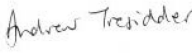



**Patient Group Direction: For the supply of Silver Sulfadiazine 1% Cream by Community Pharmacists in Somerset to patients for the second line topical treatment of minor localised impetigo under the Somerset Minor Ailments Scheme (PGD MAS 6 Version 3.1)**

**Staff involved in the development of this PGD:**

	<b>Name</b>	<b>Signature</b>	<b>Date</b>
Physician	Dr Andrew Tresidder Somerset CCG Prescribing and Medicines Management Group Chair		16.5.22
Pharmacist	Hels Bennett Medicines Manager, Somerset CCG		12.05.2022

**Name of original authors: Catherine Henley, Medicines Manager Somerset CCG and Dr Robert Baker, Consultant Microbiologist, Taunton and Somerset NHS Foundation Trust.**

**Expiry Date: 31<sup>st</sup> May 2024**

**Authorised for use across NHS Somerset CCG by:**

**Kathy French, Interim Director of Quality and Nursing for NHS Somerset CCG (Acting as Clinical Governance Lead)**

Signed  Date 18.05.2022

Date of Implementation: 1<sup>st</sup> June 2022

**Expiry Date: 31<sup>st</sup> May 2024**

**TO BE COMPLETED BY PHARMACY AUTHORISING MANAGER:**

I, ....., as authorising manager for  
 ..... pharmacy, have read and approved this PGD for use by  
 appropriate healthcare professionals employed at my pharmacy. I understand that I am  
 responsible for ensuring that pharmacy staff have adequate training to ensure that **SILVER  
 SULFADIAZINE 1% CREAM** is supplied to patients in strict accordance with this PGD

**Signed.....Dated.....**

**Patient Group Direction: For the supply of Silver Sulfadiazine 1% Cream by Community Pharmacists in Somerset to patients for the second line topical treatment of minor localised impetigo under the Somerset Minor Ailments Scheme (PGD MAS 6 Version 3.1)**

**Expiry Date: 31<sup>st</sup> May 2024**

**The healthcare professionals named below are authorised to supply Sulfadiazine Silver 1% (Flamazine<sup>®</sup>) Cream as specified under this Patient Group Direction, being employees of .....** (INSERT PHARMACY NAME)

In signing this document, I confirm the following:

- I have read and understood the above mentioned PGD.
- I agree to practice only within the bounds of my own competence and in accordance with my Code of Professional Conduct.
- I have the qualifications required under the staff characteristics detailed in the PGD
- I am competent to operate under this PGD.
- I will provide the service in accordance with the PGD

<b>NAME</b> <i>(please print)</i>	<b>TITLE</b>	<b>SIGNATURE</b>	<b>AUTHORISING MANAGER</b> <i>(please print)</i>	<b>MANAGER'S SIGNATURE</b>	<b>DATE</b>

- Complete additional pages as necessary.
- Retain original signed pages (1) and (2) with authorising manager.

**Patient Group Direction: For the supply of Sulfadiazine Silver 1% Cream by Community Pharmacists in Somerset to patients for the second line topical treatment of minor localised impetigo under the Somerset Minor Ailments Scheme (PGD MAS 6 Version 3.1)**

**N.B. You must be authorised by name, under the current version of this PGD before you attempt to work in accordance with it.**

## 1. Clinical Condition

### Definition of condition/situation

Adults and children aged six months and older requiring topical treatment for minor localised impetigo where they are excluded from MAS PGD 5 for the supply of Hydrogen Peroxide 1% cream by Community Pharmacists in the first line treatment of impetigo.

### Criteria for inclusion

Adults and children aged six months and older where all the following criteria are met:

- Informed consent from patient or person with parental responsibility has been obtained. Consider the ethical and legal implications if the biological parent or the child's representative is known or suspected of having no parental responsibility for the child
- Patient is registered with a General Practitioner (GP) in the United Kingdom and gives permission to share relevant information with other healthcare professionals and agencies
- Excluded from MAS PGD 5 for the supply of Hydrogen Peroxide 1% cream by Community Pharmacists in the first line treatment of impetigo
- Small, isolated lesions are visible
- Treatment of impetigo is required

### Off-label use

**The use of silver sulfadiazine is off-label for this indication. The decision to use silver sulfadiazine for the treatment of impetigo has been taken on the advice of local microbiologists. There is good evidence that it is effective. Patients should be made aware of this off-label use in order to give informed consent.**

