

Rubefacients for the treatment of soft-tissue disorders and topical pain relief (DROP-List)

This is one of a number of bulletins providing further information on medicines contained in the PrescQIPP DROP-List (Drugs to Review for Optimised Prescribing).¹ This bulletin focuses on rubefacients for the treatment of soft-tissue disorders and topical pain relief and provides the rationale for discontinuing supply on NHS FP10 prescriptions. It does not cover the prescribing of rubefacients for relieving muscle pain associated with methadone withdrawal or the prescribing of topical non-steroidal anti-inflammatory drugs (NSAIDs) or capsaicin cream. Further bulletins, including the DROP-List, are available on the PrescQIPP website: www.prescqipp.info

Recommendations

- All patients prescribed rubefacients should have their therapy reviewed.
- Discontinue the prescribing of rubefacients on FP10.
- Consider recommending or prescribing an effective alternative treatment if appropriate.
- If these patients still wish to use a rubefacient they should be advised that they can be purchased as self-care over-the-counter (OTC) with the support of the community pharmacist.
- Do not initiate new prescriptions for rubefacients.

Background

The PrescQIPP DROP-List is a list of medicines regarded as low priority for prescribing, poor value for money or medicines for which there are safer alternatives. There are also medicines which could be considered for self-care with the support of the community pharmacist included on the DROP-List. Some National Institute for Health and Care Excellence (NICE) do not do recommendations have also been included.¹ Rubefacients features on the DROP-List as an item which has limited clinical value, has a NICE do not do recommendation associated with it and is suitable for self-care and should be purchased over-the-counter (OTC) if a patient wishes to use them.

Approximately £6.9 million is spent annually in England on the prescribing of rubefacients (ePACT March - May 2015). If the prescribing of all rubefacients on FP10 was discontinued the cost savings released could be invested in improving local NHS healthcare services. As with all prescribing, individual patient circumstances need to be borne in mind, however, with assistance from practice nurses, support from your local CCG medicines management teams and the experiences of CCGs/GPs that have already undertaken this work, it is hoped that GPs will participate in realising these cost savings.

Rationale for discontinuation of prescribing rubefacients

Rubefacients are used for the treatment of soft-tissue disorders and pain relief. Topical rubefacient preparations may contain nicotinate compounds, salicylate compounds, essential oils and camphor. They act by counter-irritation of the skin relieving superficial and deep-seated pain; however the evidence available does not support the use of topical rubefacients in acute or chronic musculoskeletal pain.²

There are a number of systematic reviews published which examine the evidence for rubefacients. The most recent was published in 2014 by the Cochrane Library entitled “Salicylate-containing rubefacients for acute and chronic musculoskeletal pain in adults”.³ This review was an update of “Topical rubefacients for acute and chronic pain in adults” published in 2009 which found that the evidence does not support the use of topical rubefacients containing salicylates for acute injuries, and suggests that in chronic conditions their efficacy compares poorly with topical NSAIDs. There is no evidence at all for topical rubefacients with other components.⁴ The criteria for a trial to be included in the 2014 systematic review was that it had at least ten participants per treatment arm, and reporting outcomes at approximately seven days (minimum three, maximum ten) for acute conditions and 14 days (minimum seven) or longer for chronic conditions.³ The trials included in the review were:

- Six placebo studies (560 participants) in acute pain.
- One active-controlled study (137 participants) in acute pain.
- Seven placebo studies (489 participants) in chronic pain.
- Three active-controlled studies (182 participants) in chronic pain.³

All the studies had a potential risk of bias, substantial differences between the participants, the treatments and the methods. Not all of the studies contributed usable information for all of the outcomes sought. The review found for acute and chronic pain any evidence of efficacy for salicylate-containing rubefacients came from the older, smaller studies, while the larger, more recent studies showed no effect and therefore their use was not supported by evidence.³

