Vol 4. Issue 5: December 2023

MEDwatch *is the e-bulletin for all NHS Grampian Staff who are involved with patients and medicine management.*

Its aim is to improve the safety of medicines by sharing learning, and encouraging adverse event reporting from all staff groups.

Inside This Issue

MHRA Drug Safety Newsletters

Latest MHRA Drug Safety Newsletters:

- September 2023
- October 2023
- November 2023

Adrenaline Auto-Injector Devices

Earlier this year the MHRA launched a safety campaign to raise awareness of anaphylaxis and provide advice on the use of adrenaline auto-injectors (AAIs). AAIs are devices used to deliver adrenaline and are intended to be self-administered by a patient, or administered by a carer. They should be carried by patients considered to be at risk of anaphylaxis so the medicine is available for immediate use.

Clinical Scenarios in which Prescription Should be Considered & Issues/Adjuncts to Prescription

The following has been prepared to describe clinical scenarios where prescriptions for AAIs should be considered:

- Previous/current anaphylaxis where there is a high risk of re-exposure or ongoing exposure to inciting allergens, unknown allergens or other relevant contributing cofactors (e.g. non-allergic precipitants of mast cell inflammatory mediator release)
    - Where allergen(s) cannot easily be avoided (including many foods as both overt or hidden allergens, latex, insect venoms, physical precipitants such as heat, cold, pressure)
    - Where there is a continuing, likely, significant or uncertain risk of anaphylaxis (e.g. exercise-related anaphylaxis, idiopathic anaphylaxis)
    - Domestic or occupational exposure to allergen (bee keeper, family or neighbour of beekeeper, roofer, gardener, jam worker, fruit picker, bakery worker)
    - Patients with high basal serum tryptase levels (including systemic mastocytosis)
- Crescendo allergic reactions where multiple attacks of increasing clinical severity occur, especially over a short period of time
- Where moderate/severe allergic reactions occur in response to even small/trace amounts of allergen
- Active, known, high-risk allergies at any severity (especially food allergies) in the setting of asthma (especially unstable or poorly-controlled asthma)
    - e.g. nut allergies, even where previous reactions have been relatively mild
- Moderate systemic allergic reactions which may not reach criteria for a diagnosis of anaphylaxis but where the affected individual's social/domestic circumstances might prevent early access to emergency assistance (remote location, no telephone) or might warrant prescription for other relevant reasons (e.g. single parent with young children, infirm patient living alone)

(adapted from Ewan P et al. British Society for Allergy and Clinical Immunology (BSACI) guideline: prescribing an adrenaline auto-injector. Clinical & Experimental Allergy (2016); 46: 1258-1280)

Practical Severity Grading & Risk Assessment

Mild: Isolated localised/systemic urticaria or simple lip angioedema without airway/breathing involvement

Moderate: Urticaria/angioedema with mild airway involvement

Severe: Airway involvement or hypotension

Additional Considerations

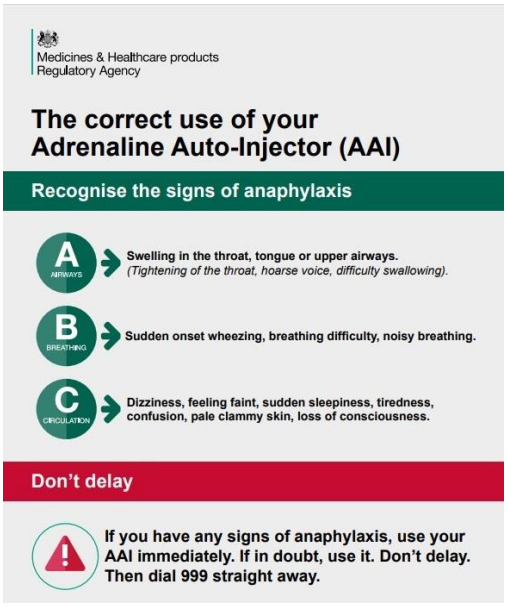
As emphasised in the CHM/MHRA report on Recommendations to support the effective and safe use of adrenaline auto-injections (November 2021) core elements of care additional to auto-injector prescription comprise:

