

SHARED CARE GUIDELINE

Grazax for paediatric use only

Implementation Date: March 2016

Review Date: March 2019

This guidance has been prepared and approved for use within Sunderland in consultation within the CCG, and Secondary Care Trusts.

The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe this treatment within a shared care setting

Approved by:

Committee	Date
Sunderland Joint Formulary Committee	March 2016

Instructions for completion:

<input type="checkbox"/> Consultant to counsel patient on medication and ensure patient has been provided with information leaflet
<input type="checkbox"/> Consultant to ensure all clinical details completed on this document
<input type="checkbox"/> Consultant to complete 'confirmation the patient understands the monitoring arrangements' section
<input type="checkbox"/> Consultant to ensure patient understands proposed monitoring and prescribing arrangements if a shared care agreement is entered into
<input type="checkbox"/> GP to complete final section of form and return to specialist prescriber within 28 days
<input type="checkbox"/> GP to retain copy of document on patient record within surgery

Clinical details:

SHARED CARE GUIDELINE					
Non-proprietary name	Grass pollen extract	Brand name	Grazax®	Licensed Y/N?	Y
Dosage form and strength	Oral lyophilisate containing grass pollen extract 75,000 units			BNF class	3.4.2
Indication	Treatment of seasonal allergic hay fever due to grass or tree pollen in children over 5 who have failed to respond to anti-allergy drugs				
Dosage and Administration	<p>One oral lyophilisate daily.</p> <p>The oral lyophilisate should be taken from the blister unit with dry fingers, and placed under the tongue, where it will disperse. Swallowing should be avoided for about 1 minute. Food and beverage should not be taken for the following 5 minutes.</p> <p>The oral lyophilisate should be taken immediately after opening the blister.</p> <p>It is recommended to continue treatment for a period of 3 years</p> <p>If there is no improvement in the first season then Grazax should be discontinued.</p>				
Eligibility criteria for shared care	Following initiation of first dose and is tolerated by the patient				
Excluded patients	Children < 5 years; adults				
Initiation	<p>One oral lyophilisate daily – to be taken under medical supervision. Initiation will be undertaken in hospital.</p> <p>Treatment should commence at least 4 months before the expected start of the grass pollen season (May)</p>				
Specialist Responsibilities	<ul style="list-style-type: none"> • Assessing suitability of patients for treatment. • Discuss the treatment options with the patient, their parent(s) and carer(s). • Initiation and supply of one month after dose has been initiated in hospital. • Ensure the patient has at least 4 weeks supply remaining from the date the GP accepts the request to continue prescribing (to allow 2 weeks for the surgery to set up the prescription and provide it to the patient and then 2 weeks for the pharmacy to obtain supplies). 				

	<p>Assess and monitor patient's response to treatment after each grass pollen season.</p> <ul style="list-style-type: none"> Request the GP to take over prescribing in a clear letter; this letter should include full clinical details, and state consent has been obtained. Ensure the patient is fully aware of the need to obtain a prescription from their GP within 2 weeks and take it immediately to their chosen community pharmacy so that arrangements can be made to obtain stocks. Report any suspected ADRs to the MHRA. <p>Discontinuation – advising GPs when treatment should be stopped</p>		
GP Responsibilities	<ul style="list-style-type: none"> Prescribe appropriate quantities of Grazax® for the patient on FP10 once dose is stabilised Monitor for s/e for first 2 months before considering repeat prescribing with review 6-12monthly. Liaison with consultant regarding any complications of treatment which might require early discontinuation or alteration of prescribing. Refer to consultant where appropriate <p>Only ask the Consultant to take back the prescribing should unmanageable problems arise</p>		
Adverse Effects, Precautions and Contraindications	<p>Adverse effects: Local allergic reactions in the mouth are common, throat irritation, sneezing and ear pruritis. In the majority of patients these reactions developed early in therapy, lasted from minutes to hours after each treatment and spontaneously resolved within one to seven days. More severe reactions reported in less than 1% of patients included angioedema, bronchospasm, and upper respiratory infection. If the patient experiences significant local adverse reactions from the treatment, anti-allergic medication (e.g. antihistamines) should be considered.</p> <p>In some cases the serious anaphylactic reaction has occurred at doses subsequent to the initial dose. If the patient experiences adverse effects, or prolonged symptoms, contact allergy paediatric consultant. If patient experiences serious adverse effect attend paediatric A&E.</p> <p>Precautions: In case of oral surgery, including dental extraction, and shedding of a deciduous tooth in children, treatment should be stopped for 7 days to allow healing of the oral cavity.</p> <p>In children with concomitant asthma and experiencing an acute upper respiratory tract infection. Treatment should be temporarily discontinued until the infection has resolved.</p> <p>Contra indications: Uncontrolled or severe asthma (see below)</p> <p>Inflammatory conditions in the oral cavity</p>		
Common Drug Interactions	No relevant drug interactions		
Communication/ Contact Details	<table> <tr> <td>Dr P Kumar, Consultant Paediatrician, Sunderland Royal Hospital, SR4 7TP 0191 5656256</td> <td>Kim Coxall Paediatric Allergy Nurse specialist Sunderland Royal Hospital, SR4 7TP</td> </tr> </table>	Dr P Kumar, Consultant Paediatrician, Sunderland Royal Hospital, SR4 7TP 0191 5656256	Kim Coxall Paediatric Allergy Nurse specialist Sunderland Royal Hospital, SR4 7TP
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This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF.

Shared Care Request/Confirmation

Private and Confidential

Patient information:

To be completed by specialist prescriber:

<p>Consultant</p> <p>Department</p> <p>Hospital</p>	<p>Patient details (use hospital label if preferred)</p> <p>Name</p> <p>Address</p> <p>.....</p> <p>Postcode Sex</p> <p>NHS or Hosp. Reg. No. DoB</p>
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Treatment Requested for Prescribing in Accordance with Shared Care Arrangement:

To be completed by specialist prescriber:

Drug name	
Dose	
Frequency	
Indication	
Other information	

Name (print)..... Signature (of specialist prescriber)..... Date.....

Acceptance/rejection of treatment under Shared Care Agreement:

To be completed by GP:

Please tick one box

I ACCEPT the proposed shared care arrangement for this patient

or

I ACCEPT the proposed shared care arrangement with the caveats below

or

I DO NOT ACCEPT the proposed shared care arrangement for this patient

My caveats / reason(s) for not accepting include:

Name (print)..... Signature (of GP)..... Date.....

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP