

## Lidocaine plasters (DROP-List)

This is one of a number of bulletins providing further information on medicines that should be given low priority, are poor value for money, are suitable for self care or for which there are safer, more suitable alternatives. This guidance will support Clinical Commissioning Groups (CCGs) in taking action on items that should not routinely be prescribed in primary care or on the NHS. Further bulletins, including the overarching low value medicines information bulletin are available on the PrescQIPP website: <https://www.prescqipp.info/drop-list/headline-areas/the-prescqipp-drop-list#low-value-medicines-lvm>

This bulletin focuses on lidocaine plasters; it provides the rationale for not initiating lidocaine plasters in new patients and for them to be reviewed and considered for discontinuation in current patients. Information on licensed usage, clinical effectiveness and options for alternative treatments are provided.

### Recommendations

- Ensure that the prescribing of lidocaine plasters is restricted to people diagnosed with post-herpetic neuralgia, in whom alternative treatments are contraindicated, not tolerated, or ineffective.
- Current National Institute for Health and Care Excellence (NICE) guidance does not make a recommendation about the use of lidocaine plasters for neuropathic pain, as only very limited evidence on this treatment met their inclusion criteria. For neuropathic pain, NICE recommend:
  - » Amitriptyline, gabapentin, pregabalin or duloxetine for initial treatment (note that none of the duloxetine studies considered by NICE were in people with post-herpetic neuralgia).
  - » Consideration of capsaicin cream for those with localised neuropathic pain who wish to avoid, or who cannot tolerate, oral treatments.<sup>1</sup>
- Local guidance that includes the management of post-herpetic neuralgia should be developed if it is not currently available. It should address sequential strategy of treatments and advise whether generic or branded prescribing (of the less costly Ralvo® brand) of lidocaine plasters is recommended.
- Do not initiate lidocaine plasters in new patients for unlicensed indications.
- Review patients prescribed lidocaine plasters for unlicensed indications, with a view to discontinuing them wherever possible. Where the person needs continued treatment, consider alternative treatments appropriate to the indication.
- Address peoples' expectations of treatments for neuropathic pain (and other types of chronic pain) at an early stage. Medication is unlikely to completely eliminate pain. Realistic treatment expectations should focus on reducing pain and maintaining function, with a view to improving quality of life.<sup>2</sup>
- Where lidocaine plaster treatment is considered appropriate:
  - » Ensure treatment is used correctly and that people have at least a 12 hour treatment free period every 24 hours.
  - » Ensure treatment is reviewed at four weeks and discontinued if it is ineffective.<sup>3,4</sup>
  - » With longer-term use, reassess treatment at regular intervals, e.g. every six months.<sup>5</sup>
  - » Include an assessment of pain control, impact on lifestyle and daily activities (including sleep disturbance), physical and psychological wellbeing, adverse effects and continued need for treatment.<sup>1</sup>
  - » Consider attempting to reduce the number of plasters used or increase the interval between plasters.<sup>3,4</sup>
  - » Consider a 'trial without' to assess ongoing need. A trial of unmedicated physical protection (with cling film or a suitable dressing)<sup>6</sup> is also an option.

## Background

In England and Wales, in excess of £25 million is spent annually on lidocaine plasters (ePACT Feb 2017 - April 2017). Reducing the use of lidocaine plasters by discontinuing inappropriately prescribed treatment has the potential to release significant savings. As with all medication changes, individual patient circumstances need to be considered. However, with tight discontinuation criteria, assistance from practice nurses, support from local CCG medicines management teams and the input of relevant specialist teams (e.g. local pain specialists) where appropriate, it is hoped that GPs will review patients accordingly and realise the cost savings.

## Licensed use

Post-herpetic neuralgia is a type of neuropathic pain that occurs when the pain associated with shingles becomes chronic. Symptoms may include constant or intermittent stabbing or burning pain, allodynia (pain induced by a non-painful stimulus), hyperalgesia (severe pain from a mildly painful stimulus), and intense itching. Symptoms can resolve after a few months, or may persist for longer.<sup>6</sup>

Lidocaine plasters are available under the brand names Versatis® and Ralvo®. The Marketing Authorisation for both is held by Grünenthal Limited. Both brands are the same strength and contain 700 mg lidocaine per plaster (5% w/w). Both are licensed for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia) in adults.<sup>3,4</sup> They are not licensed for any other indication.