**Exclusion criteria**

- Consent not obtained
- Children under the age of six months
- Where a course of hydrogen peroxide cream 1% cream has been given and failed
- Impetigo near the eyes - silver sulfadiazine is oculotoxic
- Known or suspected pregnancy
- Individuals presenting with extensive or long-standing impetigo lesions (systemic treatment is more appropriate)
- Patients who are systemically unwell as a result of their impetigo (systemic treatment is more appropriate)
- Impetigo infections extending to mucous membranes, or intranasal areas
- Patients known to be colonised with MRSA
- Patients taking phenytoin or oral hypoglycaemic agents
- Known glucose-6-phosphate dehydrogenase (G6PD) deficiency
- Jaundiced infants
- Known significant hepatic impairment
- Known significant renal impairment
- Any individual who has had a sensitivity reaction to a sulphonamide or silver sulfadiazine
- Known hypersensitivity to any component of the sulfadiazine silver cream or having shown hypersensitivity after previous administration. See SPC for a full list of excipients
- > 10 lesions are present
- Adults where lesions are >10cm in length or, a total surface area >100 cm<sup>2</sup>
- Children under 18 years where area to be treated is >2% body surface area

**Caution**

- If patient is taking any other medications consult the [British National Formulary \(BNF\)](#) for any potential interactions
- Impetigo close to eyes (avoid cream near eyes)
- Lactation (breast feeding) - To be avoided in neonatal period and if there is glucose-6-phosphate dehydrogenase deficiency. Small risk of kernicterus in jaundiced infants and of haemolysis in G6PD-deficient infants. Avoid use on chest area to reduce the risk of ingestion. See SPC and breastfeeding link in references for further information.

**Action if excluded**

- Further explanation to gain consent, if appropriate.
- Refer to patient's GP or relevant healthcare professional as applicable
- If a Patient Medication Record (PMR) is available, it may be useful to document in patient notes.

**Action if patient refuses medication**

- Refer to GP if appropriate

## 2. Characteristics of Staff

<b>Professional qualification to be held by staff working under this Patient Group Direction</b>	Pharmacist registered with the General Pharmaceutical Council (GPhC) and competent to work with this patient group direction (PGD), including familiarity with NICE guidance on PGDs (see references).
<b>Additional requirements</b>	<ul style="list-style-type: none"> <li>• Must have completed initial training and/or be familiar with the current service level agreement for Somerset Minor Ailments Service.</li> <li>• Must only use this PGD in conjunction with the Somerset Minor Ailments Service.</li> <li>• Must have access to a current copy of the BNF</li> <li>• Consultation room available for discussion</li> <li>• The individual pharmacist's competence with respect to their practice under this PGD will be assessed by their mentor/manager on a regular basis.</li> <li>• It is the responsibility of the pharmacist to keep up-to-date with their continued professional development, in line with GPhC requirements;</li> <li>• The pharmacist must be alert to changes in Summaries of Product Characteristics, and Drug Safety Updates from MHRA.</li> </ul>

## 3. Description of Treatment

<b>Name of Medicine</b>	Silver Sulfadiazine 1% Cream
<b>Legal Class</b>	POM (Prescription Only Medicine)
<b>Storage</b>	<ul style="list-style-type: none"> <li>• Store in original packaging to protect from light</li> <li>• Store below 25°C</li> <li>• Patients must dispose of the tube of cream 7 days after opening, even if it is not empty. Waste medicines and topical preparations should be returned to a pharmacy for safe disposal</li> </ul>
<b>Method or route of administration</b>	<ul style="list-style-type: none"> <li>• Topical</li> </ul>
<b>Dose to be used (including criteria for use of differing doses)</b>	<ul style="list-style-type: none"> <li>• Apply a layer of cream to a depth of 3-5mm to the affected area.</li> </ul>
<b>Frequency</b>	<ul style="list-style-type: none"> <li>• Three times a day for five to seven days.</li> </ul>

**Total dose and number of times drug to be given. Details of supply (if supply made)**

- One 50g tube.  
(Labelled in accordance with the *Medicines Act 1968*, as amended)
- Any further supply is outside the scope of this PGD and must be supplied by patient-specific direction (i.e. an NHS FP10 prescription) from an appropriate prescriber.

