**PHE publications gateway number: 2015-531**

## PATIENT GROUP DIRECTION (PGD)

# Supply of oseltamivir 75mg and 30mg capsules for post exposure prophylaxis of influenza

# Adult residents and staff of care homes (with or without nursing)

# For the supply of oseltamivir 75mg and 30mg capsules for post exposure prophylaxis of influenza for adult residents and staff of care homes (with or without nursing) by **INSERT HEALTHCARE PROFESSIONAL GROUPS WHICH CAN SUPPLY UNDER THE PGD [[1]](#footnote-1)**

Reference: *Oseltamivir prophylaxis PGD*

Version no: *02.00*

Valid from: *7 January 2016*

*Review date: 7 January 2018*

*Expiry date: 7 January 2019*

**Public Health England has developed this PGD Template for local authorisation**

Those using this PGD must ensure that it is formally authorised and signed by a clinical governance or patient safety lead, who has designated responsibility for signing PGDs, so this document meets legal requirements for a PGD. **THE PGD IS NOT LEGAL OR VALID WITHOUT THIS LOCAL, FORMAL AUTHORISATION.**

Authorising organisations must not alter or amend 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. Therefore sections 2, 3 and 7 can be amended.

**THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.**

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

**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 |

1. **PGD template development**

This PGD template has been developed by the following on behalf of Public Health England:

|  |  |  |  |
| --- | --- | --- | --- |
| **Developed by:** | **Name** | **Signature** | **Date** |
| Pharmacist (Lead author) | Jacqueline Lamberty  Pharmacy and Medicines Management Lead |  | 7 January 2016 |
| Doctor | Dr Gavin Dabrera  Interim Lead, Legionella and Influenza Preparedness Section, PHE Respiratory Diseases Department | *C:\Users\Johnny Stafford\AppData\Local\Microsoft\Windows\Temporary Internet Files\Content.Outlook\UH1UDH12\legionella-sig.png* | 7 January 2016 |
| Registered nurse | Alice Cowley  Senior Health Protection Specialist  South East London Health Protection Team | cid:image001.jpg@01D10B44.485CFBB0 | 7 January 2016 |

This PGD template has been peer reviewed by an expert panel in accordance with the PHE PGD Policy. It has been agreed by the PHE Medicines Management Group and the PHE Clinical Governance Group.

**Expert panel**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| Dr Richard Pebody | Chair, Head PHE Respiratory Disease Department |
| Mr Phillip Howard | Consultant Pharmacist, Leeds Teaching Hospitals NHS Trust |
| Mr Mark Borthwick | Consultant Pharmacist, Oxford University Hospitals NHS Trust |
| Dr Mat Donati | Consultant Medical Virologist, Bristol PHE laboratory |
| Dr Sally Millership | CCDC, East of England PHEC |
| Rosie Furner | Community Services Pharmacist, East Sussex Healthcare NHS Hospital Trust |

**Acknowledgements**

|  |  |
| --- | --- |
| **Name** | **Designation** |
| María Saavedra-Campos | Senior Epidemiology Scientist; National Infection Service PHE |

**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 that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

INSERT AUTHORISING BODY NAME authorises this PGD for use by the services or providers listed below:

|  |
| --- |
| Authorised for use by the following organisations and/or services |
|  |
| Limitations to authorisation |
| eg Any local limitations the authorising organisation feels they need to apply in-line with the way services are commissioned locally. This organisation does not authorise the use of this PGD by …. |

|  |  |  |  |
| --- | --- | --- | --- |
| Organisational approval (legal requirement) | | | |
| Role | Name | Sign | Date |
| Complete eg NHSE Governance Lead, Medical Director |  |  |  |

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| --- | --- | --- | --- |
| Additional signatories according to locally agreed policy | | | |
| Role | Name | Sign | Date |
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Organisations must add an individual practitioner authorisation sheet or list of authorised practitioners. This varies according to local policy but this should be a signature list or an individual agreement as included at the end of this PGD.

#### Characteristics of staff

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| --- | --- |
| **Qualifications and professional registration** | To be completed by the organisation authorising the PGD eg: Registered professional with one of the following bodies:   * Nurses currently registered with the Nursing and Midwifery Council (NMC). * Pharmacists currently registered with the General Pharmaceutical Council (GPhC). * Additional registered healthcare professionals to be added by organisation authorising the PGD |
| **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 * must be competent in the use of PGDs (see [NICE Competency framework](https://www.nice.org.uk/guidance/mpg2/resources/competency-framework-for-health-professionals-using-patient-group-directions-60468733) for health professionals using Patient Group Directions) * must be familiar with the product and alert to changes in the Summary of Product Characteristics * 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 THIS PGD BEFORE WORKING ACCORDING TO IT.** |
| **Continued training requirements** | Authorising organisation to insert any continued training requirements**.** |

**Note:** The authorising organisation should ensure that staff working with this PGD are trained in addressing issues of consent, including those individuals with dementia.