According to the manufacturer, lidocaine plasters have a dual mode of action. The lidocaine component is thought to provide a local analgesic effect by stabilisation of neuronal membranes. The hydrogel plaster itself provides physical protection to the hypersensitive area.<sup>3,4</sup>

Up to three plasters can be applied to a painful area once daily for a maximum of 12 hours within a 24 hour period.<sup>3,4</sup> The product information does not explain why each plaster should be worn for no longer than 12 hours at a time, and it is not clear from published trials whether this results in breakthrough pain during the plaster-free time.<sup>7</sup>

Treatment outcome should be re-evaluated after two to four weeks. If there has been no response during the wearing time and/or during the plaster-free interval, treatment must be discontinued as potential risks may outweigh benefits. Treatment should be reassessed at regular intervals to decide whether the amount of plasters needed to cover the painful area can be reduced, or if the plaster-free period can be extended. The manufacturer does not specify a time-frame for such reassessment.<sup>3,4</sup> Six monthly intervals may be an appropriate starting point,<sup>5</sup> which should be individualised where necessary.

## National guidance

### Management of post-herpetic neuralgia

Self-care advice for those with post-herpetic neuralgia includes the following:

- 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®.
- Consider frequent application of cold packs (unless allodynia is triggered by cold).<sup>6</sup>
- Pain relief for post-herpetic neuralgia can include paracetamol with or without codeine.<sup>6</sup>

If pain remains uncontrolled, a drug used to treat neuropathic pain may be offered. In their guidance on the management of neuropathic pain, NICE recommend amitriptyline, gabapentin, pregabalin or duloxetine for initial treatment (but note that none of the duloxetine studies considered by NICE were in people with post-herpetic neuralgia). When agreeing a treatment plan, the severity of the pain and its impact on the person's lifestyle and daily activities (including sleep disturbance) should be

considered.<sup>1</sup> For further information about treatments for neuropathic pain see PrescQIPP Bulletin 119 on Neuropathic pain: Pregabalin and gabapentin prescribing. Local guidance should be consulted where it is available to ensure that treatments are prescribed at an appropriate place in therapy.

It is important for health professionals to address expectations of treatments for neuropathic pain (and other types of chronic pain) at an early stage. People should be aware that medication is unlikely to completely eliminate pain.<sup>2</sup> Clinical trials of chronic pain treatments might consider 30% and 50% pain relief over baseline as 'moderate' and 'substantial' benefit, respectively.<sup>8</sup> Realistic treatment expectations should focus on reducing pain and maintaining function, with a view to improving quality of life.<sup>2</sup>

Some treatments require dose titration, and it can take time to titrate up to an effective dosage. This should be discussed with people when starting treatment, as should the possible adverse effects of the individual neuropathic pain drugs.<sup>9</sup> It is important to ensure that people understand when treatments are unlicensed and that informed consent is given.<sup>1</sup>

Tramadol may be considered as acute rescue therapy while people are awaiting referral to specialist pain services after initial treatment has failed.<sup>1</sup>

Capsaicin cream may be considered for those with localised neuropathic pain who wish to avoid, or who cannot tolerate, oral treatments.<sup>1</sup> Do not confuse capsaicin cream with capsaicin patches; they are not interchangeable. Capsaicin patches contain a high dose of capsaicin. Application and removal needs to be done under special conditions by a suitably trained healthcare professional.<sup>10</sup>

In some people, the severity of the pain or the limitations it causes mean that referral (to a specialist pain service or a condition-specific service) is appropriate.<sup>6</sup>

## Role of lidocaine plasters

Current NICE guidance on the management of neuropathic pain in non-specialist settings (Clinical Guideline 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 on lidocaine that met the review protocol inclusion criteria to warrant a specific recommendation.<sup>11</sup> A research recommendation on the efficacy and tolerability of topical lidocaine in neuropathic pain was made.<sup>1</sup>

