

Patient Group Direction

For the supply of

Miconazole 2% (20 mg/g) Oral Gel

By registered community pharmacists providing the
NHS Wales Clinical Community Pharmacy Service for
the treatment of oral candidiasis
in Powys Teaching Health Board

Operational from: 1st July 2023

Review Date: 31st March 2026

Version number: 1.0

*PGD for the supply of miconazole 20 mg/g oral gel for oral candidiasis as part of the
Community Pharmacy Common Ailments Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026*

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Review date 31/03/2026
Expiry Date 30/06/2026

PGD for the supply of miconazole 20 mg/g oral gel for the treatment of oral candidiasis by pharmacists delivering the Common Ailments Service component of the Clinical Community Pharmacy Service

Reference: Miconazole 20 mg/g oral gel PGD
 Version no: 1.0
 Valid from: 1st July 2023
 Review date: 31st March 2026
 Expiry date: 30th June 2026

Welsh Medicines Advice Service has developed this PGD for local authorisation

Those using this PGD must ensure that it is authorised by the Local Health Board in which they are operating and signed in section 2 by an appropriate authorising person, relating to the class of person by whom the product is to be supplied, in accordance with the Human Medicines Regulations 2012 (HMR2012)¹. **THE PGD IS NOT LEGAL OR VALID WITHOUT SIGNED AUTHORISATION IN ACCORDANCE WITH HMR2012 SCHEDULE 16 Part 2.**

Authorising organisations must not *alter*, *amend* or *add* to the *clinical* content of this document. Such action will invalidate the *clinical sign-off* with which it is provided.

As operation of this PGD is the responsibility of service providers, the authorising organisation can decide which staff groups, in keeping with relevant legislation, can work to the PGD.

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners and organisations must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date.

Any queries regarding the clinical content of this PGD should be addressed to: welshmedicines.information@wales.nhs.uk

Change history:

Version number	Change details	Date
1.0	Original PGD template developed	26 th January 2023

¹ this includes any relevant amendments to legislation (e.g. [2013 No.235](#), [2015 No.178](#) and [2015 No.323](#)).

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1. PGD development

This PGD has been developed and peer reviewed by an expert panel and approved by the Community Pharmacy Clinical Advisory Group in accordance with the PGD Policy.

This section MUST REMAIN when a PGD is adopted by an organisation

Expert panel

Name	Position	Designation
Dianne Burnett	Main author	National Lead Pharmacist Welsh Medicines Advice Service, Cardiff and Vale UHB
Amy David	CPCAG reviewer	Primary Care Pharmacist, Swansea Bay UHB
Richard Evans	CPCAG reviewer	Community Pharmacy Advisor, Aneurin Bevan UHB
Dr Sion James	Medical Reviewer	Deputy Medical Director - Primary Care and Community Services, Hywel Dda UHB.

Date CPCAG approval of PGD: 9th August 2023

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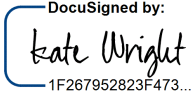
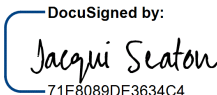
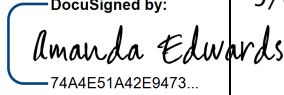

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2. Organisational authorisations

The PGD is not legally valid until it has had the authorisation of the Local Health Board in which the community pharmacy using it operates.

It is the responsibility of the Local Health Board, to ensure that all legal and governance requirements are met. The Local Health Board accepts governance responsibility for the appropriate use of the PGD.

Powys Teaching Health Board authorises this PGD for use by community pharmacies within its area that have been commissioned to provide the Common Ailments Service component of the Clinical Community Pharmacy Service. This authorisation is limited to those pharmacists that meet the requirements set out within the PGD.

