

Antiviral Prescribing

Summary of prescribing guidance for Health Protection Teams

Note: *This guidance is intended to be a summary guide to enable Health Protection Teams to overcome local queries regarding the use of oseltamivir.*

IT IS NOT A SUBSTITUTE FOR THE SUMMARY OF PRODUCT CHARACTERISTICS (SPC) available either from the manufacturer or at www.medicines.org.uk

1 Oseltamivir

Oseltamivir is licensed for the treatment of influenza in individuals one year of age or older. Treatment should begin as soon as possible after onset of symptoms and must begin within 48 hours of onset of symptoms.

Oseltamivir is also licensed for post exposure prophylaxis in individuals one year of age or older.

1.1 Oseltamivir dose summary

1.1.1 Adults and children over 13 years

Treatment: 75 mg twice daily for 5 days.

Prophylaxis: 75mg once daily for 10 days.

1.1.2 Children (1-12 years)

Dosage should be guided by age (see table 1 below) rather than weight. However, where a child is very over or under weight for their age, it may be necessary to increase or decrease their dose accordingly

1.1.3 Use of oseltamivir for children aged less than 1 year

Oseltamivir is not licensed for use in children less than 1 year and the decision to prescribe should be made on an individual risk-benefit analysis by the prescribing physician.

When treatment is required for children less than 1 year the recommended dose is 2mg/kg TWICE daily for FIVE days.

When prophylaxis is required for children less than 1 year the recommended dose is 2mg/kg ONCE daily for TEN days.

Further guidance on use of antivirals in children less than 1 year has been developed by UK Medicines Information pharmacists on:

<http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/What-is-the-dose-of-oseltamivir-Tamiflu-for-the-treatment-and-prophylaxis-of-influenza--in-children-under-1-year-of-age/>

Table 1: Oseltamivir dose for the treatment and prophylaxis of influenza

Age	Oseltamivir (Tamiflu®) dose	
	Treatment of influenza	Prophylaxis of influenza
< 1 year of age	2mg/kg twice daily for 5 days	2mg/kg once daily for 10 days
≥1 years to < 3 years (body weight under 15kg)	30mg twice daily for 5 days	30mg once daily for 10 days
≥3 years to <7 years (body weight between 15kg and under 23kg)	45mg twice daily for 5 days	45mg once daily for 10 days
≥7 years to <13 years (body weight 24kg to 40kg)*	60mg twice daily for 5 days	60mg once daily for 10 days
Children > 40kg (irrespective of age)	75mg twice daily for 5 days	75mg once daily for 10 days
Adolescents (13 to 17 years of age) and adults	75mg twice daily for 5 days	75mg once daily for 10 days

1.2 Oseltamivir formulations

30 mg capsules (yellow), 10-cap pack

45 mg capsules (grey), 10-cap pack

75 mg capsules (grey-yellow), 10-cap pack

There is a very small quantity of oseltamivir suspension 12mg/ml available as part of the national stockpile of antivirals. At this stage this must be reserved for use in children under age 1 year.

Children aged from 1 year and above should be prescribed the appropriate strength of oseltamivir capsules.

Children who may be unable to swallow capsules may be given the appropriate dose by opening the capsule and pouring the contents into a small amount (1 teaspoon maximum) of sweetened food product such as regular or sugar-free chocolate syrup, honey (only for children two years or older), light brown or table sugar dissolved in water, dessert toppings, sweetened condensed milk, apple sauce or yogurt to mask the bitter taste. The mixture should be stirred and the entire contents given to the patient. The mixture **must be swallowed immediately** after its preparation

NHS Scotland has secured a quantity of oseltamivir powder and will begin production of oseltamivir solution 15mg/ml for use in children under 1 year when this becomes necessary.

2 Zanamivir

Zanamivir (Relenza®) is licensed for the treatment of influenza in individuals five years of age or older. Treatment should begin as soon as possible after onset of symptoms and must begin within 48hours of onset of symptoms in adults and 36hours in children.

Zanamivir is also licensed for post exposure prophylaxis in individuals five years of age or older

2.1 Zanamivir dose summary

2.1.1 Adults and children aged 5 year and over

Treatment: Two inhalations i.e. 2 x 5mg blister TWICE daily for FIVE days

Prophylaxis: Two inhalations i.e. 2 x 5mg blister ONCE daily for TEN days

2.1.2 Children under 5 years of age

Zanamivir is not licenced for use as treatment or post exposure prophylaxis in children under 5 years of age. These children should be prescribed Oseltamivir as per section 1 of this guidance.

2.2 Zanamivir formulation

Powder for inhalation using a diskhaler device; supplied as a pack containing the diskhaler and 20 blisters of powder for inhalation.

3 Use of antivirals in specific populations

3.1 Pregnancy

The use of these agents in pregnancy requires a risk/benefit analysis. Due to the lack of established safety data, the manufacturers recommend that they are not used in pregnancy unless the benefit to the mother justifies the theoretical risk to the fetus. In normal times the Department of Health (DoH)/Scottish Government (SG) agree with this recommendation. However, during an influenza pandemic the SG/DoH state that appropriate treatment of pregnant women will help to reduce symptoms such as fever and will thus benefit the developing fetus. The recommendation is, therefore, that during a pandemic the balance of benefit to risk will support their use and they will be provided to pregnant women. The systemic bioavailability of inhaled

zanamivir is significantly lower than that of oral oseltamivir and it is therefore regarded as the preferred treatment choice in this patient group.

3.2 Breast feeding

There is a lack of data on antivirals in women who are breastfeeding but based on limited bioavailability the systemic exposure of a breast fed infant from maternal treatment is expected to be insignificant. Women who are breastfeeding who have symptoms of influenza should be treated with an antiviral medicine. The preferred medicine is oseltamivir, as for other adults. However, if a woman's baby is born and breastfeeding is started while the woman is taking zanamivir, she should complete the course of zanamivir; it is not necessary to switch to oseltamivir.

Further guidance on use of antivirals in breastfeeding has been developed by UK Medicines Information pharmacists on <http://www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Oseltamivir-or-zanamivir---Can-mothers-breastfeed-after-treatment-for-influenza/>

3.3 Immunocompromised

These patients should be managed, with respect to treatment or prophylaxis with antivirals, no differently from other individuals: antivirals only if they are contacts, cases or probable cases according to the algorithm. They may shed virus for longer than healthy adults. At present, it is not recommended that such patients are treated for a longer duration.

3.4 Elderly

No dose adjustment is required, unless there is evidence of severe renal impairment in case of oseltamivir

3.5 Hepatic Impairment

No dose adjustment is required in patients with hepatic impairment

3.6 Renal Impairment

No dose modification for use of zanamivir is required for patients with impaired renal function and therefore zanamivir is the treatment of choice in patients known to have renal impairment.

A dose adjustment is required for treatment/prophylaxis with oseltamivir in patients with severe renal impairment. For full details of the recommended dose refer to the marketing authorisation holder's (manufacturer) summary of product characteristics

4 Side Effects

Both oseltamivir and zanamivir are intensively monitored medicines by Medicines and Healthcare products Regulatory Agency, identified as ▼, in case of black triangle medicines all suspected adverse reactions (including any considered not to be serious) should be reported using the yellow card reporting system.

For full details of reported side effects refer to the marketing authorisation holder's (manufacturer) summary of product characteristics