



Bronllys Hospital, Bronllys, Brecon, Powys, LD3 0LU

This protocol must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the protocol should be used. Healthcare professionals should always access the protocol via the PTHB internet to ensure that they are working to the most up to date version

Protocol

for the administration of

Loratadine 10mg oral tablet or 5mg/5ml syrup or oral solution

by registered nurses

to Adults and Children **aged from 2 years**

for the **relief of minor allergic reactions**

in Powys Teaching Health Board (PTHB) Minor Injury Units

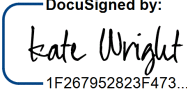
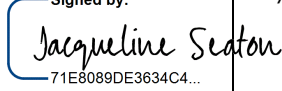

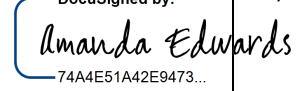
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Document Type:	Protocol	Clinical
Scope:	Authorised registered nurses in PTHB MIUs	

Do not print this document. The latest version will be accessible via the internet. If the expiry date has passed, please contact the Author for advice.

Change history

Version number	Change details	Date
MMP 468 V1	New protocol (a PGD is not required for administration of a P medicine) to replace PGD 0002 (chlorphenamine), as NICE CKS: Urticaria states guidelines now recommend against routinely prescribing sedating antihistamines, due to their short and long-term effects on the central nervous system.	03/02/2025

Protocol authorisation

Name	Job title and organisation	Signature	Date
Senior doctor Dr Kate Wright	Lead doctor for PTHB	 DocuSigned by: <i>Kate Wright</i> 1F267952823F473...	2/3/2025
Chief Pharmacist Jacqui Seaton	Chief Pharmacist for PTHB	 Signed by: <i>Jacqueline Seaton</i> 71E8089DE3634C4...	2/3/2025
Senior representative of professional group using the Protocol Claire Roche	Executive Director of Nursing and Midwifery for PTHB	 DocuSigned by: <i>Claire Roche</i> F07413E114E04B1...	2/17/2025
Clinical Governance Lead Amanda Edwards	Clinical Governance Lead for PTHB – Assistant Director for Innovation and Improvement	 DocuSigned by: <i>Amanda Edwards</i> 74A4E51A42E9473...	2/26/2025

[Appendix A](#) provides a staff permitted to use protocol accreditation sheet. Individual practitioners must be authorised by name to work to this protocol.

The final authorised copy of this protocol should be kept by PTHB for 25 years after the protocol expires.

Training and competency of registered health professionals

<p>Qualifications and professional registration</p>	<p>Practitioners must only work under this protocol where they are competent to do so. Practitioners working under this protocol must also be a registered healthcare professional with the following body:</p> <ul style="list-style-type: none"> • Nurses currently registered with the Nursing and Midwifery Council (NMC) and working in a Minor Injury Unit (MIU) in PTHB <p>Current contract of employment with PTHB. Practitioners must also fulfil the training and Additional requirements listed below.</p> <p>Check Appendix A – Staff permitted to use protocol accreditation sheet to confirm whether all practitioners listed above have organisational authorisation to work under this protocol.</p>
<p>Initial Training</p>	<ul style="list-style-type: none"> • The administration of loratadine oral preparations and knowledge of its uses, contraindications and adverse effects • Undertaken organisation approved training and successfully completed the competencies to enable the practitioner to make a clinical assessment to establish the need for the medication covered by this protocol • Knowledge of the assessment and management of minor allergic reactions (refer to MIU Clinical Guidelines and Allergies Specialities CKS NICE) <p>Additionally, practitioners:</p> <ul style="list-style-type: none"> • must be authorised by name as an approved practitioner under the current terms of this protocol before working to it • must have undertaken appropriate training for working under protocols for administration of medicines • must be familiar with the product and alert to changes in the BNF (https://bnf.nice.org.uk) and Summary of Product Characteristics (www.medicines.org.uk) • must have undertaken training appropriate to this protocol as required by local policy • must have undertaken and completed at least level 2 Safeguarding of Children, Young People and Vulnerable Adults - Training and Competency Passport, as applicable to the role