Local Health Board approval (legal requirement) as per health board policy			
Role	Name	Sign	Date
Lead Doctor for PTHB	Dr Kate Wright	 DocuSigned by: <i>Kate Wright</i> 1F267952823F473...	9/4/2023
Chief Pharmacist for PTHB	Jacqui Seaton	 DocuSigned by: <i>Jacqui Seaton</i> 71E8089DE3634C4...	8/23/2023
Clinical Governance Lead for PTHB	Amanda Edwards	 DocuSigned by: <i>Amanda Edwards</i> 74A4E51A42E9473...	9/6/2023
Senior Pharmacist Lead for Community Pharmacies, PTHB	Emlyn Pritchard	 DocuSigned by: <i>Emlyn Pritchard</i> EB776BA7283F49B...	8/24/2023

Local enquiries regarding the use of this PGD may be directed to welshmedicines.information@wales.nhs.uk

[Appendix B](#) provides a practitioner listing sheet. Individual practitioners must be listed by name to work to this PGD. Alternative practitioner listing sheets may be used where appropriate in accordance with local policy, but this should be an individual agreement or a multiple practitioner listing sheet as included at the end of this PGD.

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3. Characteristics of Staff

Qualifications and professional registration	This PGD is for use by pharmacists currently registered with the General Pharmaceutical Council (GPhC).
Additional requirements	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ be employed by, or providing services on behalf of a pharmacy listed in the All Wales Pharmacy Database (AWPD) for the Clinical Community Pharmacy Service. ➤ be authorised by name as an approved practitioner under the current terms of this Patient Group Direction before working to it by completing Appendix B. ➤ be familiar with the medicine and alert to changes in the Summary of Product Characteristics (SmPC). ➤ have access to the Patient Group Direction and associated resources (including the service specification and the clinical guidance document supporting the PGD) and must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs). ➤ be named in the All Wales Pharmacy Database for the Common Ailment component of the Clinical Community Pharmacy Service. ➤ have met the training requirements for the service as set out by HEIW (Health Education and Improvement Wales). ➤ be familiar with the British National Formulary (BNF) and SmPC entries for miconazole. ➤ have awareness of the adverse drug reactions associated with miconazole. <p>The pharmacist must be listed by name, under the current version of this PGD that has been issued by the local health board in which area they are operating before working under its authority.</p>
Ongoing training and competency	<p>Pharmacists must:</p> <ul style="list-style-type: none"> ➤ undertake regular CPD and maintain own level of competence and knowledge in this clinical area to provide the service. ➤ be aware of any updates made to the products in the SmPC and BNF. ➤ be aware of any updates to relevant national and local guidelines.

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	<ul style="list-style-type: none"> ➤ as registered professionals, be professionally accountable and must work within their competence. <p>A record of any training and competency assessments undertaken must be maintained.</p>
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4. Clinical condition

Clinical condition or situation to which this PGD applies	For the treatment of oral candidiasis (oral thrush) in accordance with the community pharmacy Common Ailments Service (CAS) component of the Clinical Community Pharmacy Service (CCPS).
Criteria for inclusion	<p>Miconazole 20 mg/g oral gel can be given to individuals aged 4 months and over, presenting with symptoms of oral thrush including white spots or plaques in the mouth which can be wiped off leaving behind red patches, (erythema) loss of taste and:</p> <ul style="list-style-type: none"> ➤ they have an identified risk factor for oral thrush, e.g. <ul style="list-style-type: none"> ○ dentures ○ recent antibiotic or steroid treatment ○ diabetes; treatment can be offered with referral to GP for follow up – see cautions ○ excessive mouth wash use ○ iron, folate or vitamin B12 deficiency ○ smokers ○ babies and the elderly ○ individuals with known immunosuppression except for those listed in the exclusions e.g. individuals taking oral corticosteroids or disease-modifying anti-rheumatic drugs (DMARDs); treatment can be offered with referral to GP for follow up ○ individuals with poor health ➤ they have no contraindications to miconazole – see SmPC ➤ where informed consent has been given (patient, parent/guardian, carer)
Criteria for exclusion²	Miconazole 20 mg/g oral gel should not be supplied:

² Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation for supply will be required.

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(continued over page)	<ul style="list-style-type: none"> ➤ to infants less than 4 months old if born full term ➤ to infants whose swallowing reflex is not yet sufficiently developed ➤ to infants less than 5 to 6 months if born pre-term or infants exhibiting slow neuromuscular development ➤ if the individual has signs of widespread or severe infection e.g. difficulty or pain on swallowing, or retrosternal pain
Criteria for exclusion (continued)	<ul style="list-style-type: none"> ➤ if the individual has a known or suspected pregnancy ➤ if the individual is breastfeeding ➤ if the individual is systemically unwell ➤ if the individual has no obvious risk factor outlined in the inclusion criteria and is otherwise healthy ➤ if the individual has a single red or red and white plaque that cannot be rubbed off (e.g. erythroplakia, erythroleukoplakia) ➤ to individuals with known hypersensitivity to miconazole or any of the excipients – see SmPC ➤ to individuals with known hypersensitivity to imidazoles or other imidazole derivatives ➤ to individuals taking ciclosporin or tacrolimus following a transplant ➤ to individuals receiving chemotherapy ➤ individuals with known immunosuppression but the infection is extensive or severe or there is suspicion that their immunosuppressive treatment e.g. DMARDs are causing marked immunosuppression ➤ to individuals who are HIV positive ➤ to individuals with suspected immunosuppression and not currently receiving treatment ➤ to individuals with liver dysfunction ➤ to individuals with acute porphyria ➤ if the individual is also taking a contraindicated medicine (see drug interactions section) including: <ul style="list-style-type: none"> ● drugs that are known to prolong the QT interval; see BNF for all drugs that can prolong the QT interval,

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(continued over page)	<p>e.g.</p> <ul style="list-style-type: none"> ○ mizolastine ○ dofetilide, sertindole ○ pimozone ○ astemizole ○ cisapride ○ quinidine ○ terfenadine <ul style="list-style-type: none"> ● if the individual takes ergot alkaloids e.g. ergotamine
Criteria for exclusion (continued)	<ul style="list-style-type: none"> ● if the individual takes warfarin, phenindione or acenocoumarol ● if the individual takes triazolam or oral midazolam ● if the individual takes phenytoin ● if the individual takes HMG-CoA reductase inhibitors such as simvastatin and lovastatin <ul style="list-style-type: none"> ➤ if the individual continues to have symptoms despite appropriate treatment for seven days ➤ if the pharmacist is unable to undertake an appropriate assessment, in order to determine the need for the medicine and that it would be appropriate for the patient to use it ➤ to individuals who are unable to administer the product effectively themselves or who do not have a parent/guardian/carer to administer or apply the medication for them ➤ if an individual does not agree to share relevant clinical information
Cautions (including relevant actions to be taken)	<p>Please refer to the SmPC for miconazole for full details of special warnings and precautions for use.</p> <p>Hypersensitivity Reactions</p> <p>In the event of severe acute hypersensitivity reactions, such as anaphylaxis and angioedema, the patient should be advised to consult a doctor immediately.</p>

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(continued over page)	<p>Skin reactions</p> <p>In the event of serious skin reactions e.g. toxic epidermal necrolysis and Stevens-Johnson syndrome, the patient should be advised to discontinue treatment at the first appearance of a skin rash and to consult a doctor immediately.</p> <p>Diabetes</p> <p>Individuals with diabetes can be supplied with treatment if, in the opinion of the pharmacist, there are no concerns or symptoms suggestive of current poor control. For example, thirst, blurred vision, fatigue etc. Provided there are no alarming features, signs or symptoms, treatment can be supplied.</p>
<p>Cautions (including relevant actions to be taken)</p> <p>(continued)</p>	<p>Where treatment is supplied, the individual must be advised to make an appointment with their diabetic clinic/diabetic nurse for review within 7 days of supply.</p> <p>Oral hypoglycaemic agents</p> <p>Miconazole has been shown to prolong the serum half-life of oral sulphonylureas e.g. chlorpropamide, glibenclamide, glipizide, tolbutamide. Concomitant use with miconazole can result in significant hypoglycaemia.</p> <p>Careful monitoring of glucose is recommended.</p> <p>Calcium channel blockers (CCB's)</p> <p>Due to an increased risk of hypotension, caution is advised with the concurrent use of miconazole and CCB's metabolised by CYP3A4 (such as the dihydropyridines e.g. amlodipine, felodipine, nifedipine etc. and verapamil and diltiazem). Advise the individual to contact their GP if they develop signs of low blood pressure, for example: dizziness, light-headedness, fainting, blurred vision, fatigue, nausea.</p> <p>Choking in infants aged 4 months to 2 years</p> <p>With infants and young children caution is required, to ensure the gel does not obstruct the throat. Hence the gel should not be applied to the back of the throat. Each dose should be divided into smaller portions and applied into the mouth with a clean finger. Observe the individual for any choking. Also, due to the risk of choking it must not</p>

