University Hospitals of Derby and Burton NHS Foundation Trust

PATIENT GROUP DIRECTION (PGD)

Supply/Administration of Benzydamine Hydrochloride 0.15% (Difflam Spray) By Registered Nurses in Paediatric Services at UHDB

Documentation details

Reference no:	UHDB166
Version no:	V1
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Expiry date:	03/05/2025

Change history

Version number	Change details	Date
1	New UHDB format	21/03/2022

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Jane Gadie	Emergency Nurse Practitioner
Julie Vanes	Senior Pharmacist, Paediatrics / Medicines Safety
Dr Gisela Robinson	Consultant Paediatrician

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
N/A	N/A	N/A

2. Organisational authorisations

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

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Registered Nurses working in Paediatric Areas at RDH and QHB (Ward areas both sites, Children's Emergency Department at RDH, Paediatric Assessment Unit at QHB) and in ED at QHB
Limitations to authorisation
N/A

Organisational Authorisation (legal requirement).			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	**James Hooley**	**Signed copy held in Pharmacy**	**04/05/2022**

Additional signatories (required as per legislation and locally agreed policy)			
Role	**Name**	**Sign**	**Date**
Paediatric Pharmacist *Clinical Pharmacist from PGD working group*	Julie Vanes	**Signed copy held in Pharmacy**	**05/04/2022**
Consultant Paediatrician *Doctor*	Dr Robinson	**Signed copy held in Pharmacy**	22/03/2022
Lead Nurse for Paediatrics *Registered Professional representing users of the PGD*	Laura Churm	**Signed copy held in Pharmacy**	**22/04/2022**

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered Nurses working in Paediatric Areas at RDH and QHB (Ward areas both sites, Children's Emergency Department at RDH, Paediatric Assessment Unit at QHB) and in ED at QHB
Initial training	- Completion of all Essential-to-role training as outlined in the UHDB PGD policy. - Individual has read and understood full content of this PGD and signed authorisation (section 7) - Completion of Medicines Management Drug Assessment
Competency assessment	Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required. Approved drug assessment
Ongoing training and competency	NA
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Painful inflammatory conditions of Oropharynx and relief of pain in conditions such as tonsillectomy or NG tube insertion. Reduces pain and inflammation
Criteria for inclusion	Children from 1 month of age to 18 years of age
Criteria for exclusion	• Babies under 1 month of age • Patients with hypersensitivity to acetylsalicylic acid or other NSAIDs • Known allergy to the active substance benzydamine hydrochloride or to any of the excipients
Cautions including any relevant action to be taken	• Since systemic absorption can follow topical application of **NSAIDs**, the possibility of interactions should be borne in mind • Patients suffering from bronchial asthma
Action to be taken if the patient is excluded	• Record reasons for exclusion in patient notes • Advise patient on alternative treatment • Refer to a prescriber immediately
Action to be taken if the patient or carer declines treatment	• Document refusal and subsequent advice given • Advise patient on alternative treatment • Refer to a prescriber if appropriate
Arrangements for referral for medical advice	Refer to the appropriate medical practitioner in the care pathway

5. Description of treatment

Name, strength & formulation of drug	Benzydamine 0.15% oromucosal spray Benzydamine hydrochloride 1.5 mg per 1 ml
Legal category	P (pharmacy medicine)
Route / method of administration	Oromucosal spray – spray recommended number of sprays as per age and body weight to the throat or lesions in mouth
Indicate any off-label use (if relevant)	N/A
Dose and frequency of administration	**For Child 1 month–5 years (body-weight 4–7 kg)** 1 spray every 1.5–3 hours, to be administered onto the affected area. **For Child 1 month–5 years (body-weight 8–11 kg)** 2 sprays every 1.5–3 hours, to be administered onto the affected area. **For Child 1 month–5 years (body-weight 12–15 kg)** 3 sprays every 1.5–3 hours, to be administered onto the affected area. **For Child 1 month–5 years (body-weight 16 kg and above)**

	4 sprays every 1.5–3 hours, to be administered onto the affected area. **For Child 6–11 years** 4 sprays every 1.5–3 hours, to be administered onto affected area. **For Child 12–17 years** 4–8 sprays every 1.5–3 hours, to be administered onto affected area.
Duration of treatment	Uninterrupted treatment should not exceed seven days except under medical supervision
Quantity to be supplied (leave blank if PGD is administration ONLY)	Supply 1 spray Labelling must meet the requirements outlined in Trust PGD Policy and associated training. The pharmacy department supply over-labelled or ready-labelled packs to meet the legal requirements for supply. If you do not hold these appropriately labelled packs in stock, then a supply to patients is not appropriate The following information must be added to the ready-labelled TTO packs before supply if it is not already printed on the label Patient name Date of supply The dose required (as number of sprays) Name of the department issuing the TTO pack
Storage	Stock must be securely stored according to UHDB medicines policy.
Drug interactions	There are no known interactions with the oromucosal spray listed on the electronic Medicines Compendium website: www.medicines.org.uk
Identification & management of adverse reactions	The most common side effects are numbness or a stinging feeling in the mouth **Uncommon** Oral disorders **Rare or very rare** Photosensitivity reaction; respiratory disorders e.g. laryngospasm, bronchospasm; skin reactions e.g. pruritus, urticarial, rash **Frequency not known** Angioedema, anaphylaxis A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk

	• Record all adverse drug reactions (ADRs) in the patient's medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use.
Written information to be given to patient or carer	Verbal advice can be given at the time of administration. Patient information leaflet can be supplied if required – suitable leaflets available from www.medicines.org.uk
Patient advice / follow up treatment	Verbal advice can be given at the time of administration and inform patient/carer not to repeat the dose within 1.5 – 3 hours
Records	Record the following information on ePMA (Electronic Prescribing system) UHDB – currently MediTech or Lorenzo Either the system holding the record, or the healthcare practitioner working under the PGD, must capture/document all of the following: • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether supplied and/or administered and that this was done via Patient Group Direction (PGD) Records should be signed and dated (or a password controlled e-records). All records should be clear, legible and contemporaneous. If you are not recording in ePMA (or other electronic system which has ability to generate audit reports) then a record of all individuals receiving treatment under this PGD should also be in the clinical area for audit purposes as per UHDB PGD policy.

6. Key references

Key references	• https://bnfc.nice.org.uk/drug/benzydamine-hydrochloride.html (accessed 24 December 2021) • Electronic Medicines Compendium http://www.medicines.org.uk/ (accessed 24/12/2021) • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2

7. Registered health professional authorisation sheet

PGD Name [version]: UHDB – Paediatrics - Benzydamine Hydrochloride 0.15% (Difflam Spray) [v1]

PGD ref: UHDB166

Valid from: 04/05/2022 Expiry date: 03/05/2025

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read MUST match this authorisation form.

Registered health professional

By signing this patient group direction you are indicating that

a) You agree to and understand all content and commit to only work within this framework.
b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

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 and professional code of conduct.

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.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.