



**Publications number: GOV-12936** 

# Patient Group Direction (PGD) for the supply of oseltamivir for post exposure prophylaxis of seasonal influenza

For the supply of oseltamivir for post exposure prophylaxis of seasonal influenza for residents, users and staff of care facilities (with or without nursing), by registered healthcare practitioners identified in Section 3, subject to any limitations to authorisation detailed in Section 2.

Reference: 20220805 Oseltamivir Prophylaxis PGD

Version number: 05.00

Valid from: 8 August 2022 Review date: 8 August 2024 Expiry date: 7 August 2025

#### The UK Health Security Agency (UKHSA) has developed this PGD for local authorisation

Those using this PGD must ensure it is organisationally authorised and signed in Section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with Human Medicines Regulations 2012 (HMR2012)<sup>1</sup>. **The PGD is not legal or valid without signed authorisation in accordance with HMR2012 Schedule 16 Part 2**.

Authorising organisations must not alter, amend or add to the clinical content of this document (sections 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided.

As operation of this PGD is the responsibility of commissioners and service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD. Sections 2, 3 and 7 must be completed and amended within the designated editable fields provided.

The final authorised copy of this PGD should be kept by the authorising organisation completing Section 2 for 25 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 25 years after the PGD expires.

# Individual practitioners must be authorised by name, under the current version of this PGD before working according to it.

Practitioners and organisations must check they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of UKHSA seasonal influenza PGDs for authorisation can be found from: <a href="Influenza post exposure">Influenza post exposure</a> prophylaxis and treatment: PGD templates

Any queries regarding the content of this PGD should be addressed to: respiratory.lead@ukhsa.gov.uk

Enquiries relating to the availability of organisationally authorised PGDs and subsequent versions of this PGD should be directed to: pgd@cheshireandmerseyside.nhs.uk

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<sup>&</sup>lt;sup>1</sup> This includes any relevant amendments to legislation

## **Change history**

Version number	Change details	Date
01.00	Original PGD template developed	11 December 2014
02.00	Template reviewed; put into new PHE format and changes to clinical and organisational content made	7 January 2016
03.00	Template reviewed; updated title and inclusion criteria: wording changed to 'residents/users and staff of care facilities', updated references, updated at risk groups, additional minor word and formatting changes	5 June 2018
04.00	Addition of haemodialysis to criteria for exclusion; additions to off label use; note added to duration of prophylaxis for immunocompromised individuals; updated references	7 February 2019
05.00	<ul> <li>criteria for inclusion: risk groups updated to align with the Green Book Chapter 19)</li> <li>criteria for exclusion: removed unstable medical conditions</li> <li>criterial for exclusion: removed clinically significant drug interactions and added note under drug interactions</li> <li>criteria for exclusion: added immunocompromised individuals with renal impairment and those taking zanamivir</li> <li>additional information: added information for oseltamivir resistance and information for chronic kidney disease (CKD)</li> <li>route and method of administration: additional information regarding taking with food</li> <li>dose and frequency of administration: additional information for renal doses, CrCl and eGFR levels, immunocompromised individuals and obesity; updated dose and frequency table</li> <li>drug interactions: information regarding clinically significant drug interactions; information on influenza vaccinations</li> <li>special considerations: addition of information for immunosuppressed individuals</li> <li>minor wording changes in line with standard UKHSA PGD text; change from PHE to UKHSA, updated references</li> </ul>	8 August 2022

## 1. PGD development

This PGD has been developed by the following on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead author)	Jacqueline Lamberty Lead Pharmacist Medicines Governance, Health Equity and Clinical Governance Directorate, Clinical and Public Health Group, UKHSA	J. Y. LAMBERTY	8 August 2022
Doctor	Dr Matthew Donati Consultant Medical Virologist/ Head of Virology, Specialised Microbiology and Laboratories, SW Regional Laboratory and Severn Infection Sciences, UKHSA	WA	8 August 2022
Registered nurse	Lesley McFarlane Lead Immunisation Nurse Specialist, Immunisation and Vaccine Preventable Diseases Division, UKHSA	questag	8 August 2022