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(continued over page)	<p>be applied to the nipple of a breast-feeding mother as a means of administration to an infant.</p> <p>It is important to take into consideration the variability of the maturation of the swallowing function in infants, especially when giving miconazole gel to infants between the ages of 4-6 months. The lower age limit should be increased to 5-6 months of age for infants who were born pre-term, or infants exhibiting slow neuromuscular development. (see exclusion criteria).</p> <p>Alcohol</p> <p>Miconazole oral gel contains small amounts of ethanol (alcohol). The amount in 1 g is equivalent to 1 mL beer or 1 mL wine. The small amount of alcohol present will not have any noticeable effects.</p>
<p>Cautions (including relevant actions to be taken) (continued)</p>	<p>Caution should be exercised if:</p> <ul style="list-style-type: none"> ➤ an individual is trying to conceive, the possibility of pregnancy is ruled out before supplying; pregnancy is an exclusion within the PGD.
<p>Action to be taken if the individual is excluded or declines treatment</p>	<ul style="list-style-type: none"> ➤ Explain the reasons for exclusion to the individual and document in the consultation record. ➤ If the individual declines, record the reason and advise of the consequences of not receiving treatment. Document the advice given alongside details of any referral made and their (patient, parent, guardian) intended actions. ➤ If appropriate, patients may be offered a suitable alternative to miconazole from the All Wales Common Ailment Service Formulary. Alternatively, refer the individual to their GP if appropriate and/or provide them with information about further options. ➤ Where there are safeguarding concerns, seek advice from local safeguarding services. ➤ If the red or red and white plaque cannot be rubbed off, advise the individual to see a dentist.
<p>Further advice</p>	<ul style="list-style-type: none"> ➤ Further information can be found in the SmPC, BNF and the All Wales Common Ailments Service Formulary.

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5. Description of treatment

Name, strength & formulation of drug	Miconazole 20 mg/g oral gel
Legal category	POM
Black triangle ▼	No
Off-label use	No
Route / method of administration	The oral gel should be used in the mouth.
Dose and frequency of administration	<p>Infants 4 months to 24 months of age:</p> <p>1.25 mL (1/4 measuring spoon) of gel to be applied to the affected area(s) FOUR TIMES DAILY after meals.</p> <p>Each dose should be divided into smaller portions and applied with a clean finger.</p> <p>Adults and children 2 years of age and over:</p> <p>2.5 mL (1/2 measuring spoon) of gel to be applied to the affected area(s) FOUR TIMES DAILY after meals.</p> <p>Treatment should be continued for at least 7 days after lesions have healed or symptoms have cleared.</p> <p>Total treatment course: FOURTEEN days.</p>
Duration of treatment	<p>This PGD only allows for the duration stated in the dosage schedule above.</p> <p>Treatment should be continued for at least 7 days after lesions have healed or symptoms have cleared. Total treatment course: 14 days.</p>
Quantity to be supplied/administered	<p>Appropriately labelled pack(s) to provide treatment for 14 days.</p> <p>2 x 80 g pack to provide 14 days treatment for FOUR TIMES A DAY application.</p>
Drug interactions	<p>The following list is not exhaustive. A detailed list of drug interactions can be found in the SmPC and the BNF.</p> <p>Miconazole oral gel is systemically absorbed and known to produce drug interactions.</p>
(continued over page)	

