

Re: Lidocaine 5% medicated plaster (VERSATIS®)

14th February 2018

Dear Colleagues,

I refer to previous correspondence in August 2017 Circulars 032/17 and 038/17 in relation to reimbursement changes to lidocaine 5% medicated plaster (Versatis®) from 1st September 2017.

As you are aware, lidocaine 5% medicated plaster (Versatis®) is licensed for **the symptomatic relief of neuropathic pain associated with previous herpes zoster infection** known as post-herpetic neuralgia (PHN) in adults. It is a local anaesthetic agent which is applied directly to the affected area after the healing of herpes zoster (shingles) infection.

To date we have reviewed over 4,500 applications via the GP Application Suite. Of these, over 10% have been approved in cases where an indication of PHN is outlined or the application for neuropathic pain clearly indicates an unmet clinical need where all other therapeutic options have been trialed.

It is important to note that an online application **MUST** initially be made via the GP Application Suite for reimbursement to be authorised. If an indication of PHN is outlined, reimbursement will be approved. For all other indications, specific criteria must be outlined and this information is reviewed by the Medicines Management Programme (MMP) within 3 working days and a reimbursement decision communicated via the GP Application Suite.

In the case of a negative reimbursement decision, an appeals process is in place. Appeals can either be sent directly by the clinician to the MMP at mmp@hse.ie or by post to the address below. It is imperative that all additional information supporting the use of lidocaine 5% medicated plaster (Versatis®) is submitted in order to assess the unmet clinical need and to ensure an informed reimbursement decision. All appeals (265 to date) are reviewed on a case-by-case basis taking into account the initial online application and the information in the appeal submission.

Please find attached “Tips and Tools” for information on appropriate use of lidocaine 5% medicated plaster (Versatis®) including topical treatment alternatives for both PHN and other types of musculoskeletal pain.

I wish to thank you for your co-operation with this prescribing initiative.

With best wishes,



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Prescribing Tips and Tools for Lidocaine 5% Medicated Plaster (Versatis®)



Lidocaine 5% medicated plaster is a local anaesthetic producing a local, non-systemic analgesic effect.

It is licensed for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia [PHN]) in adults.

Prescribing Tips & Practice Points

- ✓ Apply the plaster to intact, dry, non-irritated skin (after healing of shingles)
- ✓ Each plaster must be worn for no longer than **12 hours**
- ✓ The minimum number of plasters that provide therapeutic relief should be used
- ✓ In total, not more than 3 plasters should be used at the same time
- ✓ The plaster should be cut to appropriate size with scissors **PRIOR** to removing the clear release liner
- ✓ Treatment outcome should be re-evaluated after **2 – 4 weeks**
- ✓ If no response is observed or if relieving effect is solely related to the protective properties of the plaster on the skin, **treatment SHOULD be discontinued**
- ✓ Treatment should be assessed at regular intervals to evaluate the need to continue treatment
- ✓ Use with caution in severe cardiac, renal and hepatic impairment

Information for Patients

- ✓ The plaster must be applied directly to the painful site as the mode of action is local and non-systemic
- ✓ When a pack (containing 5 plasters) has been opened, the plasters must be used within 14 days
- ✓ Always re-seal the pack to prevent the plasters from drying out

Criteria for the reimbursement of Lidocaine 5% Medicated Plaster

- Lidocaine 5% medicated plaster should **ONLY** be prescribed for the treatment of neuropathic pain associated with post-herpetic neuralgia (PHN) in adults
- In exceptional circumstances, there may be a need to prescribe lidocaine 5% medicated plaster for unlicensed indications

Treatment initiation

- All new patients commenced on lidocaine 5% plaster must be registered by their GP via the GP Application Suite prior to initiation of treatment
- The application will be approved if the indication of PHN is specified
- This will authorise reimbursement for a period of 3 months

Authorisation for unlicensed indications

- Reimbursement for unlicensed indications can also be applied for on the online system
- Information required to be submitted includes the patient's diagnosis, location of the pain as well as a history of past and current treatments
- The application will be reviewed by the Medicines Management Programme prior to a reimbursement approval decision

Additional information

- Reimbursement for an additional 3 months will require a further application
- Patients eligibility can be confirmed by accessing 'Eligibility Confirmation' on the GP and Pharmacy Application Suites through 'Online Services' on www.pcrs.ie

Product alternative and price comparison for the topical treatment of post-herpetic neuralgia (PHN)

<p>Lidocaine 5% plaster (Versatis®)</p> <p><i>Apply 1 to 3 plasters daily (12 hours on, 12 hours off)</i></p> <p>Price €77.52 (30) - €232.56 (90)</p>	➔	<p>Capsaicin 0.075% Cream (Axsain®) 45g</p> <p><i>Apply sparingly 3 to 4 times daily</i></p> <p>Price €17.52 (45g)</p>
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Product alternatives and price comparisons of other topical treatments for non-post herpetic neuralgia (PHN) indications

	Indication & dose	Price per 100g
<p>Lidocaine 5% plaster (Versatis®)</p> <p style="background-color: #cccccc; color: red; text-align: center; padding: 5px;">UNLICENSED USE</p> <p>Price €77.52 (30)- €232.56 (90)</p>	<p>Diclofenac 1% gel (e.g. Difene®) 50g*</p> <p>Trauma of ligaments, tendons, muscles, joints & soft tissue rheumatism. Apply 2 to 4 times daily.</p>	€2.36
	<p>Ibuprofen 5% gel (e.g. Phorpain®) 100g *</p> <p>Topical anti-inflammatory analgesic for back, rheumatic & muscular pain, strains & neuralgia. Apply sparingly up to 3 times daily.</p>	€4.07
	<p>Ketoprofen 2.5% gel (e.g. Fastum®) 100g</p> <p>Local relief of pain and inflammation associated with muscular, rheumatic & soft tissue. Apply 2 to 3 times daily.</p>	€6.69

*Where more than one product is available the lowest cost product is listed. Prices are correct as of 25 July 2017.