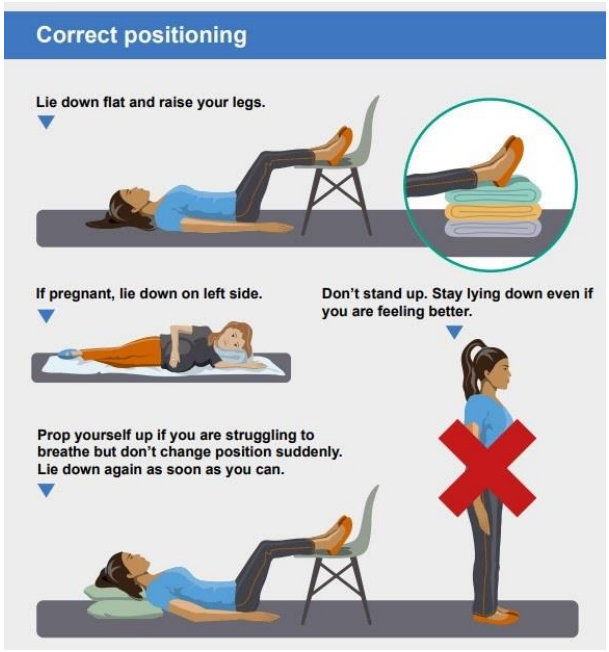
- Applying ABC criteria for anaphylaxis diagnosis in auto-injector prescription
- Risk assessment for recurrence of anaphylaxis, where relevant
- Risk assessment for cofactors (asthma, serum tryptase)
- Device-specific training for patients and contacts/carers on prescription/issue
- Direct patients to device-specific website for refresher training, registration of devices (expiry date reminders) and availability of trainer auto-injectors
- Emphasise **BE PREPARED** and **WHAT TO DO IN AN EMERGENCY** messages (below)

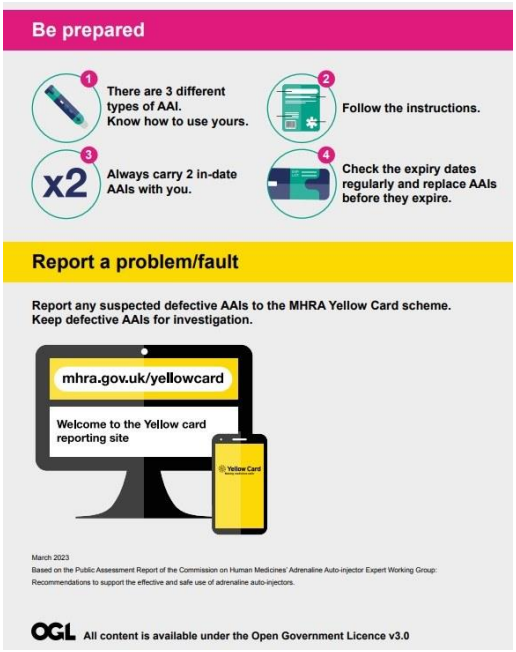
BE PREPARED

- Carry two adrenaline auto-injectors with you at all times
- Use your auto-injector as soon as you notice any signs of anaphylaxis
- Make sure you know beforehand what the signs are so you can act swiftly
- Make sure you know how to use your auto-injector before you need to
    - Get familiar with your particular auto-injector device
    - Get a trainer auto-injector from the manufacturer
    - Practise regularly
    - If you change auto-injector brand, get familiar with the new one.

WHAT TO DO IN AN EMERGENCY







- Use your auto-injector **immediately** if you have any signs of anaphylaxis
- If in doubt use your auto-injector. **Do not delay**.
- **Dial 999** - say anaphylaxis - immediately after using your auto-injector
- **Lie down and raise your legs**
- Sit up if you are struggling to breathe but **do not change position suddenly**
- **Lie down again** as soon as you can
- **Stay lying down**, even if you are feeling better
- **Do not stand up**, unless advised to do so by healthcare personnel
- Use your second auto-injector if you have not improved after 5 minutes.

Links and Resources

MHRA

Guidance: Adrenaline auto-injectors (AAIs): new guidance and resources for safe use - GOV.UK (www.gov.uk) (June 2023)

Resources: Adrenaline Auto-Injectors (AAIs) - GOV.UK (www.gov.uk)

Animation: The correct use of your Adrenaline Auto-Injector (AAI)

BSACI

Guidance: https://www.bsaci.org/wp-content/uploads/2023/06/BSACI-AAI-Guidance-June-2023.pdf

FAQ: https://www.bsaci.org/wp-content/uploads/2023/05/AAI-Frequently-Asked-Questions.pdf

Prescribing of 'Higher' Strength Buprenorphine Transdermal Patches

The Medicines Management Team (Pharmacy and Medicines Directorate) have shared guidance for prescribing 'higher' strength Buprenorphine Transdermal Patches. The guidance which has been written to ensure that patients receive an appropriate product with directions detailing the correct frequency of application.

