



AWMSG Secretariat Assessment Report – Limited submission

Oseltamivir (Tamiflu®) 30 mg, 45 mg and 75 mg capsules, and 6 mg/ml powder for oral suspension

Company: Roche Products Ltd

Licensed indication under consideration:

Oseltamivir (Tamiflu®) for treatment of infants less than 1 year of age including full term neonates who present with symptoms typical of influenza, when influenza virus is circulating in the community. Efficacy has been demonstrated when treatment is initiated within two days of first onset of symptoms.

Refer to the Summary of Product Characteristics (SPC) for the full licensed indication.

Marketing authorisation date: 5 May 2015

Comparator(s)

The applicant company suggest there are no appropriate comparators as there are no other therapies (other than best supportive care) currently available in Wales for use in the treatment of influenza for population under consideration.

Limited submission details

The limited submission criteria were met as this is a minor licence extension and the anticipated usage of oseltamivir (Tamiflu®) in NHS Wales is considered to be of minimal budgetary impact.

Clinical effectiveness

- The National Institute for Health and Care Excellence issued guidance on influenza treatment in 2009 which includes a recommendation for the use of oseltamivir in those aged 1 year and above.
- Evidence for the use of oseltamivir for the indication under consideration is provided by two open-label, controlled pharmacokinetic/pharmacodynamic studies (CASG114 [n=68] and WP22849 [n=65]) which were conducted in infants less than 1 year of age.
- Since the efficacy of oseltamivir in the treatment of influenza in children aged 1 year and above has been previously demonstrated, the Committee for Medicinal Products for Human Use (CHMP) accepted that pharmacokinetic data alone could be used to extrapolate efficacy between paediatric age groups.
- The safety profile of oseltamivir in infants below 1 year of age was consistent with the well-documented safety profile of oseltamivir in children aged 1 year and above, adolescents and adults.

Budget impact

- The applicant company calculate an average of 215 children in Wales < 1 year of age with influenza who would be eligible for treatment with oseltamivir (Tamiflu®). Budget impact calculations are based on infants less than 1 year of age, weighing 10 kg, all receiving the 6 mg/ml powder for oral suspension.
- The budget impact is estimated to be £2,208 derived from the average overall prevalence of influenza over the previous 3 years (and applied to the number of infants less than 1 year of age in Wales estimated to be approximately 1.1%). Depending on differing rates of influenza over this period, the budget impact could range from £1,063 to £2,939.
- The applicant company acknowledge that influenza is more common in the elderly and infants and therefore the incidence in the population under consideration may be slightly higher than that of the general population estimates used.

Additional information

- AWTTTC is of the opinion that, if recommended, oseltamivir (Tamiflu®) is appropriate for prescribing by all prescribers within NHS Wales for the indication under consideration. Prescribing should be in line with existing NICE recommendations for oseltamivir use in the treatment of influenza for those 1 year and older.
- The company do not anticipate that oseltamivir (Tamiflu®) will be supplied by a home healthcare provider.
- Tamiflu® hard capsules and Tamiflu® powder for oral suspension are bioequivalent formulations. The SPC however highlights that the oral suspension (6 mg/ml) is the preferred product for patients who have difficulties swallowing capsules or where lower doses are needed.

Evidence search

Date of evidence search: 15 October 2015

Date of range of evidence search: No date limits were applied to database searches.

Further information

This assessment report will be considered for review every three years.

References are available on request. Please email AWTTTC at AWTTTC@Wales.nhs.uk for further information.

This report should be cited as: All Wales Therapeutics and Toxicology Centre. AWMSG Secretariat Assessment Report. Oseltamivir (Tamiflu®) 30 mg, 45 mg and 75 mg capsules, and 6 mg/ml powder for oral suspension. Reference number: 2800. January 2016.