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PAN MERSEY AREA PRESCRIBING COMMITTEE  
PRESCRIBING POLICY STATEMENT  
FIRST APC BOARD DATE: 29 MAR 2017  
LAST APC BOARD DATE: 28 NOV 2018



Pan Mersey  
Area Prescribing Committee

## IVERMECTIN 10mg/g cream (Soolantra®)

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**The Pan Mersey Area Prescribing Committee recommends the prescribing of IVERMECTIN 10mg/g cream (Soolantra®) for second line topical treatment of moderate to severe papulopustular rosacea in adult patients**

Ivermectin cream is only licensed for the topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients. It is an anti-parasitic drug and kills Demodex mites which live on the skin; these are reported to be implicated in some symptoms of rosacea. It also exerts anti-inflammatory effects by inhibiting lipopolysaccharide-induced production of inflammatory cytokines.<sup>1</sup>

The Pan Mersey Area Prescribing Committee (APC) recommends topical ivermectin to be used for treatment of moderate to severe papulopustular rosacea only when standard topical treatments (metronidazole 0.75% gel/cream and azelaic acid 15% gel) have failed. It may be considered as an alternative option before oral antibiotics.

NICE have published [Evidence summary ESNM68](#). Inflammatory lesions of papulopustular rosacea: ivermectin 10 mg/g cream. January 2016. However this does not constitute formal NICE guidance.

**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.

## IVERMECTIN 10mg/g Cream (Soolantra®)

<p><b>EFFECTIVENESS</b></p> <p>2 randomised controlled trials (RCTs) of identical design compared ivermectin with vehicle (placebo) <a href="#">Stein Gold et al. 2014a</a>), study1 (n=683) and study 2 (n=688). In both studies statistically significantly more people receiving ivermectin cream were considered treatment successes compared with those using vehicle cream.<sup>2</sup> Cochrane considered these studies to be high quality.<sup>3</sup></p> <p>A randomised, active-comparator trial compared ivermectin cream with metronidazole cream <a href="#">Taieb et al. 2015</a>). (n=962,). Ivermectin was superior to metronidazole cream at reducing lesion count and improving rosacea severity score with participants having approximately 10% fewer lesions at 16 weeks<sup>2</sup> The Cochrane review stated that topical ivermectin appeared to be slightly more effective than topical metronidazole for papulopustular rosacea, based on this study.<sup>3</sup></p>	<p><b>SAFETY</b></p> <p>In 2 RCTs adverse events were reported by between 32 to 40% of people using ivermectin cream which was similar to that of the placebo group. Adverse events considered to be treatment-related were reported by about 4% of people receiving ivermectin. The most commonly reported adverse events were skin burning, skin irritation, pruritus and dry skin which were typically mild to moderate in severity, and usually decrease when treatment is continued.<sup>2</sup> In vitro studies have shown that ivermectin is primarily metabolised by CYP3A4. Consequently, caution is advised when ivermectin is administered concomitantly with potent CYP3A4 inhibitors as the plasma exposure may be significantly increased.<sup>1</sup> For more information see the <a href="#">SPC</a></p> <p>Ivermectin is very toxic for invertebrates. Care should be taken in order to prevent environmental contamination, in particular in the aquatic media.<sup>1</sup></p>																
<p><b>COST</b></p> <table border="1" data-bbox="65 952 786 1400"> <thead> <tr> <th>Drug</th> <th>Cost / course</th> </tr> </thead> <tbody> <tr> <td>Ivermectin 10mg/g (1%) cream</td> <td>£73.16 / 4 months</td> </tr> <tr> <td>Metronidazole 0.75% cream / gel</td> <td>£26.64-£67.89 / 4 months</td> </tr> <tr> <td>Azelaic acid 15% gel</td> <td>£29.92 / 4 months</td> </tr> <tr> <td>Oral erythromycin 500mg (using 2 x 250mg tablets) (off-label)</td> <td>£16.44 / 12 weeks</td> </tr> <tr> <td>Oral oxytetracycline 500mg (using 2 x 250mg tablets)</td> <td>£8.40 / 12 weeks</td> </tr> <tr> <td>Oral lymecycline 408mg (off-label)</td> <td>£14.34 / 12 weeks</td> </tr> <tr> <td>Oral doxycycline 100mg capsules (off-label)</td> <td>£7.98 / 12 weeks</td> </tr> </tbody> </table> <p>Doses are for general comparison and do not imply therapeutic equivalence. Unless otherwise stated costs from <a href="#">Dictionary of Medicines and Devices</a> Accessed 24/10/2018</p>	Drug	Cost / course	Ivermectin 10mg/g (1%) cream	£73.16 / 4 months	Metronidazole 0.75% cream / gel	£26.64-£67.89 / 4 months	Azelaic acid 15% gel	£29.92 / 4 months	Oral erythromycin 500mg (using 2 x 250mg tablets) (off-label)	£16.44 / 12 weeks	Oral oxytetracycline 500mg (using 2 x 250mg tablets)	£8.40 / 12 weeks	Oral lymecycline 408mg (off-label)	£14.34 / 12 weeks	Oral doxycycline 100mg capsules (off-label)	£7.98 / 12 weeks	<p><b>PATIENT FACTORS</b></p> <p>There are no special requirements or related cost in the delivery of ivermectin 10mg/g cream as it will be self-administered by the patient. Ivermectin is recommended to be applied once a day whereas the other topical treatments are recommended to be applied twice a day Ivermectin is not recommended in pregnancy or for breast feeding mothers. Concomitant use of ivermectin with other topical or systemic medicinal products for the treatment of rosacea has not been investigated. No interaction studies have been performed.<sup>1</sup> Caution in severe hepatic impairment.</p>
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### PRESCRIBING INFORMATION & IMPLEMENTATION NOTES

The recommended dose is one application a day for up to 4 months. The treatment course may be repeated. In case of no improvement after 3 months, the treatment should be discontinued.

No dosage adjustment is necessary in the geriatric population

A pea-size amount of medicinal product should be applied to each of the five areas of the face: forehead, chin, nose, and each cheek daily (approximately 1g). The medicinal product should be spread as a thin layer across the entire face, avoiding the eyes, lips and mucosa. It has been estimated that one 30g tube should last for one month.<sup>4</sup>

### REFERENCES

- Galderma (UK) Ltd. Summary of Product Characteristics – Soolantra 10mg/g Cream; Updated 06/04/2018. <http://www.medicines.org.uk/emc/medicine/30353> [Accessed 30/10/2018]
- NICE Evidence Summary ESNM68 Inflammatory lesions of papulopustular rosacea: ivermectin 10 mg/g cream. January 2016. <https://www.nice.org.uk/advice/esnm68/chapter/Key-points-from-the-evidence> [Accessed 30/10/2018]
- Cochrane database for systemic reviews; Interventions for Rosacea. April 2015. [http://www.cochrane.org/CD003262/SKIN\\_treatments-for-rosacea](http://www.cochrane.org/CD003262/SKIN_treatments-for-rosacea) [Accessed 30/10/2018]
- Consumer Medicine Information leaflet for Soolantra® cream Registration number AUST R 227125. <https://www.nps.org.au/medical-info/medicine-finder/soolantra-cream> [Accessed 30/10/2018]