This PGD has been peer reviewed by the Seasonal influenza PGD Expert panel in accordance with the UKHSA PGD Policy. It has been agreed by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

#### **Expert panel**

Name	Designation
Dr Conall Watson	Chair, Consultant Epidemiologist – influenza and seasonal respiratory viruses, Immunisation and Vaccine-Preventable Diseases Division, UKHSA. Registered pharmacist
Dr Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Mr Mark Borthwick	Consultant Pharmacist, Oxford University Hospitals NHS Foundation Trust
Rosie Furner	Community Services Pharmacist, East Sussex Healthcare NHS Hospital Trust
Gemma Hudspeth	Health Protection Practitioner, North East and Yorkshire Region, UKHSA. Registered nurse
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), Medicines Use and Safety Division, NHS England (NHSE)
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire Integrated Care Board
Kevin Shaw	Deputy Director of Nursing and Quality, NHS Lincolnshire Clinical Commissioning Group. Registered nurse
Kelly Stoker	Head of Infection Prevention Control, Safer Care Team, Cumbria, Northumberland, Tyne and Wear NHS Foundation Trust. Registered nurse

#### 2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, to ensure all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

**NHS Cheshire and Merseyside** authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisations and/or services
Any service providing influenza prophylaxis within the NHS Cheshire and Merseyside footprint
Limitations to authorisation
Only for services commissioned by NHS Cheshire and Merseyside or agreed by exception with the UKHSA

Organisational approval (legal requirement)			
Role	Name	Sign	Date
Executive Medical Director, Cheshire and Merseyside ICB NHS	Prof Rowan Pritchard Jones	R. Prod Sons.	29.04.25

Additional signatories according to locally agreed policy			
Role	Name	Sign	Date

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement, or a multiple practitioner authorisation sheet as included at the end of this PGD

#### 3. Characteristics of staff

Qualifications and professional registration	<ul> <li>To be completed by the organisation authorising the PGD for instance: Registered professional with one of the following bodies:         <ul> <li>nurses currently registered with the Nursing and Midwifery Council (NMC).</li> </ul> </li> <li>pharmacists currently registered with the General Pharmaceutical Council (GPhC).         <ul> <li>Additional registered healthcare professionals to be added by organisation authorising the PGD</li> </ul> </li> </ul>
Additional requirements	Additionally practitioners:
	must be authorised by name as an approved practitioner under the current terms of this PGD before working to it
	must have undertaken appropriate training for working under PGDs for supply/administration of medicines for example <u>Patient</u> <u>Group Directions - elearning for healthcare</u>
	must be competent in the use of PGDs (see <u>NICE Competency framework</u> for health professionals using PGDs)
	must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC)
	must have access to the PGD and associated online resources
	should fulfil any additional requirements defined by local policy
	authorising organisation to insert any additional requirements
	The practitioner must be authorised by name, under the current version of the PGD, before working according to it.
Continued training requirements	Authorising organisation to insert any continued training requirements.

**Note:** The authorising organisation should ensure staff working with this PGD are trained in addressing issues of consent, including those individuals with dementia. The healthcare professional working under this PGD should follow their existing organisational procedures in relation to consent.

