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# Shared Care Guideline

## Dapsone – Dermatitis Herpetiformis and other Dermatoses

### Executive Summary

- Dapsone is licensed for use in dermatitis herpetiformis; and is also used in a number of other dermatoses.
- Usual starting dose is 50mg/day. Maximum dose is 300mg/day. Typical maintenance dose is 25-200mg/day.
- Common side-effects are headache; lethargy; and mild haemolysis.
- Serious side-effects include severe haemolysis; agranulocytosis; methaemoglobinaemia; dapsone hypersensitivity syndrome; neuropathy; and hepatitis.
- Contra-indications include G6PD deficiency and severe anaemia.
- Regular monitoring of FBC, Reticulocyte count, and LFT is required.
- The responsibilities of the hospital specialist, GP and patient for this Shared Care Guideline can be found within this document [here](#).

Sharing of care depends on communication between the specialist, GP and the patient or their parent/carer. The intention to share care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy. The doctor/healthcare professional who prescribes the medication has the clinical responsibility for the drug and the consequences of its use. Further information about the general responsibilities of the hospital specialist and GP can be found [here](#).

## 1. Scope

Prescribing and Monitoring of Dapsone by General Practitioners to adult patients (>16 years)

## 2. Aim

To provide advice on safe prescribing and monitoring of Dapsone in dermatology patients.

## 3. Introduction

Dapsone is a sulfone antibacterial and antiprotozoal agent with additional anti-inflammatory properties. Its dermatological **licensed indication** is for dermatitis herpetiformis; and **unlicensed indications** are the following dermatoses: Linear IgA disease; subcorneal pustular dermatosis; hidradenitis suppurativa; vasculitis; pyoderma gangrenosum; severe acneiform eruption; erythema elevatum diutinum; bullous pemphigoid; pemphigus; lupus; granuloma faciale; and Sweet's syndrome).

Related medications include sulfapyridine and sulphamethoxypyridazine, which are sometimes used in cases of dapsone intolerance, but their use is out of the scope of this guideline.

## 4. Abbreviations

- FBC Full blood count
- WCC White cell count
- Hb Haemoglobin
- MCV Mean corpuscular volume
- LFT Liver function test
- U&E Urea and Electrolytes

## 5. Dose and Administration

- Dapsone is available in 50mg and 100mg tablets.
- The typical starting dose is 50mg once daily; increased by 50mg/day at 2 weekly intervals, if required, until the condition is controlled.
- The maximum dose is 300mg daily.
- Once the condition is controlled, decrease daily dose slowly to lowest dose for maintenance. This is usually 25-50mg daily, which can often be continued for a number of years.
- Dapsone may also be used in children from the age of 6 years (dosage typically 1-2mg/kg/day), but this is outside the scope of this guideline.

Further information can be found in the Summary of Product Characteristics [<https://www.medicines.org.uk/emc/product/5768>].

## 6. Adverse Effects

Adverse effects are dose related.

**Common:** Stomach upset (take Dapsone with food or milk if this occurs); anorexia; nausea; vomiting; headache; lethargy; mild haemolysis; methaemoglobinaemia; sulphaemoglobinaemia.

**Infrequent:** Depression; rash; moderate/severe haemolysis; hepatitis; motor/sensory neuropathy.

**Rare:** Agranulocytosis; hypoalbuminaemia; insomnia; psychosis; nephrotic syndrome; reduced fertility.

**Serious Adverse Effects:**

- Dapsone hypersensitivity syndrome (*incidence is 1 in 100; onset is typically 3-6 weeks after starting dapsone; initial symptoms include pruritus, fever and dermatitis*). If these symptoms occur discontinue treatment immediately and contact hospital specialist.
- Haemolytic Anaemia (*Haemolysis can occur any point between 48 hours to 4 weeks from treatment initiation. At a dose of 100-150mg, 80% of patients will experience a fall in Hb by 1g/dl; 10% of patients will experience a fall in Hb by 2g/dl*). Note that patients with a reticulocytosis are more prone to gallstones; may need additional folate supplements; and Hba1c monitoring is unreliable.
- Methaemoglobinaemia (*Peak methaemoglobin levels usually occur two weeks after starting dapsone or after increasing the dose. Methaemoglobin levels are difficult to interpret in a non-overdose situation as tolerance varies between individuals, and signs and symptoms may therefore be more appropriate for monitoring. However, in general: >15% methaemoglobin is associated with central cyanosis; >30% with dyspnoea, dizziness, and headache; and >60% is associated with coma*).
- Agranulocytosis (*incidence is 1 in 300; risk is dose-independent*).
- Hepatitis
- Neuropathy (*rare at doses less than 300mg/day*).