1. **Clinical condition or situation to which this PGD applies.**

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| **Clinical condition or situation to which this PGD applies** | Post exposure prophylaxis of influenza A and B:   1. When **all** of the following circumstances apply:  * national surveillance schemes have indicated that influenza virus is circulating in the community[[2]](#footnote-2) **and** * the person is in an ‘at-risk’ group, including being aged 65 years and over (see inclusion criteria) **and** * the person has been in close contact[[3]](#footnote-3) 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** * the person has not been effectively protected by vaccination[[4]](#footnote-4)  1. Outside the periods when surveillance indicates that influenza virus is circulating in the community, oseltamivir can be usedfor post-exposure prophylaxis during influenza outbreaks among ‘at-risk’ 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, usually based on virological evidence of infection with influenza in the index case(s).   Health Protection Teams within Public Health England Centres will advise on whether influenza is the likely causative agent. |
| **Criteria for inclusion**  (continued overleaf)  **Criteria for inclusion**  (continued) | 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 that the causative agent is influenza (as advised by the local Health Protection Team).  Individuals must:   1. Have been in close contact with a person who is exhibiting influenza-like illness symptoms or were close contacts of a probable or confirmed influenza case during the period when the latter was symptomatic **and** the last contact occurred no more than 48 hours ago **and** 2. Be a resident in a care home or an adult working in a care home[[5]](#footnote-5) **and** 3. Either be aged 65 years and over, or 13 – 64 years and in one of the defined risk groups below:  * chronic respiratory disease including COPD, chronic bronchitis and emphysema, bronchiectasis, cystic fibrosis, interstitial lung fibrosis, bronchopulmonary dysplasia (BPD), pneumoconiosis and asthma requiring continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission * chronic heart disease including congenital heart disease, hypertension with cardiac complications, chronic heart failure, and individuals requiring regular medication and/or follow-up for ischaemic heart disease * chronic liver disease including cirrhosis, biliary atresia, and chronic hepatitis * chronic neurological disease including stroke, transient ischaemic attack (TIA), conditions in which respiratory function may be compromised due to neurological disease eg polio syndrome sufferers; this patient group may also include individuals with cerebral palsy, multiple sclerosis and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability * immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, some rheumatological drugs, asplenia or splenic dysfunction, HIV infection at all stages, individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (but see immunosuppression under exclusions) * diabetes mellitus - type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet controlled diabetes  1. Be free from influenza symptoms and able to begin therapy within 48 hours of the **last** exposure.   Note: PHE guidance states that vaccination is not a reason to refuse antiviral prophylaxis. Therefore prophylaxis can be given regardless of vaccination status. |
| **Criteria for exclusion[[6]](#footnote-6)**  (continued overleaf)  **Criteria for exclusion**  (continued) | Individuals will not be considered for prophylaxis with oseltamivir under this PGD if the following criteria apply:   * they are not a resident or working in a care home * they are already exhibiting symptoms of an influenza-like illness which may indicate oseltamivir should be supplied for treatment and not prophylaxis. Use the treatment PGD. * they are less than 13 years of age * they have unstable medical conditions * they have a known allergy to oseltamivir phosphate or any of the excipients in the preparation * they are taking other drugs with clinically significant drug interactions eg chlorpropamide, methotrexate, phenylbutazone * if the health protection team has advised that the confirmed or dominant circulating influenza strain is higher risk for oseltamivir resistance **and** the patient is immunocompromised (due to disease or treatment eg adults taking steroids at a dose equivalent to prednisolone  ≥ 20mg daily for more than one week) * the last exposure to the influenza-like illness was more than 48 hours before treatment could start.   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 patient or their carer declines prophylaxis** | Advise the individual or their carer of the possible consequences of refusing prophylaxis, including the consequences to infection control for the care home and of alternative sources of treatment.  Advise about the protective effects of the prophylaxis, the risks of infection, the risk of spreading the disease to others in the care home and disease complications.  Document refusal and advice given in individual’s patient record.  Inform the care home manager andthe General Practitioner or care home doctor without delay. |
| **Action to be taken if the patient is excluded** | Consider if the individual is suitable for prophylaxis with zanamivir (see PGD for prophylaxis with zanamivir in care homes).  Any resident or member of staff in a care home excluded under this PGD who is not suitable for prophylaxis with zanamivir should be referred to local NHS services for advice without delay.  Some individuals excluded under this PGD may be suitable for post exposure prophylaxis with oseltamivir if clinically assessed and prescribed. |
| **Additional information** | It is normal practice to administer only one neuraminidase inhibitor to an individual patient at a time. Therefore supply either zanamivir or oseltamivir but not both. |