“Interventions available over-the-counter and advice for acute low back pain: Systematic review and meta-analysis” published in the Journal of Pain in 2014 concluded that there is limited evidence that NSAIDs, heat wraps, and rubefacients provide immediate pain relief for acute back pain and that bed rest and advice are both ineffective. Future research is needed to provide evidence to support rational use of over-the-counter remedies and advice for people with acute low back pain.⁵

An older systematic review from 2004 concluded that topically applied rubefacients may be efficacious in the treatment of acute pain. However, estimates for the efficacy of rubefacients were unreliable because of a lack of good clinical trials.⁶

A trial looking at the treatment of chronic non-cancer pain in older people and found that there is little evidence specifically relating to drug treatments for pain in older people, but the trial concluded that much can be extrapolated from what is already known. It stated that there was clear evidence of lack of useful effect, or insufficient evidence of effect for a number of commonly used drugs, including paracetamol, topical rubefacients, low concentration topical capsaicin, and for strong opioids in chronic non-cancer pain.⁷ Another trial published in 2008 looked at the evidence for topical agents in the treatment of rheumatic pain. This trial found that there was no evidence of efficacy for topical rubefacients.⁸

The NICE includes rubefacients in its 'do not do' recommendations database. When clinical guidelines are in development NICE's independent advisory bodies often identify NHS clinical practices that they recommend should be discontinued completely or should not be used routinely. This could be because the evidence demonstrates that the practice is not on balance beneficial or there is a lack of evidence to support its continued use. In February 2014 NICE included “do not offer rubefacients for treating osteoarthritis” to this database.^{9,10}

Scottish Intercollegiate Guidelines Network (SIGN) clinical guidelines for the management of chronic pain include topical rubefacients treatment. It states that they are more effective than topical placebo for pain reduction and they should be considered for the treatment of pain in patients with musculoskeletal conditions if other pharmacological therapies have been ineffective.¹¹

The NICE Clinical Knowledge Summary for the treatment of chilblains states that patients should be informed that no evidence supports the use of over-the-counter topical preparations for chilblains, and

they are not recommended. This includes preparations marketed for the treatment of chilblains, for example Balmosa, Deep Heat, Mentholatum Vapour Rub.¹²

Some rubefacient preparations are also listed in Part XVIII A of the Drug Tariff - Drugs, Medicines and Other Substances not to be ordered under a General Medical Services Contract. Examples include: Mentholatum Balm; Mentholatum Deep Freeze Spray; Mentholatum Deep Heat Massage Liniment; Mentholatum Deep Heat Maximum Strength Rub; Mentholatum Deep Heat Rub; Ralgex Cream and Elliman's Universal Embrocation. These are not permitted on FP10 and will not be reimbursed by the NHS Prescription Services.¹³

Benefits to patients

Patients are counselled to help them understand that using rubefacients are unlikely to help relieve their musculoskeletal pain and therefore they will not be prescribed on FP10.

If considered appropriate, patients are recommended or prescribed an effective alternative treatment.

A reduction in the prescribing of rubefacients will release cost savings for the NHS which could be invested in improving local healthcare services for patients.

Costs and savings

There are many different rubefacients on the market and the products vary widely in both composition and cost. Table 1 includes some examples of common branded rubefacients from the DROP-List, their ingredients, costs and a calculated price per 30g or 30ml.

Table 1: Examples of common branded rubefacients included in the DROP-List¹⁴

GSL= General sales List, SL= Selective List - drugs and other substances not to be prescribed on NHS prescriptions, P = Pharmacy only, MD = Medical device