Further information can be found in the current BNF and in the Summary of Product Characteristics [<https://www.medicines.org.uk/emc/product/5768/smpc>].

**7. Cautions**

- Dapsone should be used with caution in patients with cardiac, pulmonary, cerebrovascular, or peripheral vascular disease.
- Dapsone should be used with caution in anaemia. Severe anaemia should be treated before starting Dapsone.
- Dapsone should be used with caution in patients with methaemoglobin reductase deficiency, or with haemoglobin M.
- Dapsone should be used with caution in patients who are exposed to agents capable of causing haemolysis; or conditions associated with haemolysis such as certain infections.
- Refer to the current BNF and SMPC for information regarding pregnancy and lactation. Dapsone is not known to be teratogenic but there is a risk of haemolysis at birth and in breastfed infants.
- Product contains lactose.

Further information can be found in the current BNF and Summary of Product Characteristics [<https://www.medicines.org.uk/emc/product/5768/smpc>].

**8. Contraindications**

- Known hypersensitivity to sulphonamides, sulphones, or any of the excipients.
- Severe / symptomatic anaemia.
- Porphyria.
- (Severe) Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency.

- Hereditary problems of galactose intolerance, the Lapp lactose deficiency, or glucose-galactose malabsorption.

Further information can be found in the current BNF and Summary of Product Characteristics [<https://www.medicines.org.uk/emc/product/5768/smpc>].

## 9. Interactions

- Antiepileptics (fosphenytoin, phenytoin, phenobarbital, primidone) – use with caution due to increased risk of side-effects.
- Antimalarials (chloroquine, primaquine) – use with caution due to increased risk of side-effects.
- Clozapine – contraindicated due to the risk of blood dyscrasias.
- Cimetidine – may increase dapsone levels without increasing haemolysis, and given concomitantly may reduce the initial risk of methaemoglobinaemia.
- Folic acid antagonists (e.g. Methotrexate) - increase in Dapsone levels; increased risk of side-effects.
- Nitrofurantoin – use with caution due to increased risk of side-effects.
- Saquinavir - contraindicated due to the risk of cardiac arrhythmias.
- Probenecid – contraindicated due to increase in Dapsone levels and increased risk of side-effects.
- Rifampicin and rifabutin– use with caution due to decrease in Dapsone levels.
- Sulphonamides – increased risk of haemolysis.
- Trimethoprim and co-trimoxazole– use with caution due to increase in Dapsone levels, increased risk of side-effects. Be alert for evidence of increased dapsone toxicity (methaemoglobinaemia).

Further information can be found in the current BNF and Summary of Product Characteristics [<https://www.medicines.org.uk/emc/product/5768/smpc>].

## 10. Monitoring Standards & Actions to take in the event of abnormal test results/symptoms

### Monitoring:

<b>Pre-Treatment</b>	<ul style="list-style-type: none"> <li>• FBC including differential WCC, MCV, Reticulocyte count</li> <li>• Creatinine, U&amp;E</li> <li>• LFT</li> <li>• G6PD (particularly in patients of Middle and Far Eastern origin)</li> </ul> <p><i>Patients should be advised to how to recognise signs of blood disorders and if present to seek medical attention. These signs are: breathlessness, fever, sore throat, mouth ulcers, rash, bruising/bleeding, light-headedness, or any other signs of infection.</i></p>
<b>Maintenance</b>	<ul style="list-style-type: none"> <li>• FBC including differential WCC, MCV, Reticulocyte count: <i>Weekly for 1 month after a stable dose is reached / from initiation</i> <i>Then monthly for 3 months</i> <i>Then every 3 months for the first year</i> <i>Then every 6 months thereafter</i> <i>Please note FBC should be monitored more closely in patients with HIV disease.</i></li> <li>• LFTs and U&amp;Es every month for 3 months; then 3-6 monthly thereafter</li> </ul>