	<ul style="list-style-type: none"> • must be competent in the recognition, management and reporting of recognised adverse reactions, including anaphylaxis. Must be competent in the administration of adrenaline and have up to date Intermediate Life Support (ILS) skills • must have access to the protocol and associated online resources <p>THE PRACTITIONER MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PROTOCOL BEFORE WORKING ACCORDING TO IT.</p>
<p>Competency assessment</p>	<p>Individuals operating under this protocol must be assessed as competent (see Appendix A). The individual must complete a self-declaration of competence in their Personal Appraisal and Development Review (PADR) – the personal development plan (yellow) section of the PADR booklet should be used to record competency.</p> <p>Practitioners must be competent, recognise their own limitations and personal accountability and act accordingly. Evidence of training in ILS and anaphylaxis.</p> <p>Individuals operating under this protocol are personally responsible for ensuring they remain up to date with the use of the medicine included in the protocol - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the protocol and further training provided as required.</p>
<p>Ongoing training and competency</p>	<ul style="list-style-type: none"> • Update at least every 2 years, or earlier in response to new local/national guidance, on the use of protocols and loratadine and the assessment and management of allergic reactions as per MIU Clinical Guidelines and NICE CKS Allergies. • Practitioners must ensure they are up to date with relevant clinical skills and management of anaphylaxis and ILS. • Completion and submission of Continuous Professional Development (CPD) as required by NMC, which must be retained and made available on request. • Compliance with all mandatory NHS training including safeguarding at the level relevant to the role. • Evidence of ongoing / refresher training to be submitted to line manager annually. <p>It is the responsibility of the healthcare professional to maintain their own competency to practice within this protocol.</p>

<p>The decision to administer any medication rests with the individual registered practitioner who must abide by the protocol and any associated organisation policies.</p>	
<p>Clinical Condition</p>	
<p>Clinical condition or situation to which this protocol applies</p>	<p>Symptomatic control of minor allergic reactions responsive to antihistamines.</p> <p>NB: This protocol should be used in conjunction with the MIU Clinical Guidelines and other MIU PGDs, if appropriate, along with any relevant NICE guidance</p> <p>When treating a local inflammatory or allergic skin reaction, loratadine may be considered to help relieve itching, even though there is uncertainty about the effect of oral antihistamines in managing insect bites or stings.</p> <p>It is the responsibility of the administering nurse to ensure that the individual is within the inclusion criteria, and that there are no reasons for exclusion before proceeding with the medication. If there is any reason for concern, seek medical advice. These tasks cannot be delegated and so the registered nurse making the decision to administer the medication under this protocol must carry out administration to the individual.</p>
<p>Inclusion Criteria</p>	<ul style="list-style-type: none"> • Adults and children aged from 2 years with a minor allergic reaction. • Medical and drug history taken, no reason for exclusion. • Informed consent, from the individual or a person legally able to act on the person’s behalf, must be obtained prior to administration. NB Refer to PTHB Consent to Treatment and Examination Policy. In case of any doubt, contact medical team or emergency services. <p>NB. this protocol should be used in conjunction with the MIU Clinical Guidelines and appropriate NICE guidelines relevant to the specific condition being treated.</p> <p>Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Where there are safeguarding concerns (Child Protection or Protection of Vulnerable Adults (POVA)), advice from the local Safeguarding team should be sought (see below).</p>