#### 4. Clinical condition or situation to which this PGD applies.

Clinical condition or situation to which this PGD applies	Post exposure prophylaxis of influenza A and B:
	1. When <b>all</b> of the following circumstances apply:
т от принос	<ul> <li>national surveillance schemes have indicated that influenza virus is circulating in the community<sup>2</sup> as advised by the Chief Medical Officer (CMO) and</li> </ul>
	<ul> <li>the person is in an 'at-risk' group, including being aged 65 years and over (see inclusion criteria) and</li> </ul>
	<ul> <li>the person has been in close contact<sup>3</sup> with a person with an influenza-like illness (ILI) and is able to begin prophylaxis within 48 hours of last contact with the infectious case and</li> </ul>
	<ul> <li>the person has not been effectively protected by vaccination<sup>4</sup></li> </ul>
	2. Outside the periods when surveillance indicates that influenza virus is circulating in the community, oseltamivir can be used for post exposure prophylaxis during influenza outbreaks among 'atrisk' people living or working in long-term residential or nursing homes (care homes), whether or not they have been vaccinated. This should only be done if there is a high level of certainty that the causative agent in a localised outbreak is influenza. This may be based on biological evidence of infection with influenza in the index case(s).
	UKHSA Health Protection Teams (HPTs) will advise on whether influenza is the likely causative agent.
Criteria for inclusion	This PGD will come into force only when either national surveillance schemes have indicated that influenza virus is circulating or when, in a localised outbreak, there is a high level of certainty the causative agent is influenza, as advised by the local HPT.
	Individuals must:
	<ol> <li>Be a resident or user of a care facility or staff working in a care facility<sup>5</sup> and</li> </ol>
	2. Have been in close contact with a person who is exhibiting ILI symptoms, or were close contacts of a probable or confirmed influenza case during the period when the latter was symptomatic with acute illness and the last contact occurred no
Continued overleaf	more than 48 hours ago <b>and</b>

<sup>&</sup>lt;sup>2</sup> The UKHSA uses information from a range of clinical, virological and epidemiological influenza surveillance schemes to identify periods when there is a substantial likelihood that people presenting with an influenza-like illness are infected with influenza virus

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<sup>&</sup>lt;sup>3</sup> Close contact is defined as living in the same home as the probable or confirmed case; care workers working or coming within speaking distance (<1 metre) of a probable or confirmed case

<sup>&</sup>lt;sup>4</sup> People who are not effectively protected by vaccination include those who have not been vaccinated since the previous influenza season, those for whom the vaccine is contraindicated or in whom it has yet to take effect, those who have been vaccinated with a vaccine that is not well matched to the circulating strain of influenza virus (according to information from the UKHSA), those who are immunosuppressed and those who are over 65, where vaccine effectiveness may be reduced

<sup>&</sup>lt;sup>5</sup> Care workers who are in an 'at risk' group are at risk of complicated influenza and require post exposure prophylaxis

# Criteria for inclusion (continued)

- 3. Either be aged 65 years and over (regardless of risk group), **or**, if aged 13 64 years, must be in one of the defined risk groups below:
  - chronic (long-term) respiratory disease, such as asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission, chronic obstructive pulmonary disease (COPD) or bronchitis
  - chronic heart disease or vascular disease, such as heart failure
  - chronic kidney disease (CKD) at stage three, four or five<sup>6</sup> (see <u>Additional information</u>) with some exceptions (see\_criteria for exclusion)
  - chronic liver disease
  - chronic neurological disease, such as Parkinson's disease or motor neurone disease, or learning disability
  - · diabetes or adrenal insufficiency
  - immunosuppression due to disease or treatment (refer to <u>the</u> <u>Green Book Chapter 19)</u>
  - asplenia or dysfunction of the spleen
  - morbid obesity (defined as a BMI of 40 and above)
  - any other clinical risk group, as listed in <u>the Green Book</u> <u>chapter 19</u>, that puts the individual at risk of complications of influenza
  - pregnant women at any stage of pregnancy (first, second or third trimesters) and up to 2 weeks post-partum (see\_ Additional information)
- 4. Be free from influenza symptoms and able to begin therapy within 48 hours of the **last** contact. Alternatively supply can be considered after 48 hours of contact with any case when the local HPT or a specialist in infectious disease, such as a medical microbiologist or virologist, advises this could be considered<sup>7</sup>. Note such supplies are not being directed (see <u>footnote 7</u> below). This is a clinical decision which rests with the practitioner working under this PGD and this is off-label use.

Note: <u>National guidance</u> states vaccination is not a reason to refuse antiviral prophylaxis in care facility outbreaks. Therefore prophylaxis can be given regardless of vaccination status when there is a high level of certainty that the causative agent in a localised outbreak is influenza.