- Ask at intervals re: paraesthesiae, sensation loss, and weakness

**Action in the event of abnormal test result:**

Test Result	Recommended Action
>2 fold rise in aspartate transaminase (AST), alanine transaminase (ALT) (from upper limit of reference range)	Check for other causes of deranged LFTs including infection / alcohol excess / other medications. If persistently elevated without other obvious cause: suggest stopping dapsone and contacting hospital specialist.
>4 fold rise in aspartate transaminase (AST), alanine transaminase (ALT) (from upper limit of reference range)	<b>Stop dapsone</b> and discuss with hospital specialist immediately.
White cell count <2.5 x 10 <sup>9</sup> /L Neutrophils <1.5 x10 <sup>9</sup> /L Haemoglobin fall of >20g/L from baseline	<b>Stop dapsone</b> and discuss with hospital specialist immediately. Ensure not G6PD deficient.
Platelets <150 x19 <sup>9</sup> /L	Consider other causes; discuss with hospital specialist.
Methaemoglobin >20%	<b>Stop dapsone</b> and discuss with hospital specialist immediately.
Methaemoglobin >30%	<b>Stop dapsone</b> , discuss with hospital specialist immediately, consider treatment in A&E with methylene blue.

**Action in the event of abnormal signs/symptoms:**

Sign / Symptom	Recommended Action
Sore throat / mouth ulcers / fever / pallor	Arrange urgent FBC. Consider stopping dapsone and contacting specialist.
Abnormal purpura / bruising / bleeding / jaundice	<b>Stop dapsone</b> and discuss with hospital specialist. Arrange urgent FBC, Clotting, LFT.
Hypersensitivity reaction (e.g. widespread rash, pruritus, fever)	<b>Stop dapsone</b> and discuss with hospital specialist immediately. Check observations and arrange urgent FBC, LFT, Creatinine, U&E. Likely to need treatment with oral prednisolone.
Light-headedness, headache, fatigue, dyspnoea, bluish-brown lips/skin colour	Check serum methaemoglobin levels.

## 11. Shared Care Responsibilities

### a. Hospital specialist:

- Initiate treatment with dapsone and continue to prescribe and monitor until the dose has been stable for four weeks and the condition is adequately controlled.
- Check the interactions with patient's medications and check there are no contra-indications prior to initiating treatment
- Explain to the patient the need for monitoring and the abnormal signs/symptoms they should be aware of, as listed in this guideline.
- Send a letter to the GP requesting shared care for the patient; include the baseline blood results in this letter.
- Agreement to shared care will be assumed unless the GP advises otherwise (as per shared care guidelines).
- Inform GP of patients who do not attend clinic appointments.
- To provide any advice to the patient/carer/GP when requested.
- Routine clinic follow-up at least 6 monthly.
- Evaluation of any reported adverse effects by GP or patient.
- Send a letter to GP after each clinic appointment ensuring correct dose, most recent blood results, and frequency of monitoring are stated.

### b. General Practitioner:

- Agreement to shared care guideline by the GP.
- Monitor patient/blood tests in line with shared care guideline and recommendations from hospital specialist; recording results in the blood monitoring book.
- Report any adverse events to the hospital specialist, where appropriate.
- Request advice from the hospital specialist when necessary.
- Monitor patient's overall health and well-being.
- Prescribe the drug treatment as described.

### c. Patient or parent/carer:

- Report to the hospital specialist or GP if they do not have a clear understanding of their treatment.
- Patients must not exceed the recommended dose.
- Patients must attend their scheduled clinic and blood test appointments (where relevant).
- Patients must carry their monitoring book and show to GP and/or hospital specialist for review and recording of results.
- Must inform other clinical staff that they are receiving treatment.
- Report any adverse effects to the hospital specialist or GP.
- Share any concerns they have in relation to treatment with dapsone.

## 12. Contact numbers for advice and support

Cambridge University Hospital NHS Foundation Trust		
Specialist	Post	Telephone
Medicines Information Department		01223 217502
Dermatology Specialist	Dermatology specialist sisters	01223 217391

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Nursing Staff		
Dermatology Consultant team	Addenbrooke's Hospital	01223 216501 01223 216459

### 13. Equality and Diversity Statement

This document complies with the Cambridge University Hospital NHS Foundation Trust service Equality and Diversity statement.

### 14. Disclaimer

It is your responsibility to check that this printed out copy is the most recent issue of this document.

### 15. Document Management

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**The information contained in this guideline is issued on the understanding that it is accurate based on the resources at the time of issue. For further information please refer to the most recent Summary of Product Characteristics [<https://www.medicines.org.uk/emc/product/5768/smpc>].**