<p>Exclusion criteria (Exclusion under this protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required)</p>	<ul style="list-style-type: none"> • Conditions outside the remit of the PTHB MIU Clinical Guidelines • Individuals for whom valid consent, or 'best-interests' decision, in accordance with the Mental Capacity Act 2005, has not been obtained or received. Refer to sections "Action to be taken if individual is excluded" or "Action to be taken if individual declines treatment". • Pregnancy or breastfeeding • Children under 2 years old • Known hypersensitivity to loratadine and/or to any of the excipients in the medicinal product- see product SPC • Individuals with rare hereditary problems of fructose intolerance, galactose intolerance, the Lapp lactase deficiency, glucose-galactose malabsorption or sucrase-isomaltase insufficiency (Syrup or oral solutions may contain sucrose and/or mannitol and/or sorbitol; tablets may contain lactose).NB Consult individual SPC to determine if exclusion applies to individual • Individual suffering from a severe allergic reaction- follow PTHB anaphylaxis procedure. • Individuals taking the following medicines: <ul style="list-style-type: none"> ○ Isocarboxazid ○ Phenezine ○ Tranylcypromine ○ other antihistamine containing products, including antihistamine containing cough and cold medicines <p>For further information, refer to Drug interaction section</p>
<p>Cautions /reasons for seeking further advice from a prescriber</p>	<ul style="list-style-type: none"> • Individuals with: <ul style="list-style-type: none"> ○ severe hepatic impairment (risk of increased exposure). Manufacturer advises initial dose reduction to alternate days in severe hepatic impairment- this may be relevant if individual has taken loratadine the previous day ○ complex multiple pathologies, polypharmacy or multiple allergies • Oral syrup or oral solution may contain propylene glycol • Check for any other medications that the individual is taking, including topical or inhaled products, food supplements and herbal or homeopathic products. Check drug interactions section • Individual should not take loratadine for at least 48 hours before skin tests since antihistamines may prevent or reduce otherwise positive reactions to dermal reactivity index • Refer to BNF/ SPC for full list

	<p>Under Section 128 and 130 of the Social Services and Wellbeing (Wales) Act 2014, staff have a duty to inform the Local Authority if they have reasonable cause to suspect that an adult or child is at risk. Any vulnerable adult or child protection concerns should be referred to Safeguarding and PTHB safeguarding policies followed. Consider discussing with GP.</p> <p>Any safeguarding concerns need to be directed to Safeguarding Hub:</p> <ul style="list-style-type: none"> • to generic email address: PowysTHB.Safeguarding@wales.nhs.uk <p>and</p> <ul style="list-style-type: none"> • Central Safeguarding number: 01686 252806 • Out of hours: 0345 0544847 <p>Advice can also be sought from local Safeguarding leads.</p>
<p>Action to be taken if individual excluded</p>	<ul style="list-style-type: none"> • Explain reason to individual/carer. • Record reason, seek medical advice, and record any advice given. • If appropriate refer to GP / DGH (A&E) / Out of Hours Service; offer alternative management, if appropriate.
<p>Action to be taken if individual declines treatment</p>	<ul style="list-style-type: none"> • The patient information leaflet should be available to inform consent. • Explain consequences of refusing treatment. • Inform or refer to alternative sources of treatment (GP / DGH (A&E) / Out of Hours Service) as appropriate, following local procedures. Offer alternative management if appropriate. • Document refusal and any advice given. Complete a Discharge Against Advice form, if appropriate.
<p>Arrangements for referral for medical advice</p>	<ul style="list-style-type: none"> • Refer individual to hospital if they have any symptoms or signs suggesting a more serious illness or condition, such as a systemic allergic reaction, rapidly developing angio-oedema without anaphylaxis, orbital cellulitis, osteomyelitis, septic arthritis, necrotising fasciitis or sepsis, or any other cause for concern. • If individual has an infected wound, the skin is broken and: <ul style="list-style-type: none"> ○ there is a penetrating injury OR ○ there has been exposure to water-borne organisms OR ○ the infection was acquired outside the UK