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<p>Drug interactions (continued)</p>	<p>Contraindications</p> <p>Concurrent treatment with:</p> <ul style="list-style-type: none"> ➤ drugs that are known to prolong the QT interval; see BNF for all drugs that can prolong the QT interval, e.g. <ul style="list-style-type: none"> ○ mizolastine ○ dofetilide, sertindole ○ pimozide ○ astemizole ○ cisapride ○ quinidine ○ terfenadine ➤ drugs that are metabolised by the cytochrome P450 system which could be affected by miconazole, e.g. <ul style="list-style-type: none"> ○ ergot alkaloids ○ oral anticoagulants – warfarin, phenindione, acenocoumarol ○ phenytoin ○ HMG-CoA reductase inhibitors – simvastatin and lovastatin ○ triazolam, midazolam, alprazolam, ○ ciclosporin, tacrolimus, sirolimus (rapamycin) ○ HIV protease inhibitors such as saquinavir ○ antineoplastic agents such as vinca alkaloids, busulfan and docetaxel ○ carbamazepine, cilostazol, disopyramide, buspirone, alfentanil, sildenafil, rifabutin, methylprednisolone, reboxetine <p>Caution</p> <p>Miconazole should be used with caution in individuals prescribed the following drugs:</p> <ul style="list-style-type: none"> ➤ oral hypoglycaemic agents – sulphonylureas ➤ calcium channel blockers ➤ sodium zirconium cyclosilicate – decreased exposure to miconazole; manufacturer advises separate administration by at
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	least 2 hours
Identification & management of adverse reactions	<p>If the patient experiences any of the following they must discontinue treatment and seek medical help:</p> <ul style="list-style-type: none"> ➤ difficulty breathing or swallowing ➤ sudden swelling of the mouth, face, lips, tongue or throat (severe allergic reaction symptoms) ➤ severe itching of the skin, with a rash or raised lumps, hives or blisters <p>The following side effects have been reported as:</p> <p><u>Very common to common</u> (affecting between 1 in 10 and 1 in 100 patients)</p> <ul style="list-style-type: none"> ➤ Dry mouth, nausea, oral discomfort, vomiting, regurgitation, abnormal tasting product <p><u>Uncommon</u> (affecting between 1 in 100 and 1 in 1000 patients)</p> <ul style="list-style-type: none"> ➤ Loss or abnormal sense of taste <p><u>Not known</u> (cannot be estimated from the available data)</p> <ul style="list-style-type: none"> ➤ Anaphylactic reaction ➤ Hypersensitivity ➤ Choking ➤ Diarrhoea, stomatitis, tongue discolouration ➤ Hepatitis ➤ Angioedema, toxic epidermal necrolysis, Stevens-Johnson syndrome, urticaria, rash, acute generalised exanthematous pustulosis, drug reaction with eosinophilia and systemic symptoms (DRESS) <p>N.B. detailed lists of adverse reactions are available in the SmPC, and the BNE. Prior to issuing medication, please refer to these resources to check that there has been no change to the potential adverse reactions listed above.</p>

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<p>Patient or carer advice/follow up (continued over page)</p>	<p>Supply the marketing authorisation holder's patient information leaflet (PIL).</p> <p>Inform the individual or their carer:</p> <ul style="list-style-type: none"> ➤ that if they get any side effects, to talk to their doctor, pharmacist
<p>Patient or carer advice/follow up (continued)</p>	<p>or nurse and report any suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) by using the Yellow Card reporting scheme. This includes any possible side effects not listed in the PIL.</p> <ul style="list-style-type: none"> ➤ to seek medical advice if their condition deteriorates and/or they become systemically unwell. ➤ to read the PIL before taking the medication. ➤ to visit the NHS website on miconazole for more information. ➤ to administer the product after food. ➤ that for infants 4 months to 24 months of age, each dose should be divided into smaller portions and the gel applied to the affected area with a clean finger, avoiding the back of the throat. ➤ that once they have administered the gel, to hold in their mouth for as long as possible before swallowing. ➤ if they wear dentures, remove them at bedtime and rub them with the gel using a toothbrush. ➤ that treatment should be continued for at least a week after symptoms have disappeared. ➤ if the individual is immunocompromised or diabetic and treatment is supplied, refer them to their GP for follow up. ➤ of the importance of good dental hygiene. ➤ if they are a smoker, offer advice on smoking cessation. ➤ if they use a steroid inhaler advise the following: <ul style="list-style-type: none"> ○ good inhaler technique. ○ rinsing the mouth with water (or cleaning the teeth) after inhalation to remove drug particles. ○ use a spacer device to reduce the impaction of particles in the oral cavity.

