PATIENT MEDICATION REQUEST FORM

ZANAMIVIR AQUEOUS SOLUTION (AN UNLICENSED PRODUCT) REL113375

This form must be completed by the treating Consultant, who must also read the declaration at the end of this form, sign and fax to:

0207 192 6397

ALL fields must be typed or handwritten IN BLOCK CAPITALS to ensure this request can be processed.

Please call GSK Clinical Support Helpdesk on 0208 990 4855 to confirm receipt of fax. Failure to do so will delay the request process.

DATE & LOCAL TIME	

CONSULTANT CONTACT INFORMATION		
Name of requesting Consultant		
	mobile telephone	
	e-mail	

DELIVERY DETAILS	
Name of receiving healthcare professional	
Hospital/Institution Department (e.g. ITU/pharmacy) Address Town / City Postcode Country	
Telephone	
e-mail	

INCLUSION CRITERIA	PLEASE CHECK ALL THAT APPLY
Hospitalized patient severely ill with influenza infection	☐
Patient not responding to either oral or inhaled authorised antiviral medicinal products, **OR** Patient for whom drug delivery by a route other than IV (e.g. oral oseltamivir or inhaled zanamivir) is not expected to be dependable or is not feasible, **OR** Patient infected with documented influenza virus resistant to other antiviral agents and not suitable for therapy with inhaled zanamivir.	☐ ☐ ☐
Patients will be eligible for treatment if **ALL** the above apply	

EXCLUSION CRITERIA	
Females who are pregnant, unless the expected benefit to the patient is thought to outweigh any possible risk to the foetus.	☐ **Does not apply**
Patients who are known or suspected to be hypersensitive to zanamivir.	☐ **Does not apply**
Patients should not be treated in the compassionate use program if they are receiving medical care at a facility participating in one or both of the ongoing Phase II or Phase III clinical trials of IV zanamivir (protocols NAI113678 or NAI114373),are eligible for the study and willing to provide consent to enter.	☐ **Does not apply**
Patients will not be eligible for treatment if **ANY** of the above apply	

PATIENT DETAILS		
Is this is new request or a re-supply request? If this is a re-supply request state unique patient ID assigned previously	☐ **New request** ☐ **Re-supply request** **REL113375/**_ _ _ _ _ _ _	
Sex*	☐ Male	☐ Female
*If female, is patient pregnant?		☐ Pregnant ☐ Not pregnant
*If pregnant does perceived benefit outweigh any possible risk to the foetus? (**Note**: not eligible for treatment if "No")		☐ Yes ☐ No
Date of Birth		
Weight (Kg)		

Date of laboratory confirmation of influenza infection (if available)	
History of present illness (e.g. days since onset, temperature, ventilation status, O_2 saturation x-ray findings).	
Other Medical History	

RENAL FUNCTION Please refer to page 9 of The Physician's Guidance document for calculation of CL_{CRRT} (CL_{CRRT} =clearance whilst receiving continuous renal replacement therapy)					
Is Renal function (creatinine clearance) normal?	☐ Yes	☐ No			
Is patient on continuous renal replacement therapy (CRRT)?	☐ Yes	☐ No			
If renal function is abnormal, what is creatinine clearance (CLcr) or CL_{CRRT} (ml/min)?					
	CLcr or CL_{CRRT} (ml/min)				
Please select one value:	≥ 80	50 to <80	30 to <50	15 to <30	<15

DOSAGE Refer to the Physician's Guidance Document recommendations on dosage determination: Adults (pgs 6 to 10), Infants (pgs 6, 8 & 9), nebulised administration (pg 6)		
Check route of administration	☐ **iv**	☐ **nebulised**
Dose of zanamivir	Initial dose (mg) ☐	25mg four times daily
	Maintenance dose (mg) ☐	
No. of vials requested for 5-day treatment course according to age/weight and renal function **Please refer to Appendix 4 and 5 of the Physician's Guidance Document to calculate number of vials required**		

DECLARATION BY TREATING CONSULTANT

1. I have requested the supply of zanamivir aqueous solution ("the Drug") for the purpose of treating my named patient.
2. I understand this Drug is unlicensed globally but have requested supply of this Drug as I consider there are no other treatment options available for this patient.
3. I understand that completing this form does not guarantee supply.
4. I understand that the Drug to be supplied would be provided solely for administration to the named patient and for no other purpose. The intellectual property claiming and/or covering the Drug to be supplied is the property of GlaxoSmithKline (GSK) and/or its group companies, and/or is licensed to GSK and/or its group companies, and supply to the named patient and/or his or her physician shall not operate to confer any right, title or interest in or to that intellectual property.
5. I understand that I, as the patient's treating Consultant, am fully responsible for screening, eligibility evaluation, dosage calculation and administration, following the patient through therapy, and managing any side effects should they occur.
6. I will take responsibility for compliance with local and national regulatory and ethical requirements relating to the supply of unlicensed relevant medicinal products for individual patients – MHRA Guidance Note no. 14.
7. I confirm that prior to administration of the Drug, I will explain to my named patient and/or their legal guardian the fact this drug is unlicensed, the risk:benefits and take responsibility to obtain written consent from the patient or their legal guardian.
8. I understand that GSK reserves the right to temporarily suspend or terminate this named patient supply at any time for reasons including (but not limited to) safety issues, ethical issues, or severe non-compliance.
9. I will report all SAEs, AEs and pregnancies to GSK within the time frames specified in the guidance document.
10. I will report all serious suspected ADRs to MHRA. Details are given in the UK specific form on AE reporting, which I have received.
11. I agree to keep confidential any information provided by GSK in relation to this supply and to limit disclosure of such information to those members of the clinical team who require the information for the purpose of providing the medical treatment for the named patient and who have been made aware of the confidential nature of the information.

Signature: _____	**Date:**
Name (PRINT):	

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