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<sup>&</sup>lt;sup>6</sup> Chronic kidney disease: assessment and management NICE Guidance (NG203)

<sup>&</sup>lt;sup>7</sup> The practitioner making the supply under this PGD remains professionally accountable and clinically responsible for ensuring a supply is appropriate for an individual as assessed under this PGD. Where the HPT advise a course of prophylaxis can be considered, they are not directing the supply must be made – this is a clinical decision which rests with the practitioner working under this PGD

### Criteria for exclusion8 Individuals will not be considered for prophylaxis with oseltamivir under this PGD if the following criteria apply: they are not a resident or user of or working in a care facility they are already exhibiting symptoms of an ILI which may indicate oseltamivir should be supplied for treatment and not prophylaxis. they are less than 13 years of age they are receiving haemodialysis they have both renal impairment and are severely immunocompromised they have a known allergy to oseltamivir or to any of the excipients in the capsules the last exposure to the influenza-like illness was more than 48 hours before treatment could start, unless initiation is advised by the local HPT (see footnote 7) they are receiving zanamivir Note: being diagnosed with another respiratory virus infection does not negate the need for influenza prophylaxis if the individual meets the inclusion criteria. Action to be taken if the Advise the individual or their carer of the possible consequences of individual or their carer refusing prophylaxis, the protective effects of prophylaxis, the risk of declines prophylaxis infection, the risk of spreading the disease to others in the care facility, disease complications and alternative sources of prophylaxis. Consider if the individual is suitable for prophylaxis with zanamivir or refer to the local HPT or a specialist in infectious disease such as a medical microbiologist or virologist for further guidance. Document the refusal and the advice given in the individual's patient record. Inform the care home manager and the GP or care home doctor without delay. Action to be taken if the Some individuals may be suitable for post exposure prophylaxis with individual is excluded oseltamivir if clinically assessed and prescribed. If they are already exhibiting symptoms of an ILI which may indicate oseltamivir should be supplied for treatment and not prophylaxis, use the PGD for treatment with oseltamivir in care facilities. If they have both renal impairment and are severely immunocompromised, refer to a specialist in infectious disease such as a medical microbiologist or virologist for advice. If a decision to supply oseltamivir is made, a Patient Specific Direction (PSD) will be required. If the last exposure to the influenza-like illness was more than 48

Continued overleaf

hours before prophylaxis could start and there is no advice in place

<sup>&</sup>lt;sup>8</sup> Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside the remit of the PGD and another form of authorisation will be required

# Action to be taken if the individual is excluded (continued)

from the local HPT, the HPT should be consulted or advice sought from a local specialist in infectious disease such as a medical microbiologist or virologist.

Consider if the individual is suitable for prophylaxis with zanamivir (see PGD for prophylaxis with zanamivir in care facilities).

Any individual excluded under this PGD who is clinically assessed as requiring prophylaxis and who is not suitable for prophylaxis with zanamivir should be referred to local NHS services for advice without delay.

Note: primary care prescribing is restricted to when the CMO has indicated influenza is circulating in the community.

#### **Additional information**

Zanamivir inhaler is recommended as first line therapy (see PGD for treatment with zanamivir in care facilities) in the following circumstances:

- if the HPT has advised the confirmed or dominant circulating influenza strain is higher risk for oseltamivir resistance and the individual is immunocompromised<sup>9</sup> or
- the individual is known to have oseltamivir resistant influenza whether immunocompromised or not or
- the individual is strongly suspected to have oseltamivir resistant influenza whether immunocompromised or not, for example they have been in contact with known oseltamivir resistant influenza

If the individual is unable to use inhalers, seek advice from a specialist in infectious disease such as a medical microbiologist or virologist.

It is normal practice to administer only one neuraminidase inhibitor to an individual at a time. Therefore supply either oseltamivir or zanamivir but not both and confirm another neuraminidase inhibitor has not been prescribed.

Chronic kidney disease: the SPC dose recommendations for renal impairment are based on creatinine clearance (CrCl) which is no longer routinely reported by laboratories; the estimated Glomerular Filtration Rate (eGFR) is usually reported. Therefore there may be a misalignment between the laboratory result reported for renal impairment and the result required to ensure the correct dosage/frequency. Where not reported, do not delay treatment but substitute the CrCl value with the eGFR result in the dosage table and supply a dose according to eGFR. Some individuals may receive a larger oseltamivir dose as a result, but this is unlikely to be harmful as clinical experience reveals a wide margin of safety. Further information on CKD classifications can be found at <a href="Chronic kidney disease: assessment and management NICE guidance (NG203)">Chronic kidney disease: assessment and management NICE guidance (NG203)</a>.