Actions for Primary Care, Secondary Care and Community Pharmacy are detailed within the full guidance which can be found on the Medicines Management A-Z Policies internet page.

Buccal Midazolam Preparations for Prescribing in Paediatrics

The following update on buccal midazolam preparations for prescribing in paediatrics has previously been sent directly to Primary Care Teams and Community Pharmacies from the NHS Grampian Paediatric Epilepsy Service but is shared here for information.

Please note this guidance replaces the previous alert regarding Oromucosal Midazolam Solution – Prescribing (dated: 31/08/18)

Recently some new strengths and preparations (2.5mg, 5mg & 7.5mg pre-filled syringes) of buccal midazolam, as the Epistatus® brand, have become available for prescribing in children as rescue treatment for status epilepticus. The purpose of this memo is to highlight which preparations are recommended locally:

- **Epistatus® oromucosal solution pre-filled syringes (2.5mg, 5mg, 7.5mg and 10mg strengths)** – These pre-filled syringes have recently become licensed in a variety of different strengths for children aged 3 months to less than 18 years and are now the first-line formulation choice for prescribing buccal midazolam in children locally. (Note 10mg pre-filled syringe only licensed from 10 years and above). **Patients should not be switched to**

pre-filled syringes until the required training has been provided by the epilepsy specialist nurse.

- **Epistatus® 10mg/mL oromucosal solution (5mL bottle)** – This unlicensed product is available as a multi dose bottle and may still be prescribed for certain patients under the direction of the paediatric epilepsy service if a pre-filled syringe is not felt to be appropriate. When prescribing, please tick the 'specials' box on the Vision prescribing screen.
- **Buccolam® oromucosal solution pre-filled syringes** – This brand of pre-filled syringes are not recommended for use within NHS Grampian and should not be prescribed locally.

Within paediatrics, a dose of 0.3mg per kg is used for buccal midazolam (maximum 10mg per dose), as per Scottish Paediatric Epilepsy Network recommendations. Please note that this dosing differs from the age based dose banding suggested in the BNF for Children. If you are unsure which preparation a child should be prescribed, please get in touch with the epilepsy specialist nurse who will be able to confirm (gram.rachepilepsynurse@nhs.scot).

Grampian Area Formulary has been updated to reflect these changes.

Note: at the time of writing it is understood that there are ongoing out of stock issues with Epistatus® 2.5mg.

Intravenous or Oral Paracetamol?

In acute areas paracetamol is often prescribed as oral/IV meaning that at the time the patient is due paracetamol the nurse can make a clinical judgement whether to administer it orally or intravenously (IV) based on the patient's condition/circumstances. Following a recent shortage of IV paracetamol we are taking this opportunity to remind staff that when paracetamol is prescribed as IV/oral, oral should be the preferred route of administration unless there are clinical reasons that the patient cannot take it orally in which case it may be administered IV.

As per the NHS Grampian Policy and Procedure for the Prescribing, Preparation and Administration of Injectable Medicines and Infusions in Near Patient Area medicines should only be given by injection when no other route is suitable. Any medicines prescribed IV should be changed to oral as soon as the patient's condition allows.

Drug/Vaccine Fridge Standard Operating Procedures

A reminder for areas to ensure they have a completed SOP for drug/vaccine fridge - information initially went out in NHS Grampian Daily Brief on 22nd November 2023.

All managers in clinical areas with drug/vaccine fridges are reminded of the requirement to ensure that all staff involved in the day to day use and monitoring of drug/vaccine fridges are complying with the Policy for Handling Vaccines and Refrigerated Products for All Staff Working in NHS Grampian; this includes daily temperature recordings and monthly checks. Failure to do this can result in potential risks, for example, the product may not be as effective if it has not been stored appropriately.

Senior Charge Nurses/Managers are asked to ensure Appendix 1 of the policy Example Refrigerator – Standard Operating Procedure (SOP) For Refrigerated Pharmaceutical Products is completed for their area of responsibility (ward/clinic) that has a drug/vaccine fridge by 31st December 2023. The purpose of this SOP is to detail the local department or ward process and the staff responsible for undertaking each task.

All staff in clinical areas with drug/vaccine fridges should complete the Management of medicines refrigerators eLearning module in Turas and Senior Charge Nurses/Managers are asked to ensure that this is done.

Nurse Managers will be asked for assurance that SOPs have been completed and eLearning undertaken by 12th January 2024.

Contact

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