	<p>before cleaning, send a pus or a deep wound swab for microbiological testing, stating on the form that the swab is from an infected wound, following MIU Clinical Guidelines.</p> <ul style="list-style-type: none"> • Immediate hospital admission should be arranged for anyone who has been stung on the face or mucous membranes, and is at risk of airway obstruction or compromised vision • Contact or refer to GP / DGH (A&E) / Out of Hours Service or microbiologist for advice, if applicable. Document advice given.
<p>Details of the Medicine</p>	
<p>Name, form and strength of medicine</p>	<p>Loratadine 10mg tablet or Loratadine 5mg/5ml syrup or oral solution</p> <p>Note: Tablets must not be administered to children under 6 years old, or to children from 6-11 years who are under 31kg. See Dose and Frequency section below.</p>
<p>Legal category</p>	<p>GSL (general sales list) or P (pharmacy) or POM (prescription only medicine)</p> <p>Note: the SPS website confirms the MHRA has advised that when a P medicine is administered under a local protocol and where the legal classification of the medicine is based on the pack size, administration of single doses can be made from a POM or P pack which has been legally obtained by the organisation.</p>
<p>Off label use</p>	<p>Not all brands of loratadine are licensed for treating insect bites and stings, but oral antihistamines may be considered when treating a local inflammatory or allergic skin reaction to help relieve itching.(NICE guidance NG182).</p> <p>Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the local Medicines Management team must be consulted. Where medicines have been assessed by Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this protocol. The responsibility for the decision to release the affected medicines for use lies with Medicines Management.</p>

Route/Method of Administration	Oral			
Dose and frequency	A single dose may be administered in MIU			
	Age	Weight	Single Dose	Quantity of medication to be administered
	2-5 years	Up to 31kg	5mg	5ml syrup or oral solution (5mg/5ml)
		31kg and over	10mg	10ml syrup or oral solution (5mg/5ml)
	6-11 years	Up to 31kg	5mg	5ml syrup or oral solution (5mg/5ml)
		31kg and over	10mg	One 10mg tablet
12 years and over	Any weight	10mg	One 10mg tablet	
Quantity to be administered	A single dose may be administered using this protocol in MIU			
Storage	<p>Stock must be securely stored according to organisation medicines policy and in conditions specified in the individual SPC.</p> <p>NB. Check date of first opening of container if syrup or oral solution is administered. Different brands must be discarded at varying times, for example, between one and six months after opening.</p>			
Drug interactions	<p>The interactions as listed in the BNF are:</p> <ul style="list-style-type: none"> • Isocarboxazid- predicted to increase the risk of antimuscarinic adverse effects when given with Loratadine. Manufacturer advises avoid – see exclusions • Phenzelzine - predicted to increase the risk of antimuscarinic adverse effects when given with Loratadine. Manufacturer advises avoid – see exclusions • Tranylcypramine - predicted to increase the risk of antimuscarinic adverse effects when given with Loratadine. Manufacturer advises avoid – see exclusions • Betahistine - Loratadine is predicted to decrease the effects of Betahistine. Manufacturer makes no recommendation. <p>NB. This list is not exhaustive. Refer to BNF/SPC for full details.</p> <p>Call medical cover for advice and document advice given.</p>			

Identification, management and reporting of adverse effects

Common/very common side effects:

- Drowsiness. Non-sedating antihistamines such as loratadine cause less sedation and psychomotor impairment than the older antihistamines but can still occur; sedation is generally minimal.
- Nervousness (in children)
- Fatigue (very common in children)
- Headache (very common in children)

This list may not represent all reported side-effects of this medicine, a detailed list of adverse reactions is available in the [BNF](#) and the product's SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk.

Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <http://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. For established medicines, serious adverse events in adults or all suspected adverse reactions in children that may be attributable to the medication should be reported.

Report any suspected adverse reactions to a doctor.

