HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE

SUMMARY

19 MAY 2021

The legally binding text is the original French opinion version

delamanid
DELTYBA 50 mg film-coated tablets

New indication

Key points

Favourable opinion for reimbursement in the indication extension to “treatment of pulmonary multi-drug resistant tuberculosis (MDR-TB) in adults, **adolescents and children with a body weight of at least 30 kg** when an effective treatment regimen cannot otherwise be composed for reasons of resistance or tolerability.

What therapeutic improvement?

Therapeutic improvement in the care pathway for multi-drug resistant tuberculosis.

Role in the care pathway?

The management of tuberculosis is well standardised and is the subject of national (HCSP) and international guidelines (WHO).

Role of the medicinal product in the care pathway

DELTYBA (delamanid) is a reference treatment option for the treatment of patients with pulmonary multi-drug resistant tuberculosis sensitive to delamanid, when the use of a WHO group C anti-tuberculosis drug is indicated and following the opinion of the mycobacteria reference centre.

The prescription of DELTYBA (delamanid) in adolescents and children must take into account a potential risk of increased occurrence of adverse effects (in particular, QT interval prolongation and increased transaminases) due to overexposure to drugs.

The Summary of Product Characteristics (SPC) and the Risk Management Plan (RMP) must be complied with.

Special recommendations

In accordance with its previous opinion, the Committee recommends restricting the prescription of DELTYBA (delamanid) to physicians experienced in the management of patients with multi-drug resistant tuberculosis. In addition, the decision to initiate treatment with this drug should be based on a written recommendation issued at a meeting of a multidisciplinary team (MDT) with an expert group for the choice of treatment regimen (e.g. CNR-MyRMA).

COMMITTEE'S CONCLUSIONS

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

Clinical benefit

◗ Multi-drug resistant tuberculosis is a rare disease in France, which is frequently fatal. Its frequency is increasing sharply worldwide.

◗ DELTYBA (delamanid) is a curative treatment for multi-drug resistant tuberculosis.

◗ Its efficacy/adverse effects ratio has still not been adequately established in clinical studies and remains to be verified specified in the context of the conditional marketing authorisation. However, preliminary data are reassuring at present and deemed to be satisfactory in view of the medical need.

◗ At this stage of the infection, there are few therapeutic alternatives.

◗ DELTYBA (delamanid) is one of the reference treatment options (according to WHO recommendations) for the treatment of multi-drug resistant tuberculosis.

Public health impact

Considering:

- the seriousness of tuberculosis infection, which makes it a public health priority,
- the small number of patients concerned in France,
- the significant medical need to have access to enough second-line anti-tuberculosis drug combinations to be able to adjust treatment in the event of contraindication or intolerance,
- the fact that DELTYBA (delamanid) provides a response to the identified medical need, due to its bactericidal activity against multi-resistant strains, but for which the impact on morbidity and mortality and/or quality of life cannot be assessed on the basis of the limited data available,
- a potential impact on the care and life pathway by reducing the duration of contagion (reduction of the isolation period for patients and additional air precautions), and recourse to injectable aminoglycosides,
- an expected impact in terms of breaking the multi-drug strain transmission chain due to conversion of bacteriological cultures,

DELTYBA (delamanid) is likely to have an additional impact on public health in the treatment of multi-drug resistant tuberculosis.

Given all these elements, the Committee deems that the clinical benefit of DELTYBA (delamanid) is substantial in the MA indication.

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

Clinical Added Value

Considering:

- **the substantial medical need in multi-drug resistant tuberculosis,**
- **the bactericidal activity of delamanid and limited data in adolescents suggesting an efficacy comparable to that described in adults,**

- **the fact that delamanid is one of the reference treatment options in adults and children in accordance with the updated WHO guidelines,**

the Committee deems that, as in adults, DELTYBA (delamanid), as part of an appropriate combination regimen, provides a moderate clinical added value (CAV III) in adolescents and children with a body weight of at least 30 kg with multi-drug resistant tuberculosis sensitive to delamanid, when the use of a WHO group C anti-tuberculosis drug is indicated and following the opinion of the mycobacteria reference centre.