This is in contrast with previous NICE guidance, Clinical Guideline 96 on neuropathic pain in non-specialist settings (March 2010). This guidance had suggested that topical lidocaine could be considered as a third line therapy for localised neuropathic pain (unlicensed use if not post-herpetic neuralgia) for those unable to take oral medication because of medical conditions and/or disability, while they wait for a referral to specialist services.<sup>12</sup>

In 2008 the Scottish Medicines Consortium (SMC) accepted lidocaine plasters for restricted use within NHS Scotland. It is accepted for the treatment of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia). Use is restricted to those intolerant of first-line systemic therapies for post-herpetic neuralgia or where these therapies have been ineffective. The SMC noted that comparative data for lidocaine plasters are limited, and comparative clinical effectiveness was unclear.<sup>13</sup>

## Clinical effectiveness

### Neuropathic pain - placebo-controlled studies

Evidence for the effectiveness of lidocaine plasters is weak and limited. A 2014 Cochrane review found no evidence from good quality randomised controlled trials (RCTs) to support the use of topical lidocaine to treat neuropathic pain in adults.<sup>8</sup> The review included randomised, double-blind studies of at least two weeks' duration comparing topical lidocaine (plaster, cream, gel or spray) with placebo or another active treatment in chronic neuropathic pain. Twelve studies (508 participants) were identified:

- Six studies enrolled participants with moderate or severe post-herpetic neuralgia, four of which investigated the lidocaine 5% plaster formulation (Binder 2009,<sup>14</sup> Galer 1999,<sup>15</sup> Galer 2002<sup>16</sup> and Rowbotham 1996<sup>17</sup>).
- Six studies enrolled different, or mixed, neuropathic pain conditions, including trigeminal neuralgia and post-surgical or post-traumatic neuralgia.

All 12 studies 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).<sup>8</sup>

For NICE CG173, the GDG considered data from one double-blind crossover RCT (n=28) that compared lidocaine plasters with placebo for post-surgical neuropathic pain after surgery for cancer.<sup>1</sup> No significant intergroup differences were detected in pain intensity ratings.<sup>18</sup>

The 4 studies of lidocaine plasters in post-herpetic neuralgia included in the Cochrane review above did not form part of the evidence base for NICE CG173. These studies were excluded by NICE either because they used an enriched design (Binder 2009, Galer 1999) or had a study period of less than four weeks (Galer 2002, Rowbotham 1996).<sup>1</sup> In the enriched design studies, those randomised into the study had already been identified as responders to lidocaine plaster treatment.<sup>14,15</sup>

A double-blind RCT comparing lidocaine plaster and placebo was performed to search for phenotype differences in effect. It was hypothesised that a pain-relieving effect would mainly or only be seen in the irritable nociceptor group and not in those without this phenotype. Forty six people with neuropathic pain due to nerve injury or post-herpetic neuralgia were randomised. In the total sample, pain was statistically significantly lower with lidocaine than with placebo, but the effect size was modest with a difference of 0.3 points on an 11-point numeric rating scale (95% confidence interval = 0.1 - 0.5), which is of questionable clinical significance. No significant interaction between treatment and phenotype was seen for this (the primary) outcome.<sup>19</sup>

### Neuropathic pain - comparative studies

Comparative data for lidocaine plasters vs existing treatments are also very limited. No double-blind RCTs are available. An open label, non-inferiority RCT compared lidocaine plasters with pregabalin in people with post-herpetic neuralgia (n=96) or diabetic polyneuropathy (n=204). A similar proportion of participants in each intervention group were considered responders (66.4% in the lidocaine plaster group compared with 61.5% in the pregabalin group). In those with post-herpetic neuralgia, more participants responded to 5% lidocaine medicated plaster treatment than to pregabalin (63.3% vs. 46.8% in the full analysis set).<sup>20</sup> The lack of blinding means that the risk of bias is high.<sup>21</sup>

Further study was undertaken in this cohort to investigate if those not sufficiently responding to monotherapy with lidocaine plaster or pregabalin could benefit from combination therapy. In those receiving combination therapy, the investigators reported an improvement in reported pain intensity according to a numeric rating scale.<sup>22</sup> Both comparative studies were excluded from the evidence considered by NICE for CG173 because of their open label design.<sup>1</sup>

### Non-neuropathic pain

There has been interest in the use of lidocaine plasters for non-neuropathic pain, including various types of musculoskeletal pain. Even where RCTs have been published, such as in chronic back pain,<sup>23</sup> rib fractures,<sup>24,25</sup> and myofascial pain,<sup>26-28</sup> studies are often limited by small size or negative findings.