Version 1.2 MMP July 2017. Full evaluation available on www.hse.ie/yourmedicines. Contact mmp@hse.ie for more details. References: SmPC Axsain®, Difene®, Fastum®, Phorpain® & Versatis® available at www.hpra.ie; PCRS online available at www.pcrs.ie

CLINICAL EVIDENCE DEMONSTRATING THE BENEFIT OF LIDOCAINE 5% MEDICATED PLASTER IN ALL TYPES OF PAIN OTHER THAN POST-HERPETIC NEURALGIA IS LIMITED

Please see overleaf for more information on alternative treatment options for post-herpetic neuralgia (PHN) and other types of pain

CLINICAL EVIDENCE DEMONSTRATING THE BENEFIT OF LIDOCAINE 5% MEDICATED PLASTER IN ALL TYPES OF PAIN OTHER THAN POST-HERPETIC NEURALGIA (PHN) IS LIMITED AND THEREFORE ITS USE FOR INDICATIONS SUCH AS MUSCULAR, JOINT OR SOFT TISSUE PAIN IS NOT RECOMMENDED

If Lidocaine 5% Medicated Plaster is prescribed it MUST be reviewed regularly and treatment SHOULD be discontinued if ineffective or if the relieving effect is solely related to the protective properties of the plaster. Licensed alternatives for both PHN and muscular type pain are outlined below

Example	Alternative topical treatment options for PHN indication Capsaicin 0.075% cream (Axsain®)	Alternative topical treatment options for non-PHN indications Diclofenac 1% gel (e.g. Difene®, Diclac®, Voltarol Emulgel®)
Indication	Symptomatic relief of neuralgia associated with & following PHN after the healing of lesions & painful diabetic peripheral polyneuropathy* <small>*specialist prescribing only</small>	Symptomatic relief of pain & inflammation in trauma of the ligaments, tendons, muscles, joints & localised forms of soft tissue rheumatism
Prescribing information	Apply to the affected area 3 to 4 times daily after the healing of herpes zoster infection	Apply to the affected area 2 to 4 times daily for up to 14 days Treatment duration for the above indications should not normally exceed 6 weeks
Cost	➤ €17.52 (45g tube)	➤ €1.18 – €1.80 (50g tube)
Patient information	<ul style="list-style-type: none"> • Apply a pea size amount • Wash hands immediately after application • Apply only to intact skin • Do not apply near the eyes 	<ul style="list-style-type: none"> • The amount to be applied is dependant on the size of the area to be treated e.g. 2g to 4g (size of a cherry to the size of a walnut) is sufficient to treat an area of 400cm² to 800cm² • Applied only to intact skin • Wash hands after application
Special precautions	<ul style="list-style-type: none"> • A transient burning sensation can occur if: <ul style="list-style-type: none"> ➤ applied more than 4 times daily ➤ applied too often ➤ applied just before or after a hot shower • The vapour can cause brief irritation of the eyes, nose & throat • Skin irritation can occur e.g. stinging or itching 	<ul style="list-style-type: none"> • Application over extensive areas or in excess of recommended dosage may give rise to systemic effects. Refer to the individual SmPCs for more information • To reduce undesirable effects use the minimum effective dose for the shortest possible duration • Use with caution in the elderly & treatment is contraindicated in patients <14 years • Discontinue if a rash develops after applying the gel

Appropriate management of pain

- ✓ If topical treatment does not provide sufficient pain control, consider the use of oral agents for the treatment of pain e.g. Paracetamol ± NSAIDs (see below)
- ✓ Patients should be counselled on the importance of maintaining a healthy lifestyle including exercise (e.g. walking or swimming) and weight loss to enhance strength and balance and help ease pain
- ✓ Use best practice guidelines to guide treatment choices for certain types of pain (e.g. NCEC Clinical Guideline for the Management of Cancer Pain in Adults)
- ✓ Always refer to the individual Summary of Product Characteristics (SmPCs) and other appropriate reference sources (e.g. British National Formulary [BNF]) to inform decisions with individual patients

First-line oral therapies for the treatment of pain

Paracetamol: 500mg to 1g every 4 to 6 hours
➤ Maximum 4g in 24 hours

NSAIDs e.g. ibuprofen: Initially 200 to 400 mg 3 to 4 times daily
• Increase if necessary up to 600mg 4 times daily
➤ Aim for a maintenance dose of 200 to 400mg 3 times daily

± Adjuvant. Adjuvant analgesics are medicines that are not primarily designed to treat pain but can be used for this purpose
➤ Adjuvants that may be used in the treatment of neuropathic pain include:
gabapentin & amitriptyline (unlicensed use)

References and Useful Resources

- **British National Formulary (BNF) July 2017.**
- **International Association for the Study of Pain (IASP).**
- **National Clinical Effectiveness Committee (NCEC)- Pharmacological Management of Cancer Pain in Adults.** Clinical Guideline No. 9- November 2015.
- **National Institute for Health and Care Excellence (NICE) Guidance CG173- Neuropathic pain in adults: Pharmacological management in non-specialist settings.** Updated February 2017.
- **Summary of Product Characteristics (SmPCs) Axsain®, Difene®, Diclac® & Voltarol Emulgel®.**
- **The Irish Pain Society.**
- **World Health Organisation (WHO) Pain Ladder for Adults.**