

## Shared Care Guideline for Stiripentol (GP Summary)

It is essential that a transfer of care only takes place with agreement of the GP and when sufficient information has been received. If the GP does not agree to share care they will inform the Consultant responsible for the patient's care.

Basingstoke,  
Southampton  
& Winchester  
District  
Prescribing  
Committee

Specialist Contact Details	Patient ID Label
Name: _____	Surname: _____
Location: _____	Forename: _____
Date: _____	NHS Number: _____
Tel: _____	Date of Birth: _____

Indications	Adjunctive treatment of Dravet syndrome in children, adolescents and adults as per NICE CG 137. Used in conjunction with clobazam and valproate.
Exclusions	Children less than 3 years of age.
Dose & response	Initially 10 mg/kg daily in 2–3 divided doses, increased weekly up to 50 mg/kg daily in 2–3 divided doses.
Specialist responsibilities	<ol style="list-style-type: none"> <li>To ensure the patient fulfils the criteria for treatment as per NICE guidance.</li> <li>Assess full blood count and liver function tests prior to initiation</li> <li>Prescribe initial treatment until the dose is stable.</li> <li>Adjust the doses of other AEDs as appropriate.</li> <li>Conduct regular follow-up of patient (at least 6 monthly until seizure and dose stability is achieved, then annually thereafter). Advise GP on dosage adjustment and when and how to stop treatment.</li> <li>Respond to requests for advice on patients experiencing adverse effects or events whilst on treatment (see cautions and adverse effects sections below)</li> </ol>
GP Responsibilities	<p><b>Key roles to be undertaken in primary care once a decision to work under shared care is made</b></p> <ol style="list-style-type: none"> <li>Prescribe maintenance dose of stiripentol according to the dose regimen suggested by the specialist.</li> <li>Ensure no drug interactions with concomitant medicines that are added at a later time.</li> <li>Report to and seek advice from the specialist on any aspect of patient care which is of concern and may affect treatment.</li> <li>Report adverse events to the specialist.</li> </ol>
Primary care monitoring	<ul style="list-style-type: none"> <li>Full blood count/Liver function tests 6 monthly - In the result of neutropenia or abnormal liver function tests advice should be sought from the specialist regarding the cessation of therapy.</li> </ul>
Contra-indications	<p>Stiripentol is contraindicated in:</p> <ul style="list-style-type: none"> <li>Those with hypersensitivity to the active substance or to any of the excipients</li> <li>A past history of psychoses in the form of episodes of delirium.</li> </ul>
Cautions	<ul style="list-style-type: none"> <li>Neutropenia may be associated with the administration of stiripentol, clobazam and valproate. Blood counts should be assessed prior to starting treatment with stiripentol. Unless otherwise clinically indicated, blood counts should be checked every 6 months.</li> <li>Stiripentol is not recommended for use in patients with impaired hepatic and/or renal function.</li> </ul>
Important adverse effects & management	<p>The most common adverse effects are nausea, vomiting, aggression, anorexia, ataxia, drowsiness, dystonia, hyperexcitability, hyperkinesia, hypotonia, irritability, sleep disorders, weight loss, neutropenia and less commonly fatigue, photosensitivity, rash, and urticarial.</p> <p>If adverse effects are detected in a primary care setting the specialist should be contacted as soon as possible.</p>
Important drug interactions	<p>The influence of other antiepileptic medicinal products on stiripentol pharmacokinetics is not well established. Stiripentol metabolism is catalysed by a range of cytochrome P450 enzymes and additionally inhibits a variety of these enzymes. Therefore patients should be vigilant for adverse effects when medicines that induce or inhibit cytochrome P450 enzymes, or are metabolised by these enzymes are used. Further information can be sought from the BNF or local medicines advice service.</p> <p>The following medicines should be avoided unless strictly necessary</p> <ul style="list-style-type: none"> <li>Ergot alkaloids</li> </ul>

- Theophylline
- Cisapride, halofantrine, pimozone, quinidine, bepridil
- Immunosuppressants (tacrolimus, cyclosporine, sirolimus)
- Statins

Stiripentol should not be taken with milk or dairy products (yoghurt, soft cream cheese, etc.), carbonated drinks, fruit juice or food and drinks that contain caffeine or theophylline.

**The manufacturer's summary of product characteristics (SPC) and the most current edition of the British National Formulary should be consulted for full information on contraindications, warnings, side effects and drug interactions.**

#### **References**

1. Summary of product characteristics for stiripentol, accessed via [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR - Product\\_Information/human/000664/WC500036518.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000664/WC500036518.pdf)
2. British National Formulary for children Accessed online 19/09/18