### Precautions and adverse effects

Contraindications to lidocaine plasters include hypersensitivity to the active substance, the excipients or other amide-type local anaesthetics. The plasters must not be applied to inflamed or injured skin, or to mucous membranes.<sup>3,4</sup>

Lidocaine plasters should be used with caution in people with severe cardiac impairment, severe renal impairment or severe hepatic impairment.<sup>3,4</sup>

Approximately 16% of patients can be expected to experience localised adverse reactions, which are most commonly administration site reactions and include burning, dermatitis, erythema, pruritus, rash, skin irritation and vesicles. Anaphylactic reactions and hypersensitivity have been reported very rarely (<1/10,000).<sup>3,4</sup>

Systemic adverse reactions following the appropriate use of lidocaine plasters are unlikely due to very low systemic absorption.<sup>3,4</sup>

In an open-label comparative RCT, lidocaine plasters were associated with improved tolerability compared with pregabalin.<sup>20</sup> There are no direct comparative data with other agents for post-herpetic neuralgia.

One lidocaine metabolite has been shown to be genotoxic and carcinogenic in rats. Secondary metabolites have been shown to be mutagenic. The manufacturer states that clinical significance of this finding is unknown. Long-term treatment is therefore only justified if there is a therapeutic benefit.<sup>3,4</sup> This underscores the need for regular reassessment.

## Costs

There is a significant difference in cost between treatments available for post-herpetic neuralgia and other neuropathic pain. Table 1 below illustrates the cost differences. Drug costs for lidocaine plasters are higher than all other treatment options.

**Table 1: Product and price comparison of treatments for post-herpetic and other neuralgia (prices from Drug Tariff August 2017)**

Product	Cost per 30 days	Comments
Amitriptyline tablets (up to 75mg daily)	£2.70	A first line treatment option for neuropathic pain. Use for this indication is off-label. <sup>1</sup>
Tramadol capsules (up to 400mg per day)	£6.07	Acute rescue treatment for neuropathic pain whilst waiting for specialist referral after initial treatment has failed. Short term use only. <sup>1</sup>
Gabapentin capsules (up to 3600 mg daily)	£7.88	A first line treatment option for neuropathic pain. <sup>1</sup> Usual treatment dose of 1800 mg would make cost lower.
Capsaicin 0.075% cream (applied sparingly up to four times a day)	£14.58 (45g tube, may last > 30 days)	Consider for people with localised neuropathic pain who wish to avoid/cannot tolerate oral treatments. Licensed for post-herpetic neuralgia and painful diabetic peripheral polyneuropathy. Use for other conditions would be off-label. <sup>1</sup>
Pregabalin capsules (up to 600mg daily)	£4.47	A first line treatment option for neuropathic pain. Licensed for treatment of peripheral and central neuropathic pain. <sup>1</sup> Price for twice a day dose. More costly if prescribed three times a day.
Lidocaine 5% plasters (up to three plasters applied daily)	£72.40 to £217.20	NICE do not make a recommendation about the use of lidocaine in neuropathic pain due to very limited evidence on this treatment meeting their inclusion criteria. <sup>11</sup> Licensed for symptomatic relief of post-herpetic neuralgia. <sup>3,4</sup>

The current Drug Tariff price for lidocaine plasters is based on the Versatis® brand. Generically written prescriptions will be charged at this price. Another lidocaine 5% medicated plaster is also available by the brand name of Ralvo®. This brand costs 15% less than the Drug Tariff price, with 30 days treatment costing between £61.54 and £184.62. Prescriptions would need to be written as the Ralvo® brand to be charged the lower price.