**Breastfeeding:** the UK Drugs in Lactation Advisory Service (UK DILAS) advises oseltamivir is acceptable for use in breastfeeding mothers and the benefits of breastfeeding are considered to outweigh any, albeit unidentified, risks. Use of oseltamivir is not a reason to discontinue, or put limitations on breastfeeding. (see NHS/

Continued overleaf

<sup>&</sup>lt;sup>9</sup> For definition of immunocompromised see Green Book Chapter 19

Additional information (continued)	UKMI Medicines Q and As: Oseltamivir or zanamivir—can mothers breastfeed after treatment for influenza?)
Cautions	<ul> <li>Refer individuals to a medical practitioner if:</li> <li>they are exhibiting sudden onset of symptoms of confusion, chest pain, breathing difficulties or any other symptoms giving cause for concern</li> <li>they have long term conditions such as chronic respiratory or cardiovascular disease exhibiting rapidly worsening symptoms</li> <li>If the individual develops influenza whilst taking prophylaxis, seek advice from a local specialist in infectious disease such as a medical microbiologist or virologist</li> </ul>

## 5. Description of prophylaxis

Name, strength and formulation of drug	Oseltamivir 75mg capsules	
Tormulation of drug	Oseltamivir 30mg capsules	
Legal category	POM - Prescription only medicine	
Black triangle▼	No	
Off-label use	<ul> <li>Yes</li> <li>when used outside the periods when national surveillance indicates that influenza virus is circulating generally in the community - see footnote below¹0</li> <li>when used after 48 hours of contact</li> <li>in renal impairment with CrCl ≤10mL/min, the SPC states 'not recommended'. The UKHSA guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza gives the dose in the table overleaf</li> <li>Where a product is recommended off-label consider, as part of the consent process, informing the individual or carer that the product is</li> </ul>	
	consent process, informing the individual or carer that the product is being offered in accordance with national guidance but that this is outside the product licence.	
Route / method of administration	Oral  The capsules should be taken preferably in the morning with breakfast because taking with food can reduce nausea or vomiting.	
	The capsules should be swallowed whole with water. For individuals with swallowing difficulties, the capsules can be opened and the contents mixed with a small amount of sweetened food, such as syrup, dessert toppings or sugared water, just before administration (see <a href="Patient Information Leaflet">Patient Information Leaflet</a> ).	
Dose and frequency of	See table overleaf	
administration	Initiate post exposure prophylaxis as soon as possible ideally within the first two days (48 hours) of the last exposure to influenza.	
	Individuals with no known renal impairment should be supplied with a full dose.	
	The doses given in the table overleaf are for individuals with stable CKD. If there is a history of renal impairment, supply as per the latest documented creatinine clearance (CrCl) results.	
Continued overleaf	Estimated glomerular filtration rate (eGFR) may be more readily available. If eGFR is the only value available, do not delay and supply a dose according to eGFR, substituting eGFR for the CrCl figure in the table below. Some individuals may receive a larger dose of oseltamivir	
22.14.1404 07011041	Table below. Come marriadale may receive a larger dose of oscitamini	

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<sup>&</sup>lt;sup>10</sup> The product licence covers post exposure prevention following contact with a clinically diagnosed influenza case when influenza virus is circulating in the community. However NICE guidelines recommend oseltamivir can be used during localised outbreaks of ILI outside the periods when national surveillance indicates that influenza virus is circulating generally in the community, in 'at-risk' people living in long-term residential or nursing homes (care homes).