**Advice and information to patient/carer including follow-up**

- Explain to patient/ carer that use of silver sulfadiazine cream in impetigo is 'off label' however, there is good evidence that it is effective. The decision to use silver sulfadiazine for the treatment of impetigo has been taken on the advice of local microbiologists.
- Inform patient/carer that impetigo is very contagious and advise on self-management strategies – see [NHS Choices Impetigo webpage](#) for further information
- Advise the patient/carer on the importance of regular application and course completion (five to seven days)
- The patient/carer should contact a GP or relevant specialist if there is no improvement or a worsening in the affected area after 2-3 days of treatment
- If impetigo has not resolved after 7 days, further medical advice should be sought.
- The bacteria that causes the infection live under the crusts so it is important to remove the crusts with warm soapy water before each application
- When silver sulfadiazine 1% cream is used on face, take care to avoid the eyes, nasal mucosa, mouth or lips; if the cream accidentally gets on to the eyes, nasal mucosa, mouth or lips, wipe and rinse off immediately
- In the event of local irritation occurring with silver sulfadiazine 1% cream, treatment should be discontinued and the product should be rinsed off. The patient should seek further medical advice regarding a possible alternative therapy
- Patients should be advised to seek urgent medical attention if they develop early symptoms of anaphylaxis such as breathlessness, swelling, and rash
- Concurrent application of other topical medicinal products to the same area of skin has not been studied, and is not recommended
- Children with impetigo should not go to school or nursery until the ointment has been used for at least 48 hours and there are no new blisters or crusts appearing
- Individuals with impetigo who prepare food as part of their job should stay off work for at least one week and until all spots, blisters, and crusts have disappeared and completely healed
- Inform the patient of the possible side-effects and their management (see SPC, current BNF and "Adverse reactions" section below)
- Advise the patient or carer to read the Patient Information Leaflet (PIL) before using the medicine and that the pharmacy can be contacted if any queries

**Adverse effects:** Any serious adverse reaction should be documented e.g. in the consent forms, patient's medical record and the GP should also be informed. Unusual /persistent side effects should be followed up with a medical practitioner.

Common reactions:

- Application site burning and rash (including eczema and contact dermatitis)
- Pruritis

Rare reactions: Argyria (usually after long term use +/- use over large areas)

Very rare reactions: Renal failure

Any **serious** adverse events that may be attributable to silver sulfadiazine 1% cream should be reported to the MHRA using the yellow card system

<https://yellowcard.mhra.gov.uk/> and also follow the local incident reporting procedure.

See the Summary of Product Characteristics (SPC)

<https://mhraproducts4853.blob.core.windows.net/docs/6593ae301137d63e78f119d695bf4b24aa71cd8f> and the current edition of the BNF for full details and updates.

**Specify method of recording supply /administration including audit trail**

It is a legal requirement to keep auditable records of administration and supply of medication via a PGD.

Information entered into a patient clinical record should include:

- Patient's name, address and date of birth
- Consent given
- Indication
- Name strength form and pack size of medication supplied
- Date supplied
- Information and advice given to the patient.
- Signature/name and GPhC number of pharmacist who supplied the medication, and name and address of pharmacy
- Details of any drug interactions experienced
- Details of any adverse reactions experienced
- Any patient decline or reason for exclusion
- Record that medicine supplied via Patient Group Direction

The GP practice should be informed of the consultation and supply of medication.

A computer or manual record of all individuals receiving treatment under this Patient Group Direction should also be kept for audit purposes within each pharmacy. Check with employer which method of recording is to be used.

Data must be stored in accordance with Caldicott guidance and the Data Protection Act.

**References used in the development of this PGD:**

- SPC Reference for silver sulfadiazine 1% cream (Flamazine® cream) <https://mhraproducts4853.blob.core.windows.net/docs/6593ae301137d63e78f119d695bf4b24aa71cd8f>
- NICE guideline (NG153) Impetigo: Antimicrobial Prescribing Published 26 February 2020 <https://www.nice.org.uk/guidance/ng153>
- Current edition of BNF <https://bnf.nice.org.uk/drug/silver-sulfadiazine.html#medicinalForms>
- Sulfadiazine Silver and breastfeeding. Is Sulfadiazine Silver compatible with breastfeeding? | E-lactation <https://www.e-lactation.com/en/sulfadiazine-silver-pr/>
- General Pharmaceutical Council [standards](#)
- 'National Institute for Health and Care Excellence. Medicines Practice Guidelines, 'Patient Group Directions' last updated March 2017. <https://www.nice.org.uk/Guidance/MPG2>
- NHS Choices - Impetigo <https://www.nhs.uk/conditions/impetigo/>

**Please refer to the summary of product characteristics for full information**

**This Patient Group Direction is operational from 1<sup>st</sup> June 2022 and expires 31st May 2024**

**Version History**

Version	Date	Brief Summary of Change	Owner's Name
1.0	29/04/2020	PGD MAS 3 amended to bring into line with NICE guidance in treatment on Non-bullous impetigo and to make silver sulfadiazine second line treatment after topical hydrogen peroxide.	Catherine Henley
2.0	13/05/2020	Minor amendments after comments from microbiologists and reviewed and approved by the Somerset Prescribing and Medicines Management Group.	Catherine Henley
3.0	30/03/2022	PGD reviewed and updated. Lactation moved from Exclusion to Caution section. Minor formatting changes. Approved for use by Somerset Prescribing & Medicines Management (PAMM) group.	Hels Bennett
3.1	12/05/2022	Wording on page 2 revised from ' <i>I agree to administer/supply the above preparation in accordance with this PGD</i> ' to ' <i>I will provide the service in accordance with the PGD</i> '	Hels Bennett