HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE

SUMMARY

24 MARCH 2021

The legally binding text is the original French opinion version

nalmefene

SELINCRO 18 mg film-coated tablets

Reevaluation

Key points

Maintenance of the favourable opinion for reimbursement, in conjunction with continuous psychosocial support, in the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification.

◗ Role in the care pathway?

The therapeutic methods used in the treatment of primary alcohol dependence are multidisciplinary and include, in particular, psychotherapy or support groups for former drinkers, medicinal products and hospitalisation. Used simultaneously or consecutively in variable proportions, these methods are proposed to treat a polymorphous problem.

Psychosocial support of patients is essential throughout medicinal treatment and forms the foundation for the management of any individual with alcohol problems. The French Alcohology Society (SFA) indicates in its various recommendations that “the prescription of medicinal treatment - particularly in addictive behaviours - should always be part of a holistic care approach and medicinal treatment cannot be the only therapy for addiction”.

At the current time, six medicinal products have an MA in the treatment of alcohol dependence in the following two indications:

- three medicinal products are indicated in the maintenance of abstinence after detoxification: AOTAL 333 mg and its generics (acamprosate), generics of REVIA 50 mg (naltrexone, with REVIA no longer marketed), and ESPERAL 500 mg (disulfiram);
- three medicinal products indicated in the reduction of alcohol consumption in high-risk patients:
  - o SELINCRO (nalmefene);
  - o two baclofen-based medicinal products only indicated following the failure of the other medicinal treatments available: BACLOCUR (baclofen) and BACLOFENE ZENTIVA (baclofen).

Role of SELINCRO (nalmefene) in the care pathway:

The management of alcohol dependence is based on multidisciplinary treatment methods (psychotherapy, support groups for former drinkers, medicinal products, hospitalisation, psychosocial support, etc.). When a medicinal treatment is envisaged in the context of the holistic care of alcohol dependence, SELINCRO (nalmefene), in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption, remains the first-line medicinal product for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. The potential benefit of the treatment is dictated by the patient’s compliance.

The choice of SELINCRO from the various medicinal and non-medicinal supportive methods available is based on shared decision-making between the physician and the patient, after providing the patient with honest information on the various therapeutic options that exist and their characteristics, in particular, the risks of dissociation reported in clinical studies with SELINCRO.

In the French observational study initiated at the request of the Committee following the assessment on 4 December 2013, a profile of patients included on the basis of a broader drinking risk level than that validated by the MA for SELINCRO (nalmefene) was identified. Consequently, the Committee highlights that, with the aim of ensuring good practice, SELINCRO (nalmefene) should be reserved purely for patients with a high DRL (alcohol consumption >60 g/day for men and >40 g/day for women according to the WHO DRLs of alcohol consumption). In addition, patients must not present physical withdrawal symptoms or require immediate detoxification, in accordance with the MA indication.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

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, family and professional exclusion) and result in major impairment of quality of life and damage to the community.
◗ The proprietary medicinal product SELINCRO 18 mg film-coated tablets (nalmefene) is part of a curative treatment regimen, aimed at reducing excessive alcohol consumption in adult patients with alcohol dependence who have a high or very high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. SELINCRO (nalmefene) should be initiated only in patients who continue to have a high DRL two weeks after initial assessment.

◗ The efficacy/adverse effects ratio remains low.

◗ There are no medicinal alternatives to this proprietary medicinal product.

◗ SELINCRO (nalmefene), in conjunction with continuous psychosocial support focused on treatment adherence and reducing alcohol consumption, remains the first-line medicinal product for the reduction of alcohol consumption in adult patients with alcohol dependence who have a high drinking risk level (DRL), without physical withdrawal symptoms and who do not require immediate detoxification. The potential benefit of the treatment is dictated by the patient's compliance (see section 09. Role in the care pathway).

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,
- the substantial medical need to have access to treatments for the reduction of alcohol consumption in patients at high or very high risk,
- the partial response to the identified need in view of the modest data for reduction of morbidity resulting from three phase 3 studies and the new observational data from the post-inclusion study,
- the burden on society and the major public health challenge of identifying at-risk drinkers and reducing their drinking,
- the possibility offered by nalmefene of identifying and providing medical support to dependent patients, and of reinforcing risk reduction messages, which could help address the public health need,

SELINCRO 18 mg film-coated tablets (nalmefene) is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of SELINCRO 18 mg film-coated tablets (nalmefene) remains moderate in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and dosages.

◗ **Recommended reimbursement rate: 30%**