for the patient. It can have long-term effects on the gastrointestinal organs and liver and the central nervous system, as well as psychological effects. Regular, excessive drinking can also have serious social repercussions (social isolation, rejection by family and professional exclusion, domestic violence, etc.) and result in major impairment of quality of life.

◗ BACLOCUR is part of a curative treatment regimen, aimed at reducing excessive alcohol consumption in adult patients with alcohol dependency with high-risk drinking, following the failure of available medicinal treatments.

◗ The efficacy/adverse effects ratio of baclofen compared to placebo in the MA indication and dosage (maximum daily dose of 80 mg per day) has not currently been adequately established. Additional data are required and expected to be able to determine, with a better level of evidence, the efficacy, effects and risks related to its use at the MA dosages and indication.

◗ Since BACLOCUR is indicated following the failure of the other medicinal treatments available in the treatment of alcohol dependency, there are no therapeutic alternatives.

◗ In combination with psychosocial follow-up focusing on treatment compliance and the reduction of alcohol consumption, BACLOCUR (baclofen) is a treatment option of last resort in the reduction of alcohol consumption, following the failure of other available medicinal treatments, in adult patients with alcohol dependency and high-risk alcohol consumption (> 60 g/day for men and > 40 g/day for women), not presenting physical symptoms of withdrawal and not requiring immediate abstinence.
Despite numerous clinical uncertainties, the role of baclofen in the care pathway has been defined considering its potential usefulness for some high-risk alcohol-dependent patients, particularly in view of the identified medical need expressed by healthcare professionals and patients' and users' associations. In addition, the Committee deems that, over and above the effect - even minimal and uncertain - of baclofen, excessive alcohol consumption should be managed as a part of a global approach, including psychosociological aspects; it is therefore important to guarantee access to all the recommended therapies, including baclofen, for individuals requiring them.

Public health impact

Considering:

- the seriousness of alcohol dependence and its high prevalence, estimated to be between 1.5 and 2 million people dependent on alcohol in France[Erreur ! Signet non défini.,Erreur ! Signet non défini.],

- the substantial medical need for access to treatments, due to the modest efficacy of the treatments available,
- the unmet medical need following the failure of current treatments, taking into account the lack of any appropriate and reimbursable alternatives,
- the current absence of robust data supporting an additional impact on the reduction of morbidity and mortality and the improvement of quality of life of alcohol-dependent patients, which is particularly regrettable in view of the number of patients treated in France,
- the burden on society and the major public health challenge of identifying at-risk drinkers and reducing their drinking,
- the possibility offered by baclofen of identifying and providing medical support to dependent patients, and of reinforcing risk reduction messages, which could help address the public health need,

BACLOCUR is likely to have an impact on public health.

The Committee deems that the clinical benefit of BACLOCUR is low in the indication and in strict compliance with the MA dosage (maximum dose of 80 mg per day), pending new data. The Committee wishes to reevaluate BACLOCUR within a maximum period of 3 years. The information and additional studies essential for reevaluation of the clinical benefit to be submitted to the Committee by the pharmaceutical company within this period are detailed below.

01.1 Clinical Added Value

Considering:

- **demonstration of the superiority of baclofen compared to placebo inadequately established in the MA indication and dosage despite large-scale use of the medicinal product in France, particularly in the context of a temporary recommendation for use (RTU);**
- **the effect size of baclofen compared to placebo, which is at best low, observed in a context of discordant, heterogeneous studies with a low level of evidence;**
- **the substantial medical need for access to treatments in the management of alcohol dependence, due to the modest efficacy of the treatments available and the lack of any appropriate and reimbursable alternatives in patients in whom these treatments have failed;**

the Committee considers that BACLOCUR provides no clinical added value (CAV V) in the current treatment of patients with alcohol dependency.

◗ **Recommended reimbursement rate: 15%**