**Drug Shortages Bulletin**

**Naftidrofuryl oxalate 100mg capsules**

July 2014

<table>
<thead>
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<th>What products are affected?</th>
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<td>Both generic and branded (Praxilene) naftidrofuryl oxalate 100mg capsules</td>
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**Background**

Naftidrofuryl oxalate exerts direct effects on intracellular metabolism by increasing ATP levels and decreasing lactic acid in ischaemic conditions. It is licensed for the treatment of peripheral arterial disorders such as intermittent claudication, night cramps, rest pain, incipient gangrene, trophic ulcers, Raynaud's syndrome, diabetic arteriopathy and acrocyanosis.

Naftidrofuryl oxalate is used as a component of a wide approach to care of patients with peripheral arterial disease, which includes both pharmacological and non-pharmacological approaches. It relieves symptoms, but does not affect disease progression or reduce cardiovascular risk.

Supervised exercise is the first line is recommended as a first line treatment option. Naftidrofuryl is only recommended in patients who have not had a satisfactory improvement following exercise and who prefer not to be referred for consideration of angioplasty or bypass surgery.

**What is the supply issue?**

There is a shortage of both generic and branded naftidrofuryl oxalate. Supplies are expected to resume in September 2014.

**What are the implications for patient care?**

Patients may have to be switched onto an alternative. This may have cost implications and may lead to distress for patients. People who hold bus, coach, or lorry licenses may need to inform the DVLA if their condition worsens.

**What are the available management options?**

- **Consider a trial withdrawal of treatment**
  The shortage may be a useful opportunity to review treatment efficacy and tolerability and to ensure that non-pharmacological management (lifestyle and exercise) is optimised. A trial withdrawal of treatment may be possible in patients who have stable peripheral arterial disease or Raynaud's phenomenon, particularly given the warmer weather.

- **Switch to an alternative agent**
  There is no direct equivalent available for naftidrofuryl. Cilostazol, inositol and pentoxyfylline may be considered alternatives, though they are not approved for use by NICE as they appear to be less effective than naftidrofuryl. Of these options, cilostazol 50mg and 100mg tablets appears to be the preferred option for use by some secondary care specialists. These alternatives may be considered “red” or “restricted” drugs in some local formularies. They may be reallocated as green drugs for the duration of the shortage, depending on local decisions.

Valid for six months from time of writing.
For Raynaud’s phenomenon, a trial of nifedipine may be considered instead.

Patients will need to be carefully monitored if a switch in therapy occurs.

- **Seek advice from a specialist**
For complex or severe cases, such as those with rest pain, incipient gangrene, trophic ulcers, or cerebral vascular disease, advice should be sought from a specialist vascular team.

### What is the preferred management option?
It is difficult to provide one specific management option for all patients who require naftidrofuryl oxalate treatment. Choice of management option should depend on what is being treated, individual patient factors and a pragmatic approach. Specialist advice should be sought where necessary.

### References
- Summary of Product Characteristics: Praxilene (Naftidrofuryl) 100mg capsules – Merck Serono (last updated on the eMC 14/03/2014)
- Summary of Product Characteristics: Naftidrofuryl capsules 100mg–Actavis UK Ltd (last updated on the eMC 22/12/2010)
- Clinical Knowledge Summaries: Raynaud’s Phenomenon. Last revised April 2014.
- Clinical Knowledge Summaries: Peripheral arterial disease. Last revised April 2014.
- Communication with Merck Serono 25th June 2014
- Lincolnshire Prescribing and Clinical Effectiveness Bulletin May 2014; 8(9): 10-11

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We welcome your feedback.

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