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(continued over page)	<ul style="list-style-type: none"> ○ stepping down the dose of corticosteroid when appropriate and in accordance with the instructions given by their managing healthcare professional. ➤ if the person wears dentures, advise them to: <ul style="list-style-type: none"> ○ leave the dentures out for at least 6 hours in each 24 hour period to promote healing of the gums. ○ if the gums are inflamed, they may benefit from the dentures being left out for longer.
Patient or carer advice/follow up (continued)	<ul style="list-style-type: none"> ○ clean dentures by brushing and then soaking them in a disinfectant solution (for example chlorhexidine or hexetidine) overnight ○ the dentures can be soaked in any solution marketed to sterilize baby's bottles (providing the dentures contain no metal) ○ allow the dentures to air-dry after disinfection — this also kills adherent <i>Candida</i> ○ brush the mucosal surface regularly with a soft brush ○ see a dentist to correct ill-fitting dentures
Records	<p>The consultation details including any medication supplied under the PGD must be recorded in Choose Pharmacy at the time of the consultation. Where the Choose Pharmacy platform is not available, temporary records must be made using the paper-based consultation record. Paper based records must be transferred onto the Choose Pharmacy as soon as practically possible following the consultation.</p> <p>If the patient is excluded, and any specific advice that has been given, a record of the reason for exclusion must be documented within the consultation notes.</p>

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Appendices

Appendix A: Key references

- British National Formulary (BNF) – current edition. Available from: <https://bnf.nice.org.uk/> [accessed 26 January 2023]
- Summary Product Characteristics (SmPC). Available from: <https://www.medicines.org.uk/emc> [accessed 26 January 2023]
- Patient Group Directions. Medicines practice guideline [MPG2]. Updated March 2017. Available from: <http://www.nice.org.uk/guidance/mpg2/resources> [accessed 26 January 2023]
- General Pharmaceutical Council. In Practice: Guidance on Consent. Revised June 2018. Available from: <https://www.pharmacyregulation.org> [accessed 26 January 2023]
- General Pharmaceutical Council. In Practice: Guidance on Confidentiality. Revised June 2018. Available from: <https://www.pharmacyregulation.org> [accessed 26 January 2023]
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- National Institute for Health and Care Excellence: Clinical Knowledge Summaries. Candida – oral. Last revised May 2022. Available from: <https://cks.nice.org.uk> [accessed 26 January 2023]
- Specialist Pharmacy Service. Lactation Safety Information: Miconazole. For oropharyngeal use. Reviewed 22nd September 2020. Available from: <https://www.sps.nhs.uk> [accessed 26 January 2023]
- Yellow Card Reporting. Available from: <http://yellowcard.mhra.gov.uk> [accessed 26 January 2023]
- NHS 111 Wales Health A-Z. Available from: <https://111.wales.nhs.uk> [accessed 26 January 2023]
- NHS Medicines A-Z. Available from: <https://www.nhs.uk> [accessed 26 January 2023]

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Appendix B: *Healthcare Professionals Agreement to Practice*

Authorisation for the use of the Patient Group Direction for the supply of miconazole oral gel by community pharmacists under the Clinical Community Pharmacy Service, Common Ailments Service (oral candidiasis) commissioned by Powys Teaching Health Board

Patient Group Directions do not remove inherent professional obligations or accountability.

Once completed and approved, health professionals wishing to use the PGD must sign up to the PGD for the local health board in which they will be providing services. Only pharmacists who are accredited in line with the National Service Specification can operate under the PGD.

This Patient Group Direction is to be read, agreed and signed by all registered healthcare professionals authorised to operate the PGD. By signing this document, the professional operating the PGD confirms that they have read and understood the content of this PGD and are willing and competent to work under it within their professional code of conduct. One copy should be given to each named pharmacist and a signed copy must be kept within the pharmacy by the nominated member of staff with responsibility for PGDs. This will usually be the Superintendent Pharmacist or Responsible Pharmacist.

Name and address of pharmacy:

For registered professional

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work under it within my professional code of conduct.

Name of registered pharmacist	Signature	GPhC number	Date

*PGD for the supply of miconazole 20 mg/g oral gel for oral candidiasis as part of the
Community Pharmacy Common Ailments Service
Valid from: 1st July 2023 Expiry Date: 30th June 2026*

PGD 0216
Valid From 01/07/2023
Review date 31/03/2026
Expiry Date 30/06/2026