#### Dose and frequency of as a result, but this is unlikely to be harmful as clinical experience administration reveals a wide margin of safety. (continued) If the individual is definitely known to have chronic renal impairment and CrCl or eGFR results are not available, consider if they are suitable for zanamivir prophylaxis (see PGD for zanamivir prophylaxis in care homes), or refer to a medical practitioner. If a decision to supply oseltamivir is made, a Patient Specific Direction (PSD) will be required. No dose adjustment is needed in obese individuals. For individuals with renal impairment and who are immunocompromised, refer to a specialist in infectious disease such as a medical microbiologist or virologist for advice. If a decision to supply oseltamivir is made, a Patient Specific Direction (PSD) will be required. For immunocompromised individuals see **Special considerations** Renal impairment<sup>11</sup> Dose Normal renal function; One 75mg capsule once a day for weight 40kg+ 10 days Normal renal function; Two 30mg capsules once a day for weight >23kg to 40kg 10 days One 30mg capsule once a day for CrCl >30 to 60 mL/min 10 days One 30mg capsule every 48 hours CrCl >10 to 30mL/min for 10 days One 30mg capsule once, repeated CrCl ≤10mL/min after 7 days

#### **Duration of prophylaxis**

See dosage schedule above.

Haemodialysis

Peritoneal dialysis

#### Quantity to be supplied

 No known chronic renal impairment and weight above 40kg: 10 x 75mg capsules

Refer to a medical practitioner; do

One 30mg capsule once, repeated

not supply under this PGD

after 7 days

- No known chronic renal impairment and weighing >23kg to 40kg:
   x 30mg capsules
- CrCl >30 to 60 mL/min: 10 x 30 mg capsules
- CrCl >10 to 30mL/min: 5 x 30mg capsules
- CrCl ≤10mL/min: 2 x 30mg capsules
- Peritoneal dialysis: 2 x 30mg capsules

When supplying under PGD, this should be from the manufacturer's original pack or over-labelled pre-packs so the individual's name, the date and additional instructions can be written on the label at the time of supply. As split packs cannot be supplied, an over-supply might be

# Continued overleaf

<sup>&</sup>lt;sup>11</sup> <u>UKHSA Guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza</u> <u>Version 11, November 2021</u>

Quantity to be supplied (continued)	required. Individuals must be advised to take any remaining capsules to a community pharmacy for destruction.
Storage	Do not store above 25°C
Disposal	Any unused product or waste material should be disposed of in accordance with local arrangements.
	Individuals receiving an over-supply should be advised to return any remaining capsules to a community pharmacy for destruction.
Drug interactions	Clinically important drug interactions such as chlorpropamide, methotrexate, phenylbutazone, leflunomide, nitisinone or teriflunomide are unlikely, due to the known safety margin for most of these products, the elimination characteristics of the active metabolite (glomerular filtration and anionic tubular secretion) and the excretion capacity of these pathways.
	The <u>Green Book</u> states administration of influenza antiviral agents within two weeks of administration of a live attenuated influenza nasal spray vaccine, as used in the school-age vaccination programme, may adversely affect the effectiveness of the vaccine. Adult influenza vaccinations are inactivated and are not affected by antiviral administration.
	A detailed list of drug interactions is available in the SPC
Identification and	Frequently reported adverse reactions include nausea and vomiting.
management of adverse reactions	These reactions may only occur on a single occasion, on either the first or second treatment day, and resolve spontaneously within one to two days. However, if symptoms persist, individuals should consult a healthcare professional.
	Individuals should be advised not to discontinue treatment without consulting a doctor or pharmacist.
	Other commonly reported adverse reactions include bronchitis, dizziness (including vertigo), fatigue, headache, insomnia, herpes simplex, nasopharyngitis, upper respiratory tract infections, sinusitis, cough, sore throat, pyrexia, rhinorrhoea, pain including limb pain, abdominal pain and dyspepsia.
	A detailed list of adverse reactions is available in the <u>SPC</u>
Reporting procedure of adverse reactions	Any reported adverse reaction to the product should be documented in the medical records.
	Alert an appropriate clinician in the event of a serious adverse reaction.
	Report any suspected severe adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store.
Written information to be given	Supply the marketing authorisation holder's <u>patient information leaflet</u> (PIL) <sup>12</sup> .

