University Hospitals of Derby and Burton NHS Foundation Trust

PROTOCOL

Biotene Oralbalance® (GelXylitol/peroxidase and oxidase enzymes 4.76% gel)

Registered Nurses, Advanced Clinical Practitioners in the following clinical areas: Nightingale Macmillan Unit, Wards 410, 312, 407, 409, 402, 404, 403, 405, 406, 401, 311 (RDH), Wards 3, 4, 7 & 20 (QHB), Wards 2, 3 & 5 (FNCH)

Documentation details

Reference no:	UHDB275
Version no:	2.0
Valid from:	07/09/2023
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Expiry date:	06/09/2026

Change history

Version number	Change details	Date
1.0	Addition of all respiratory wards and all DME	May 2019
2.0	Addition of all respiratory wards and all DME at QHB	Nov 2022

Glossary

Abbreviation	Definition

1. Protocol template development (Protocol Working Group)

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

Name	Designation
Kath Hulkorey	Deputy Lead Nurse Professional Development
Jane Moreland	End of Life Care Facilitator
Dr Ruth England	Consultant Palliative Medicine
James Kerr	Directorate Pharmacist
Dr Nitin Kolhe	Consultant Nephrologist and Deputy Divisional Medical Director for Medicine
Dr Wei Chua	Consultant Physician Medicine for the Elderly

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 Protocol is not valid until it has had the relevant organisational authorisation.

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

Authorised for use by the following organisation and/or services
Registered Nurses, Advanced Clinical Practitioners in the following clinical areas of UHDB: Nightingale Macmillan Unit, Wards 410, 312, 407, 409, 402, 404, 403, 405, 406, 401, 311 (RDH), Wards 3, 4, 7 & 20 (QHB), Wards 2, 3 & 5 (FNCH)
Limitations to authorisation
Agreed rationale for protocol use in place of a PGD (Patient Group Direction)
Trust authorisation for registered staff to provide and document oral balance gel to patients under this protocol until a prescriber can provide a prescription

Organisational Authorisation			
Role	**Name**	**Sign**	**Date**
Medicines Safety Officer *Pharmacist: Medicines Safety Officer, Chief Pharmacist or assigned deputies)*	**James Hooley**	**Signed copy held in Pharmacy**	**07/09/2023**

Additional signatories			
Role	**Name**	**Sign**	**Date**
Divisional Lead Pharmacist - Medicine *Clinical Pharmacist from Protocol working group*	James Kerr	**Signed copy held by Pharmacy**	**22/08/2023**
Consultant Palliative Medicine *Doctor*	Ruth England	**Signed copy held in Pharmacy**	**05/09/2023**
Deputy Lead Nurse Professional Development *Registered Professional representing users of the PROTOCOL*	Kathryn Hulkorey	**Signed copy held by Pharmacy**	**31/08/2023**

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

Section 7 provides a healthcare worker authorisation sheet. Individual healthcare workers must be authorised by name to work to this PROTOCOL.

3. Characteristics of staff

Qualifications and professional registration	Registered Practitioners (RN's, ACP's) in the areas specified. A registered professional with current professional registration operating within their usual scope of practice
Initial training	- Completion of Medicines Management Drug Assessment - Individual has read and understood full content of this Protocol and signed authorisation (section 7)
Competency assessment	Medicines (Drug Assessment) Individuals operating under this Protocol are personally responsible for ensuring they remain up to date with the use of all medicines included in the Protocol - if any training needs are identified these should be discussed with the either authorising manager (section 7) or the manager within the Protocol working group (section 1) so that further training can be provided as required.
Ongoing training and competency	Indications and use, use of the oral assessment tool Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the PROTOCOL Has undertaken appropriate training for working under Patient Group Directions for the supply and administration of medicines
The decision to administer or supply any medication rests with the individual healthcare worker operating under this protocol who must abide by the protocol and any associated organisation policies.	

