

## LIDOCAINE plaster 5% (Ralvo<sup>®</sup>, Versatis<sup>®</sup>) in adults and children in primary care

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**The Pan Mersey Area Prescribing Committee does not recommend the prescribing of lidocaine plaster 5% (Ralvo<sup>®</sup>, Versatis<sup>®</sup>), except in limited circumstances outlined below.**

**LIDOCAINE PLASTERS ARE DESIGNATED BLACK.** NHS England guidance "[Items which should not routinely be prescribed in primary care: Guidance for GPs](#)" advises <sup>(1)</sup> that:

- Prescribers in primary care should not initiate lidocaine plasters for any new patients, unless for post-herpetic neuralgia (PHN) as described below and should be supported in deprescribing lidocaine plasters in all patients.
- Where there are exceptional circumstances with a clinical need for lidocaine plasters to be prescribed in primary care this should be undertaken in a cooperation arrangement with a multi-disciplinary team and / or other healthcare professional.

**GREEN**

The Pan Mersey Area Prescribing Committee recommends the prescribing of lidocaine plaster 5% (Ralvo<sup>®</sup>, Versatis<sup>®</sup>) **for post-herpetic neuralgia (PHN), ONLY in patients who have been treated in line with [NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings](#)<sup>(2)</sup> but are still experiencing neuropathic pain associated with previous herpes zoster infection<sup>(1)</sup>. Review: Where GP has initiated treatment for PHN they must review the patient for effectiveness after 2 – 4 weeks to ensure the patient has gained worthwhile clinical benefit. Re-assess treatment at regular intervals e.g. every 6 months<sup>(3)</sup>.**

**AMBER INITIATED**

The Pan Mersey Area Prescribing Committee recommends the prescribing of lidocaine plaster 5% (Ralvo<sup>®</sup>, Versatis<sup>®</sup>) **for neuropathic pain ONLY following pain specialist or palliative care specialist initiation, and ONLY in the limited circumstances as described below:**

- Patients who have been treated in line with [NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings](#)<sup>(2)</sup> but are still experiencing neuropathic pain (off-label indication). Consideration must be given to protecting sensitive areas by applying a protective layer, e.g. cling film or a plastic wound dressing such as Opsite<sup>®</sup> <sup>(3)</sup> instead of using lidocaine plaster.

- **OR** patients with neuropathic pain who are physically unable to take oral medication because of medical conditions and/or disability.

Review: A review of effectiveness at 2 – 4 weeks must be carried out by the specialist who must prescribe until review occurs. This is to ensure the patient has gained worthwhile clinical benefit, and where insufficient benefit has been gained prescribing must be discontinued. Where worthwhile clinical benefit has been obtained the specialist may request the patient's GP to continue prescribing. They must provide the GP and patient with a full explanation of why lidocaine plaster is necessary (and is off-label use) and provide a further prescription sufficient to supply the patient for the time period prior to their communication reaching the GP and patient obtaining their first prescription from their GP. GP to re-assess regularly e.g. every 6 months<sup>(3)</sup>. See: [Pan Mersey Pharmacological Management of Chronic Pain in Children](#) for use in paediatrics.

**De-prescribing** Review patients prescribed lidocaine plasters in circumstances outside of the above recommendations, with a view to discontinuing them wherever possible. Where the person needs continued treatment, consider alternative treatments appropriate to the indication. **See Implementation Notes overleaf.**