<sup>&</sup>lt;sup>12</sup> Pre-packs will contain a copy of the PIL

#### Advice /follow up

Inform the individual or their carer:

- to read the PIL before taking the medication
- taking the medication with food can reduce nausea or vomiting
- if they have difficulty swallowing, the capsules can be opened and taken with a small amount of sweetened food (see PIL)
- of any possible side effects and their management
- to seek medical advice in the event of a severe adverse reaction
- to seek advice if common side effects do not spontaneously resolve 48 hours after presentation
- to complete the course
- that prophylaxis is not 100% effective and if a flu-like illness occurs, clinical advice should be sought urgently
- if an over-supply has been required, individuals must be advised to take any remaining capsules to a community pharmacy for destruction

#### Special considerations

Use of oseltamivir is not a substitute for influenza vaccination. The protection against influenza lasts only as long as oseltamivir is taken.

Immunosuppression: when a decision has been made to administer antiviral prophylaxis to contacts of a confirmed case, diagnostic sampling of the contacts for influenza virus detection is recommended before or at the time of commencing antiviral prophylaxis in immunocompromised and critically ill individuals. This is based on expert advice as symptoms and signs of influenza may be absent or minimal in these groups, or may be difficult to assess due to their clinical status. Antivirals administered at prophylactic doses can promote antiviral resistance when given to individuals already infected with influenza virus, especially when there is underlying immunosuppression. Prophylaxis should not be postponed while the results of influenza testing are awaited and influenza virus testing should be expedited. If testing reveals an individual who commenced on a prophylactic dose of an antiviral is actually infected with influenza virus, then prophylaxis should be stopped and treatment-dose antivirals should be commenced immediately.

#### Records

#### Record:

- whether valid informed consent was given or a decision to supply was made in the individual's best interests in accordance with the Mental Capacity Act 2005
- name of the individual, address, date of birth and their GP
- name of the member of staff who supplied the product
- name and brand of product
- date of supply
- dose, form and route of administration of the product
- quantity supplied
- batch number and expiry date
- advice given; including advice given if the individual is excluded or declines treatment
- details of any adverse drug reactions and actions taken
- the medicine was supplied via PGD

#### Continued overleaf

Records (continued)	if an over-supply has been required, record this and that advice to return the remaining product to a community pharmacy for destruction has been given
	All records should be signed and dated, contemporaneous, clear and legible.
	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy
	Inform the individual's GP oseltamivir has been supplied under this PGD

#### 6. Key references

#### **Key references**

- Summary of Product Characteristics accessed July 2022
- British National Formulary accessed July 2022
- NICE guidelines on the use of oseltamivir, amantadine (review) and zanamivir for the prophylaxis of influenza TA158 28 reviewed November 2014
- Guidance on the management of outbreaks of influenza-like illnesses in care homes V5.0 updated November 2020
- NHS Specialist Pharmacy Service page re NHS PGDs accessed July 2022
- NHS/ UKMI Medicines Q and As: Oseltamivir or zanamivir—can mothers breastfeed after treatment for influenza? updated July 2020
- <u>UKHSA guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza</u> updated November 2021
- Green Book Chapter 19 Influenza updated 29 October 2020
- Chronic kidney disease: assessment and management NICE guidance (NG203) updated 24 November 2021
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions updated 27 March 2017
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions updated 27 March 2017
- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste Department of Health and Social Care 20 March 2013

#### 7. Individual practitioner authorisation sheet

By signing this PGD you are indicating you agree to the contents and you will work within it

PGDs do not remove inherent professional obligations or accountability

It is the responsibility of each professional to practice only within the bounds of their own competence

#### **Practitioner**

I confirm I have read and understood the content of this PGD and I am willing and competent to work to it within my professional code of conduct

Signed	Date
Name (Print)	
Designation	
<b>Authorising manager</b> Manager to give authorisation on behalf o healthcare professional who has signed th	of insert name of organisation for the named he PGD
Signed	Date
Name (Print)	
Designation	

#### Note to authorising manager

By signing above, you are confirming you have assessed the staff member as competent to work under this PGD and they have the organisational approval to do so.

You must give this signed PGD to each authorised practitioner as it shows their authorisation to use the PGD