4. Clinical condition or situation to which this Protocol applies

Clinical condition or situation to which this Protocol applies	Xerostomia: Adult patients with a dry mouth caused by dysphagia, prolonged nil by mouth status, medication, 'mouth-breather' (patients on oxygen), End of life (EOL), unconscious/intubated.
Criteria for inclusion	• Patients aged 16 and over who present with: symptoms of a dry mouth and unable to moisten with oral fluids • Reduced salvia production • Sore mouth • Increased risk of xerostomia due to medications • Existing medical conditions • Dysphagia • Radio/chemotherapy or oxygen therapy In accordance with Trust Policy for The Implementation of Minimum Standards For Adult Inpatient Oral Care.
Criteria for exclusion	• Previous sensitivity or intolerance to the product or any ingredient- seek medical advice, • Patients under 16 years of age.
Cautions including any relevant action to be taken	Oral application use only
Action to be taken if the patient is excluded	• Refer to medical team for review and prescribing of an alternative agent if appropriate.
Action to be taken if the patient or carer declines treatment	• Document advice given • Advise patient on alternative treatment • Refer to medical team
Arrangements for referral for medical advice	Discuss potential consequences/referral/records to be kept.

5. Description of treatment

Name, strength & formulation of drug	Biotene Oralbalance® 50g (GelXylitol/peroxidase and oxidase enzymes 4.76% gel)
Legal category	Not classified (device/appliance)
Route / method of administration	Oral application to oral mucosa, gums, and tongue (remove previous application before reapplying with an oral care device e.g., toothbrush) Apply using a toothbrush, finger or squirted onto the tongue and spread around the mucosa, tongue and gums. If patient is concurrently using a topical oral antifungal (Nystatin or Miconazole mouthwash/gel) then Biotene should not be applied until 30mins after administration of the antifungal.
Indicate any unlicensed or off-label use	No relevant.

(if relevant)	
Dose and frequency of administration	• Apply 1-2cm of gel • Maximum 4-6 hourly. • No more than 50g per day or 5 applications in a day
Duration of treatment	3 days, maximum of one 50g tube supplied per patient.
Quantity to be supplied (leave blank if protocol is administration ONLY)	*n/a*
Storage	Stock must be securely stored according to UHDB medicines policy
Drug interactions	No Interactions Noted.
Identification & management of adverse reactions	Consult medical advice if an adverse event occurs. Document in medical notes. All serious adverse reactions must be reported under the national yellow card system.
Management of and reporting procedure for adverse reactions	• Healthcare workers 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	Give marketing authorisation holder's patient information leaflet (PIL) provided with the product.
Patient advice / follow up treatment	Verbal advice on why product is administered, action and subsequent management of condition. Avoid use with toothpastes containing detergents (including foaming agents).
Records	Record the PGD or Protocol in the relevant ePMA (Meditech & Lorenezo) Document the utilisation of the medicine under PROTOCOL by ordering the appropriate drug order item against the correct patient. Complete all mandated fields on the prescription form. Document the administration of the medicine. All records should be clear, legible and contemporaneous.

6. Key references

Key references	Aliko et al (2012) Evaluation of the clinical efficacy of Biotene oral Balance in patients with secondary Sjogren's syndrom: a pilot study. Rheumatology International, Vol 32, No 9, pp 2877-2881 Alves M, Motta A, Messina W, Migliari D (2004) Saliva substitute in xerstomic patients with Sjogren's syndrome: a single-blind trial. Quintessence International, Vol 35, No 5, PP 392-6 Warde P, Kroll B, O'Sullivan B, Aslandis J, Tew-George E, Waldron J, maxymiw W, Liu F, Payne D, Cummings B (2000) A phase II study of Biotene in the treatment of postradiation xerostomia in patients with head and neck cancer. Support Care Cancer Vol 8, No 3, pp 203-8 Epstein J, Emerton S, Le N. D, Stevenson-Moore P (1999) A double-blind crossover trial of oral balance gel and Biotene toothpaste versus placebo in patients with xerstomia following radiation therapy. Oral Oncology, Vol 35, No 2, pp 1368-8375

7. Registered health professional authorisation sheet

Protocol [version]: RDH/FNCH - Biotene Oralbalance [v2.0] Protocol ref: UHDB275

Valid from: 07/09/2023 Expiry date: 06/09/2026

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 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 protocol.

The decision to administer or supply any medication rests with the individual healthcare worker operating under this protocol who must abide by the protocol and any associated organisation policies.

I confirm that I have read and understood the content of this Protocol and that I am willing and competent to work to it.			
Name	**Designation**	**Signature**	**Date**

Authorising manager / Assessor

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

Note to authorising manager

Score through unused rows in the list of healthcare workers to prevent additions post managerial authorisation.

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