## Reviewing treatment

There are several options available for reviewing treatment with lidocaine plasters. Individual review, including consideration of past treatments and co-morbidities, is essential.

### Unlicensed indications

Review the need for continued use. Assess for suitability to change to an alternative treatment appropriate to the indication.

The General Medical Council (GMC) has guidance for prescribers relating to unlicensed medicines. When prescribing an unlicensed medicine the prescriber must:

- Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy.
- Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so.
- Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.<sup>29</sup>

### Post-herpetic neuralgia

Review the need for continued use. Assess for suitability to change to an appropriate treatment for post-herpetic neuralgia. Discuss self care advice and treatment expectations (see 'Management of post-herpetic neuralgia' section, page 2).

Use of lidocaine plasters may be considered appropriate in a very small number of patients with post-herpetic neuralgia in whom alternative treatments are contraindicated, not tolerated, or ineffective.

Where lidocaine plaster treatment is considered appropriate:

- Ensure treatment is used correctly and that people have at least a 12 hour treatment free period every 24 hours.
- Ensure treatment is reviewed at four weeks and discontinued if it is ineffective.
- With longer-term use, reassess treatment at regular intervals (e.g. every six months).<sup>5</sup> As for any neuropathic pain treatment, this should include an assessment of pain control, impact on lifestyle and daily activities (including sleep disturbance), physical and psychological wellbeing, adverse effects and continued need for treatment.<sup>1</sup>
- Consider attempting to reduce the number of plasters used or increase the interval between plasters.<sup>3,4</sup>
- Consider a 'trial without' to assess ongoing need. A trial of unmedicated physical protection (with cling film or a suitable dressing)<sup>6</sup> is also an option.

Local guidance should be consulted, or be developed where it is not available. The need for existing guidance to be reviewed should be considered. As well as addressing sequential strategy of treatments, local guidance should advise, if lidocaine plasters are approved for use in certain circumstances, whether generic or branded prescribing (of the less costly Ralvo® brand) is recommended.

## Savings

In England and Wales in excess of £20.4 million is spent annually on lidocaine plasters (ePACT May 2017 to July 2017).

Any savings will depend on what stage of the neuropathic pain treatment pathway a person is on, how many plasters are used at a time and whether an alternative treatment needs to be prescribed. The following examples illustrate the potential annual savings per patient.

Change to treatment	Potential annual saving per patient using one plaster per day*
Lidocaine plasters discontinued, no alternative started	£880.87
Lidocaine plasters discontinued, amitriptyline started	£845.71
Lidocaine plasters discontinued, pregabalin started	£826.48
Generically prescribed lidocaine plasters changed to Ralvo® brand	£132.13

\*Savings will be proportionally greater for those using two or three plasters per day.

The examples below illustrate the significant population level savings that could be realised by reducing and optimising the use of lidocaine plasters (based on ePACT May 2017 to July 2017 figures).

	National figure	Per 100,000 patients
Annual savings if 10th percentile of cost per 1000 patients reached by all currently above it.	£14.9 million	£22,429
Annual savings if 25th percentile of cost per 1000 patients reached by all currently above it.	£11.2 million	£16,429
Annual saving if Versatis and generic lidocaine plasters are switched to Ralvo brand (15% cheaper).	£3.04 million	£4,729

## Summary

The place in therapy of lidocaine plasters is currently unclear. Evidence supporting both their licensed use in post-herpetic neuralgia and in other unlicensed indications is limited. Lidocaine plasters are a relatively costly treatment option. Several other neuropathic pain treatment options are available that are both endorsed by NICE and have a lower acquisition cost; they should be preferred where they are suitable. Significant savings are available by reviewing treatment and discontinuing it if it is ineffective or inappropriately prescribed.

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## Additional PrescQIPP resources



Briefing



Data pack

Briefing: <https://www.prescqipp.info/b200-lidocaine-plasters-drop-list/category/54-lidocaine-plasters>

Data pack: [https://pdata.uk/#/views/B200\\_LidocaineplastersDROP-List/FrontPage?:iid=1](https://pdata.uk/#/views/B200_LidocaineplastersDROP-List/FrontPage?:iid=1)

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