1. **Description of prophylaxis**

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| **Name, strength & formulation of drug** | Oseltamivir 75mg capsules  Oseltamivir 30mg capsules |
| **Legal category** | POM - Prescription only medicine |
| **Black triangle▼** | No |
| **Off-label use** | No – except outside the periods when national surveillance indicates that influenza virus is circulating generally in the community - see footnote below[[7]](#footnote-7) |
| **Route / method of administration** | Oral  Capsules should be swallowed whole with water. However, for patients with swallowing difficulties, capsules can be opened and the contents mixed with a small amount of sweetened food, such as honey, flavoured syrup or sugared water, just before administration (see Patient Information Leaflet) |
| **Dose and frequency of administration**  (continued overleaf)  **Dose and frequency of administration**  (continued) | Post exposure prophylaxis should be initiated as soon as possible within the first two days (48 hours) of last exposure to influenza.   |  |  | | --- | --- | | **Renal impairment[[8]](#footnote-8)** | Dose | | No known chronic renal impairment | One 75mg capsule once a day for 10 days | | Moderate impairment  (CrCL 30-60 mL/min)\* | One 30mg capsule once a day for 10 days | | Severe impairment  (CrCL 10-30mL/min)\* | One 30mg capsule every 48 hours for 10 days | | Established renal failure  (CrCL <10mL/min)++ | One 30mg capsule once, repeated after 7 days | | Haemodialysis\* | One 30mg capsule once, and then one 30 mg capsule after every second haemodialysis session | | Peritoneal dialysis\* | One 30mg capsule once, repeated after 7 days |   Source: Summary of Product Characteristics (\*). The recommendations for established renal failure are based on expert opinion (++)  Patients with no known renal problems should be supplied with a full dose; if there is a history of renal failure supply as per latest documented creatinine clearance (CrCL) results.  If the individual is definitely known to have chronic renal impairment and CrCL results are not available, consider if they are suitable for zanamivir prophylaxis (see PGD for zanamivir prophylaxis in care homes).  For individuals weighing > 23kg to 40kg: supply 60mg (two 30mg capsules) once a day for 10 days (ref: PHE guidance on the use of antivirals) [[9]](#footnote-9).  The capsules should be taken preferably in the morning with breakfast. Taking with food can reduce nausea or vomiting. |
| **Duration of prophylaxis** | See dosage schedule above |
| **Quantity to be supplied** | No known chronic renal impairment: 10 x 75mg capsules  Moderate renal impairment: 10 x 30 mg capsules  Severe impairment: 5 x 30mg capsules  Established renal failure: 2 x 30mg capsules  Haemodialysis: see dosage schedule above  Peritoneal dialysis: 2 x 30mg capsules  For individuals weighing >23kg to 40kg: 20 x 30mg capsules |
| **Storage** | Do not store above 25oC |
| **Disposal** | Any unused product or waste material should be disposed of in accordance with local requirements. |
| **Drug interactions** | Patients taking the following medicines are excluded from this PGD:   * chlorpropamide * methotrexate * phenylbutazone |
| **Identification & management of adverse reactions** | Frequently reported adverse reactions include nausea, vomiting, abdominal pain and dyspepsia.  If an individual experiences any of these adverse reactions they 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, limb pain, pain.  A detailed list of adverse reactions is available in the Summary of Product Characteristics, which is available from the electronic Medicines Compendium website: [www.medicines.org.uk](http://www.medicines.org.uk) |
| **Reporting procedure of adverse reactions** | Any adverse reaction to the product should be documented in the medical records.  Alert a doctor in the event of a serious adverse reaction.  Report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <http://yellowcard.mhra.gov.uk> |
| **Written information to be given to patient or their carer** | Supply the marketing authorisation holder's patient information leaflet (PIL). |
| **Patient advice /follow up** | Inform the individual or their carer that taking the medication with food can reduce nausea or vomiting.  The individual or their carer should be advised to seek medical advice in the event of a severe adverse reaction.  Advise the individual or their carer to seek advice if common side effects do not spontaneously resolve 48 hours after presentation.  Advise that the individual should complete the course.  Advise the individual or their carer to read the PIL before taking the medication and draw their attention to the common side effects listed in the PIL.  Advise that prophylaxis is not 100% effective and if a compatible illness occurs, clinical advice should be sought urgently. |
| **Special considerations / additional information** | Oseltamivir is **not** recommended for post exposure prophylaxis for individuals who are aged less than 65 years and who are not in ‘at risk’ groups.  Use of oseltamivir is not a substitute for influenza vaccination. The protection against influenza lasts only as long as oseltamivir is administered.  Administration of influenza antiviral agents within two weeks of administration of live attenuated influenza vaccine eg Fluenz Tetra® may adversely affect the effectiveness of the vaccine. |
| **Records**  (continued overleaf)  **Records**  (continued) | Record:   * whether valid informed consent was given * name of patient, address, date of birth and GP with whom the patient is registered * name of member of staff who supplied the product * name and brand of product * date of supply * dose, form and route of administration of product * quantity supplied * batch number and expiry date * advice given; including advice given if excluded or declines treatment * details of any adverse drug reactions and actions taken * record supplied via Patient Group Direction (PGD) * records should be signed and dated   All records should be clear, legible and contemporaneous.  A record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes in accordance with local policy.  It is recommended that the general practitioner for the individual is informed in writing, if oseltamivir has been supplied under this PGD. |

