HAUTE AUTORITÉ DE SANTÉ

# TRANSPARENCY COMMITTEE
## SUMMARY
## 24 JUNE 2020

*The legally binding text is the original French opinion version*

***oseltamivir***
**TAMIFLU 30 mg, 45 mg and 75 mg hard capsules**
**TAMIFLU 6 mg/ml powder for oral suspension**

**Maintenance of reimbursement in a limited context**

### Key points

Favourable opinion for reimbursement as preventive treatment only in a pandemic influenza outbreak situation.

Unfavourable opinion for maintenance of reimbursement in the other situations (for more details, see MA).

## COMMITTEE'S CONCLUSIONS

# Clinical benefit

### Curative treatment for influenza

◗ Influenza is a highly contagious acute viral disease. Sometimes serious complications develop more readily in subjects already weakened by underlying diseases and/or over 65 years of age.

◗ TAMIFLU (oseltamivir) is a curative antiviral treatment in this indication.

◗ In the context of curative treatment, the efficacy/adverse effects ratio of TAMIFLU has not been adequately established.

◗ There are therapeutic alternatives with an MA as a curative treatment for influenza: EBILFUMIN, a generic of TAMIFLU (oseltamivir), DECTOVA (zanamivir for injection), RELENZA (zanamivir for oral inhalation).

◗ No reduction in mortality, hospitalisations or serious complications has been demonstrated with these treatments. Consequently, TAMIFLU (oseltamivir) no longer has a role in the treatment strategy, like the other abovementioned antivirals with an MA.

**Public health impact**

Considering:

- the frequency (2.5 million people affected each year) and potential severity of influenza, which can cause serious complications, particularly in individuals with specific risk factors (almost 2,000 serious cases admitted to intensive care units in the 2018-2019 season);
- the medical need to have access to an effective and well-tolerated curative antiviral treatment, particularly for at-risk populations in whom influenza is potentially life-threatening;
- data from clinical studies, which do not enable the impact of this medicinal product in terms of morbidity and mortality to be quantified, in the absence of data on mortality and the weakness of the effect size on morbidity endpoints;
- the absence of any demonstrated impact on the organisation of care, in particular in terms of reduction of hospitalisations;

TAMIFLU (oseltamivir) is unlikely to have an impact on public health in the context of curative treatment of influenza infections.

**Considering all these elements, the Committee deems that the clinical benefit of TAMIFLU is insufficient to justify its funding by the French national health insurance system in the context of the curative treatment of influenza in the event of a seasonal epidemic or influenza pandemic.**

**The Committee issues an unfavourable 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 treatment of "adults and children including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community" and at the MA dosages.**

### Influenza prevention

◗ Influenza is a highly contagious acute viral disease. Sometimes serious complications develop more readily in subjects already weakened by underlying diseases and/or over 65 years of age.

◗ TAMIFLU (oseltamivir) is a preventive antiviral treatment in this indication.

◗ In the context of curative treatment, the efficacy/adverse effects ratio has not been adequately established.

◗ There are therapeutic alternatives with an MA in the preventive treatment of influenza, in particular influenza vaccines, which are the cornerstone of influenza prevention, along with EBILFUMIN (oseltamivir, generic of TAMIFLU).

◗ In view of the data available (in favour of a reduction in the influenza attack rate in the general population and in the elderly living in communal facilities), TAMIFLU (oseltamivir) may be used as a complement to vaccination only in the event of an established or potential influenza pandemic, in accordance with the arrangements defined by national guidelines, if applicable.

**Public health impact**

Considering:

- the frequency (2.5 million people affected each year) and potential severity of influenza, which can cause serious complications, particularly in individuals with specific risk factors (almost 2,000 serious cases admitted to intensive care units in the 2018-2019 season);
- the medical need to have an effective and well tolerated preventive antiviral treatment in addition to the available preventive measures (vaccination and protective measures);
- clinical data available in the general population and in the elderly living in communal facilities, in favour of a reduction in the influenza attack rate, without any clearly demonstrated benefit in terms of a reduction in mortality and associated serious complications, particularly in at-risk populations;
- the absence of any demonstrated impact on the organisation of care, in particular in terms of reduction of hospitalisations;

TAMIFLU (oseltamivir) is unlikely to have an impact on public health in the context of preventive treatment of influenza infections during seasonal influenza epidemics. However, in the event of an established or potential influenza pandemic, TAMIFLU (oseltamivir) is likely to have a public health impact.

**Considering all these elements, the Committee deems that the clinical benefit of TAMIFLU is:**

- **low in the context of preventive treatment in an established or potential influenza pandemic scenario;**
- **insufficient in the other situations (as prophylaxis during seasonal influenza epidemics).**

**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 only in the context of preventive treatment in an established or potential influenza pandemic scenario.**