In the case of an acute anaphylactic reaction occurring, adequate treatment provision must be available for immediate use:

Anaphylaxis and resuscitation equipment including adrenaline (1 in 1000) injection and a working telephone must be available. In case of anaphylaxis:

- Refer to [adrenaline PGD 0017](#) and [anaphylaxis procedure](#)
- Request medical assistance urgently. If the GP is not immediately available dial 999 to transfer to A&E
- Ensure reaction is fully documented in individual's notes
- Ensure all individual's records are marked **ALLERGIC TO LORATADINE**
- The individual may be advised to wear a MedicAlert or similar device to alert other healthcare providers
- Report via [Datix Once for Wales Reporting system](#)

<p>Records to be kept</p>	<p>Record consultation details as required by local procedures. In addition, record:</p> <ul style="list-style-type: none"> • That valid informed patient consent to treatment was obtained or a decision to treat was made in the individual’s best interests in accordance with the Mental Capacity Act 2005. Record name of representative who gave consent, if appropriate. • Name of individual, address, date of birth. • GP contact details where appropriate. • Relevant past and present medical history, including medication history, known allergies and nature of reaction. • Any reasons for exclusion or referral, including advice given and actions taken. • Examination or microbiology findings, where relevant. • Weight of child, in kg • Printed name and signature of registered health professional responsible for administration. • Date of administration. • Name, form, route, strength and dose of drug administered. • Expiry date. • Details of any adverse reactions and actions taken. • Advice given about the medication including side effects, benefits, and when and what to do if any concerns. • Any advice received from medical cover and advice given to individual / carer. • Record that medication was administered via protocol, record protocol title and version number. <p>Records should be signed and securely kept for a defined period in line with local policy. All records should be clear, legible and contemporaneous.</p> <p>A record of all individuals receiving treatment under this protocol should also be kept for audit purposes in accordance with local policy.</p>
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Patient information

<p>Written/verbal information to be given to individual or carer</p>	<p>Offer PIL (Patient Information Leaflet) and draw the individual/carers’ attention to it. Provide Loratadine for allergy leaflet, if appropriate (if loratadine was administered to a child).</p> <p>Explain indication, contraindications, cautions and potential side effects, as documented in the PIL, plus expected duration of the effect.</p>
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Advise:

- Not to take other antihistamine containing products (including antihistamine containing cough and cold medicines) on the same day that loratadine has been administered.
- On appropriate oral pain relief, if applicable.
- To visit a pharmacy/ GP for a further supply or further investigation/treatment if required.
- That drowsiness can occur and may affect performance of skilled tasks (e.g. cycling or driving).
- To seek medical help if symptoms worsen rapidly or significantly at any time, if symptoms or signs of an infection develop, or the individual becomes systemically unwell.
- To avoid the allergen as much as possible; where possible, identify and manage the underlying [causes/trigger factors](#) of the allergic reaction. (Also refer to [NICE CKS Allergic Rhinitis](#) Causes if appropriate)
- For people with mild urticaria with an identifiable and avoidable cause/trigger, advise that urticaria is likely to be self-limiting without treatment.
- To avoid scratching to minimise inflammation and reduce the risk of infection.

Provide [TARGET self-care leaflet](#) on managing infection, if appropriate.

For individuals with an insect bite or sting:

- Explain that redness, itchiness, or pain and swelling after an insect bite or sting is much more likely to be an inflammatory or allergic reaction rather than an infection, especially when there is a rapid onset- most insect bites and stings can be treated at home with simple first aid.
- Advise to seek medical help if the individual has severe pain out of proportion to the wound, which may indicate the presence of toxin-producing bacteria.
- Advise that skin redness and itching are common and may last for up to 10 days
- Advise on measures to take to avoid future insect bites and stings - provide the individual/carer with appropriate [information](#).
- Provide [information](#) on insect bites and stings from the NHS website.
- Provide the following information: The Anaphylaxis Campaign – [Insect sting allergy- the facts](#)

If bites are thought to be due to infestation with:

