



National Institute for Health and Clinical Excellence

Tel: 0845 003 7782

www.nice.org.uk

Ref: 2011/086

ISSUED: Wednesday 25 May 2011

PRESS RELEASE

NICE recommends naftidrofuryl oxalate for the treatment of painful symptoms of peripheral arterial disease

The National Institute for Health and Clinical Excellence (NICE) has today issued final guidance recommending naftidrofuryl oxalate as an option for the treatment of people who have intermittent claudication caused by peripheral arterial disease and for whom vasodilator therapy is considered appropriate after taking into account other treatment options.

Peripheral arterial disease is a condition in which there is a blockage or narrowing of the arteries that carry blood to the legs and arms caused mainly by fatty deposits on the arterial walls. Intermittent claudication, and the pain associated with it, is a result of muscles being starved of oxygen. Pain is relieved with rest. As well as having a detrimental impact on quality of life, intermittent claudication also indicates that there is an increased risk of heart attack and stroke. Additionally, people with intermittent claudication are at higher risk of dying from a heart attack or stroke than patients with PAD who do not have symptoms.

Self-help measures, including lifestyle changes such as quitting smoking, taking regular exercise and eating a healthy diet, are the most important components in reducing the chance of developing peripheral arterial disease. However, for some people the severe pain that is often associated with intermittent claudication means that their ability to engage in regular exercise, particularly walking, can be severely limited. Although it does not halt the progress of peripheral arterial disease, naftidrofuryl oxalate has been shown to be the most clinically and cost effective

treatment option for people with the condition in terms of improving maximum walking distance.

Dr Carole Longson, Health Technology Evaluation Centre Director at NICE, said: “We’re pleased to recommend naftidrofuryl oxalate as an option for treating intermittent claudication, a condition that can have a significant impact on an individual’s life, including loss of independence, employment and social activities. Naftidrofuryl oxalate is one of four drugs, often referred to as vasodilators, that NICE assessed as part of this appraisal. Vasodilators relax the smooth muscle in blood vessels, which causes the vessels to dilate and therefore increases blood supply to the muscles. The evidence considered by the Appraisal Committee showed that the others – cilostazol, pentoxifylline and inositol nicotinate – are not as clinically effective compared with placebo as naftidrofuryl oxalate. Only naftidrofuryl oxalate was shown to be a cost-effective treatment option.”

As well as a branded preparation (Praxilene, Merck Serono), naftidrofuryl oxalate is also available as a cheaper, generic preparation; the final guidance recommends that treatment should be started with the least costly preparation. The guidance ‘Cilostazol, naftidrofuryl oxalate, pentoxifylline and inositol nicotinate for the treatment of intermittent claudication in people with peripheral arterial disease’ is available at: <http://guidance.nice.org.uk/TA223>.

Ends

For more information, please call the NICE press office on 0845 003 7782 or (out of hours) 07775 583 813.

Notes to Editors

About the guidance

1. Naftidrofuryl oxalate is an oral peripheral vasodilator that selectively blocks vascular and platelet 5-hydroxytryptamine 2 (5-HT₂) receptors. It has a UK marketing authorisation for peripheral vascular disorders, including intermittent claudication. Naftidrofuryl oxalate is available as a branded preparation of 100mg capsules at a cost of £8.10 (excl VAT) for a 84-capsule pack. Generic preparations are also available at a cost of £5.30 (excl VAT) for a 100mg 84-capsule pack and since January 2011 at a cost of £4.52 (excluding VAT; BNF edition 61) for a 100 mg 84-capsule pack.. The recommended dose is one or two 100mg capsules three times daily. Therefore, for the branded preparation the average monthly cost is £8.80 assuming three 100mg capsules daily or £17.60 assuming six 100mg capsules daily. For the generic preparation (that is at a cost of £5.30, excluding VAT; BNF edition 60) the average monthly cost is £4.90 for three 100 mg capsules daily or £9.79 assuming six 100 mg capsules daily. Costs may vary in different settings because of negotiated procurement discounts.

2. Cilostazol (Pletal, Otsuka Pharmaceuticals) is an oral phosphodiesterase III inhibitor. Cilostazol is a direct arterial vasodilator and it also inhibits platelet aggregation. Cilostazol has a UK marketing authorisation for the 'improvement of the maximal and pain-free walking distances in patients with intermittent claudication, who do not have rest pain and who do not have evidence of peripheral tissue necrosis (peripheral arterial disease Fontaine stage II)'. Cilostazol is available as a 100 mg tablet at a cost of £35.31 (excl VAT) for a 56-tablet pack. The recommended dose is 100 mg twice daily. Therefore, the average monthly cost is £38.26.
3. Pentoxifylline (Trental 400, Sanofi-Aventis) is an oral peripheral vasodilator derived from methylxanthine. Pentoxifylline has a UK marketing authorisation for the 'treatment of peripheral arterial disease, including intermittent claudication and rest pain'. Pentoxifylline is available as a 400 mg tablet at a cost of £19.68 (excl VAT) for a 90-tablet pack. The recommended dose is one tablet three times daily. Therefore, the average monthly cost is £19.90. However, the summary of product characteristics states that two tablets daily may prove sufficient in some patients, particularly for maintenance therapy.
4. Inositol nicotinate (Hepoxal, Genus Pharmaceuticals) is an oral peripheral vasodilator that slows the release of nicotinic acid. Inositol nicotinate has a UK marketing authorisation for 'the symptomatic relief of severe intermittent claudication and Raynaud's phenomenon'. It is available as a 500 mg tablet at a cost of £30.76 for a 100-tablet pack. It is also available as a 750 mg tablet at a cost of £51.03 (excl VAT) for a 112-tablet pack. The recommended dose is 3 g daily (that is, two tablets three times a day), increased to 4 g daily if necessary. The average monthly cost, assuming two 500 mg tablets three times a day, is £56.14.

About NICE

1. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance and standards on the promotion of good health and the prevention and treatment of ill health
2. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments, medical technologies (including devices and diagnostics) and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.
3. NICE produces standards for patient care:
 - **quality standards** – these reflect the very best in high quality patient care, to help healthcare practitioners and commissioners of care deliver excellent services
 - **Quality and Outcomes Framework** – NICE develops the clinical and health improvement indicators in the QOF, the Department of Health scheme which rewards GPs for how well they care for patients
4. NICE provides advice and support on putting NICE guidance and standards into practice through its **implementation programme**, and it collates and accredits high quality health guidance, research and information to help health professionals deliver the best patient care through **NHS Evidence**.