#### Key references

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| **Key references** | * Summary of Product Characteristics [www.medicines.org.uk](http://www.medicines.org.uk) * NICE guidelines on the use of oseltamivir, amantadine (review) and zanamivir for the prophylaxis of influenza TA158 issued September 2008 <http://publications.nice.org.uk/oseltamivir-amantadine-review-and-zanamivir-for-the-prophylaxis-of-influenza-ta158> * PHE guidance on use of antiviral agents for the treatment and prophylaxis of seasonal influenza (2015−16) Version 6.0, September 2015 [www.gov.uk/government/uploads/system/uploads/attachment\_data/file/457735/PHE\_guidance\_antivirals\_influenza\_2015\_to\_2016.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457735/PHE_guidance_antivirals_influenza_2015_to_2016.pdf) * NHS public health functions agreement 2015-16 Service specification No.13 Seasonal influenza immunisation programme (2015-16 programme) <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/383187/1516_No13_Seasonal_Influenza_Immunisation_Programmeflu_FINAL.pdf> * British National Formulary (BNF) <http://www.evidence.nhs.uk/formulary/bnf/current/5-infections/53-antiviral-drugs/534-influenza> * NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions <https://www.nice.org.uk/guidance/mpg2> * NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions <https://www.nice.org.uk/guidance/mpg2/resources> * Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20th March 2013 <https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste> |

1. **Individual practitioner authorisation sheet**

BY SIGNING THIS PATIENT GROUP DIRECTION YOU ARE INDICATING THAT YOU AGREE TO ITS CONTENTS AND THAT YOU WILL WORK WITHIN IT.

PATIENT GROUP DIRECTIONS DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

IT IS THE RESPONSIBILITY OF EACH PROFESSIONAL TO PRACTISE ONLY WITHIN THE BOUNDS OF THEIR OWN COMPETENCE.

**Practitioner**

**I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.**

Signed……………………………….………………………….…..Date……….….…………..............

Name (Print)…………….…………..………….………………………………………….…….............

Designation……………………………………………………………….…..………………................

**Authorising manager**

Manager to give authorisation on behalf of INSERT **NAME OF ORGANISATION** for the named healthcare professional who has signed the PGD.

Signed…………………………………….………………………. Date………………………..........

Name (Print)………………………..…………………………………….……………..………..........

Designation………………………………………………………………..…………….…….............

**Note to authorising manager**

By signing above you are confirming that you have assessed the staff member as competent to work under this PGD and that 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.

1. PGDs can be used for the NHS and those services funded by the NHS that are provided by the independent, voluntary or charitable sectors. **However, PGDs do not extend to independent and public sector care homes that provide healthcare entirely outside the NHS.** An NHS body cannot authorise a PGD for a care home to supply or administer medicines under PGD.

   Therefore the supply of oseltamivir under PGD to care home residents must be undertaken by NHS-employed healthcare professionals. The medicine may then be self administered or administered by care home staff where there are appropriate governance arrangements in place.  Further information is available on the NHS PGD Website. [↑](#footnote-ref-1)
2. Public Health England 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 [↑](#footnote-ref-2)
3. Close contact is defined as living in the same home where the probable or confirmed case was living or working or coming within speaking distance (<1 metre) of a probable or confirmed case or someone exhibiting symptoms of an influenza-like illness [↑](#footnote-ref-3)
4. 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 and those who have been vaccinated with a vaccine that is not well matched to the circulating strain of influenza virus, according to information from Public Health England [↑](#footnote-ref-4)
5. Care workers who are in an ‘at risk’ group are at risk of complicated influenza and require post exposure prophylaxis [↑](#footnote-ref-5)
6. Exclusion under this Patient Group Direction 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 [↑](#footnote-ref-6)
7. 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. [↑](#footnote-ref-7)
8. Reference: PHE Seasonal Influenza antivirals guidance October 2015 [↑](#footnote-ref-8)
9. [www.gov.uk/government/uploads/system/uploads/attachment\_data/file/457735/PHE\_guidance\_antivirals\_influenza\_2015\_to\_2016.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/457735/PHE_guidance_antivirals_influenza_2015_to_2016.pdf) [↑](#footnote-ref-9)