	<ul style="list-style-type: none"> • Bedbugs — advise the person to contact their local council or pest control services. Pest control is necessary as bedbugs can be difficult to eradicate and insecticide resistance is common. • Fleas — advise the person that flea bites are often associated with contact with domestic pets (especially cats and dogs) and that animals should be examined and treated if necessary. If the person has recently moved house, flea infestations may remain from previous pet owners. • Lice — see the CKS topics on Head lice and Pubic lice for information on treatment of symptoms and eradication. • Scabies — see the CKS topic on Scabies for information on treatment of symptoms and eradication <p>Where relevant, provide the following information:</p> <ul style="list-style-type: none"> • UKHSA - Tick Awareness <ul style="list-style-type: none"> • NHS A-Z has useful information on Urticaria (hives). • The British Association of Dermatologists (BAD) has produced an information leaflet on Urticaria and Angioedema. • Allergy UK, a national charity dedicated to supporting allergy sufferers in the UK, has a useful factsheet on Urticaria (hives) and other skin allergy. It also has a dedicated helpline.
<p>Follow-up advice to be given to individual or carer</p>	<ul style="list-style-type: none"> • Refer to MIU Clinical Guidelines and NICE guidance relevant to the condition being managed. • Inform individual of possible side effects and their management. • Arrange referral to an allergy specialist for further assessment and management, if appropriate, as advised by NICE CKS (refer to the specific condition being treated) and MIU Clinical Guidelines. • If symptoms do not improve, or worsen, or individual becomes unwell, if there are any signs of unexpected reaction, or any other cause for concern, seek medical advice immediately. Contact GP via surgery or emergency on call service/111 out of hours service or A&E as appropriate.

Key references

- [British National Formulary \(BNF\)](#) and [British National Formulary for Children \(BNFC\)](#) - accessed 13/01/25
- [Summary of product Characteristics \(SPC\)](#) and PILs- available at www.medicines.org.uk accessed 16/01/25
- NICE CKS [Food allergy](#) revised July 2024
- NICE CKS [Angio-oedema and anaphylaxis](#): Non-sedating antihistamines when there is no airway involvement revised in August 2024
- NICE CKS [Urticaria](#) revised in March 2024
- NICE CKS [Allergic rhinitis](#) revised January 2024
- NICE guideline [[NG182](#)] – Insect bites and stings: antimicrobial prescribing, published 22 September 2020
- NICE guideline [[NG141](#)] – Cellulitis and erysipelas: antimicrobial prescribing, published 27 September 2019

Appendix A Staff permitted to use protocol accreditation sheet

Authorising Manager: I confirm that the practitioners named below have declared themselves suitably trained and competent to work under this protocol. I give authorisation on behalf of Powys Teaching Health Board for the named healthcare professionals below who have signed the protocol to work under it.
The authorising manager must use the competency checklist (below).

Practitioner: By signing this protocol you are indicating that you agree to its contents and that you will work within it. Protocols 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 protocol and that I am willing and competent to work to it within my professional code of conduct.

Printed name of registered health professional	Signature of registered health professional	Printed name of senior representative authorising health professional	Signature of senior representative authorising health professional	Date

The authorising manager should retain a copy of the list, which will be required for audit purposes. This list should be kept by PTHB for 25 years after the protocol expires.

The healthcare professional should retain a copy of the document after signing.

Competency check list for manager or senior team lead to use as part of the authorising process for health professionals to work to a protocol. Review of authorisation will take place on each Protocol update and at the individual’s annual PADR.

Name: Role:		Sign / Initial	Further training identified (Y/N) Specify in "comments"	Comments
1	The protocol sign off is for the following protocol:(document the exact title and protocol number) _____			
2	We have discussed the expiry of the protocol and are using a version accessed electronically			
3	The member of staff has the appropriate qualifications and professional registration as outlined in the protocol			
4	The protocol has been read in full by the staff member			
5	The identified training has been completed as specified in the protocol and is in date			
6	We have discussed some examples of inclusion criteria and exclusion criteria			
7	The staff member is confident in the administration method and doses			

Staff member print & sign name		Date
Manager or senior team lead to print & sign name		Date

Please send a copy of this completed form to individual’s line manager, to the staff member, in conjunction with the protocol Appendix A staff accreditation sheet. A copy of this form should also be kept by service lead in the training file.