Product	Content/generic name	Legal class	Size and retail price	Price to the patient for 30g/30ml
Movelat Gel and Cream	Salicylic acid 2%	P	125g=£12.94	£3.11
Movelat Relief Gel and Cream	Mucopolysaccharide polysulfate 0.2% w/w, salicylic acid 2% w/w	P	40g=£4.62	£3.47
			80g £7.36	£2.76
Algesal Cream	Diethylamine salicylate 10% w/w	P	50g=£2.18	£1.31
			100g=£4.33	£1.30
Diffiam 3% Cream/ Diffiam-P Cream 3%	Benzydamine hydrochloride 3% w/w	P	35g=£5.10	£4.37
			100g=£13.23	£3.97
Transvasin Heat Rub	Ethyl nicotinate 2%, hexyl nicotinate 2%, tetrahydrofurfuryl salicylate 14%	GSL	40g=£2.89	£2.17
			80g=£4.89	£1.83
Balmosa Cream	Menthol 2%, methyl salicylate 4%, camphor 4%, capsicum oleoresin 0.035%	GSL	40g=£1.99	£1.49
Radian-B Pain Relief Spray	Menthol 1.4%, camphor 0.6%, ammonium salicylate 1%, salicylic acid 0.54%	GSL	100ml=£2.85	£0.86

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Product	Content/generic name	Legal class	Size and retail price	Price to the patient for 30g/30ml
Deep Heat Spray	Ethyl salicylate 5%, hydroxyethyl salicylate 5%, methyl nicotinate 1.6%, methyl salicylate 1.0%	GSL	150ml=£4.69	£0.94
Deep Heat Rub Maximum Strength	Methyl salicylate 30%, menthol 8%	MD	35g=£4.79	£4.11
Mentholatum Vapour Rub	Camphor 9%, menthol 1.35%, methyl salicylate 0.33%	GSL	30g=£2.65	£2.65
Ralgex Heat Spray	Ethyl salicylate 4.8% w/v, glycol salicylate 4.8% w/v, methyl nicotinate 1.6%, methyl salicylate 0.96%	GSL	125ml=£3.66	£0.88
Bell's Muscle Rub ¹⁵	Sweet birch oil 0.12% v/w, cajuput oil 0.12% v/w, eucalyptus oil 1.00% v/w, levomenthol 0.5% w/w, methyl salicylate 9.0% v/w	GSL	40g=£2.15	£1.61
Deep Freeze Cold Gel 2%	M-pentane 40%, menthol 2%	GSL	35g=£2.49	£2.13
			100g=£4.79	£1.44
Ralgex Freeze Spray	Isopentane 67.77%, methoxymethane 14.47%	GSL	125ml=£3.56	£0.85
Deep Freeze Cold Spray	M-pentane 40%, menthol 2%	MD	150ml=£3.79	£0.76
Elliman's Universal Muscle Rub Lotion	Acetic acid 10.37% v/v, turpentine oil 35.41% v/v	GSL SL	100ml=£3.95	£1.19

In England over £6.9 million was spent on prescribing rubefacients over the course of a year (ePACT data March - May 2015). It is hoped that prescribers will recognise that the evidence available does not support the use of rubefacients and they will participate in releasing cost savings by reviewing their use. **An 80% reduction in the prescribing of rubefacients, could release savings of approximately to £5.5 million across England. This equates to £9,770 per 100,000 patients.**

Summary

There is a lack of evidence to support the use of rubefacients in acute or chronic musculoskeletal pain.² A recently updated Cochrane review looked at salicylate-containing rubefacients for acute and chronic musculoskeletal pain in adults and found that any evidence of efficacy came from the older, smaller studies, while the larger, more recent studies showed no effect.³ Therefore all patients currently prescribed rubefacients should have their therapy reviewed and no new patients should be initiated on rubefacients. Prescribing of rubefacients on FP10 should be discontinued and consideration given to recommending or prescribing an effective alternative treatment. If patients still wish to use a rubefacient they should be advised that they can be purchased them OTC from a community pharmacy.

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Additional PrescQIPP resources

Available here: <http://www.prescqipp.info/resources/viewcategory/402-rubefacients-drop-list>



Briefing



Data pack



Patient letter, audit

Information compiled by Sarah Clarke, PrescQIPP Programme, September 2015 and reviewed by Katie Smith, East Anglia Medicines Information Service, October 2015.

Non-subscriber publication February 2015.

At the time of publication the PrescQIPP NHS Programme was hosted by Papworth NHS Trust and the Eastern Academic Health Science Network.

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