**Note:** Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

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<p><b>EFFECTIVENESS</b></p> <p>Lidocaine plaster is only licensed for post-herpetic neuralgia (PHN). Evidence for the effectiveness of lidocaine plasters is weak and limited<sup>(3)</sup>. A 2014 Cochrane review<sup>(3)</sup> found no evidence from good quality randomised controlled trials (RCTs) to support the use of topical lidocaine to treat neuropathic pain in adults. All 12 studies in the review were judged to be at high risk of bias because of the small size or incomplete outcome assessment, or both. Very low-quality evidence indicated that lidocaine was better than placebo for some measures of pain relief, in all but one study (which showed no difference between topical lidocaine and placebo). For NICE CG173<sup>(4)</sup> on the management of neuropathic pain in non-specialist settings, data from one double-blind crossover RCT (n=28) that compared lidocaine plasters with placebo for post-surgical neuropathic pain after surgery for cancer was considered. No significant intergroup differences were detected in pain intensity ratings. NICE CG 173 does not make a recommendation about the use of lidocaine plasters for neuropathic pain. This is because the Guideline Development Group (GDG) felt that there was not enough evidence<sup>(4)</sup> on lidocaine that met the review protocol inclusion criteria to warrant a specific recommendation.</p>	<p><b>SAFETY<sup>(5)</sup></b></p> <p>One of the lidocaine metabolites, 2,6 xylidine, has been shown to be genotoxic and carcinogenic in rats. Secondary metabolites have been shown to be mutagenic. The clinical significance of this finding is unknown. Consequently, long term treatment is only justified if there is a therapeutic benefit for the patient. The most commonly reported adverse reactions are administration site reactions (such as burning, dermatitis, erythema, pruritus, rash, skin irritation, and vesicles). Approximately 16% of patients can be expected to experience localised reactions. See <a href="#">SmPC</a> for full contraindications and adverse effects</p>
<p><b>COST</b> (Dictionary of medicines and devices, NHSBSA, accessed 01/05/2018)</p> <p>1 - 3 plasters applied for up to 12 hours out of every 24 hours: Versatis<sup>®</sup>: £67.48 - £202.44 per 28 days Ralvo<sup>®</sup>: £57.40 - £172.20 per 28 days (Each plaster covers 10 x 14cm area)</p> <p>Current annual expenditure in Pan Mersey area is £2 million. Seven out of the nine Pan Mersey CCGs are in the top 12 highest prescribing CCGs in England (as cost per 1000 patient population)</p>	<p><b>PATIENT FACTORS</b></p> <p><u>Self-care advice:</u> Wear loose clothing or cotton fabrics, which usually cause the least irritation. Consider protecting sensitive areas by applying a protective layer, e.g. cling film or a plastic wound dressing such as Opsite<sup>®</sup>. Consider frequent application of cold packs (unless allodynia is triggered by cold). Pain relief can include paracetamol with or without codeine<sup>(3)</sup>.</p>

**PRESCRIBING INFORMATION** GPs must ensure that where the specialist has reviewed the effectiveness of lidocaine plaster, that they have received a full explanation of why the choice of lidocaine plaster is necessary and that this fits the criteria overleaf, before taking over prescribing of lidocaine plaster from the specialist. Plasters may be cut into smaller sizes with scissors, so consideration should be given to this where area to be treated allows this.

**IMPLEMENTATION NOTES.**

**De-prescribing should be the default for all patients** unless they fall into the specific categories overleaf. The preferred option would be for patients to have a 'trial without' to assess ongoing need. If pharmacological treatment is still required, then consider alternative therapy appropriate to the indication.

Alternatively, the following options could be considered:

- A trial of un-medicated physical protection (with cling film or a suitable dressing)
- Reduction in number of plasters, cutting plasters to smaller size where possible
- Increase in the interval between plasters
- Detailed information on reviewing existing patients is available from PrescQipp<sup>(6)</sup>, contact the local Medicines Management team for details.

**REFERENCES**

1. NHS England "[Items which should not routinely be prescribed in primary care: Guidance for GPs](#)" March 2018
2. National Institute for Health and Care Excellence. Clinical Knowledge Summary, [Neuropathic pain – drug treatment](#). Last updated June 2015
3. Presquipp: [Lidocaine Plasters](#) Nov. 2017
4. [NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings](#) November 2013
5. [SmPC, Versatis](#) accessed 01/05/2018
6. PrescQipp. [Lidocaine plasters \(DROP list\)](#), Nov. 2017
7. British Pain Society. [Position statement on lidocaine plasters](#). Aug. 2018