

Product proprietary name: ViralGuard Throat Spray

Dosage form and strength: Elderberry (*Sambucus Nigra*) 250 mg; Pelargonium Extract (*Pelargonium Sidoides* 12,5 %) 136 mg; Peppermint Oil (*Mentha Piperita*) 10 mg; Zinc 1 mg per 1ml of liquid

Applicant/PHCR: Adcock Ingram Limited

Type A's - Amended: 7/03/2017

PART 1 C LABELLING

a) Package insert

The under-mentioned information with regard to this medicine shall appear on the package insert. The information shall be presented in the format stipulated, provided that the Council may authorize any deviation from such information or such format (refer to Regulation 9 of the Act).

1. Scheduling status
2. Proprietary name and dosage form
3. Composition
4. Pharmacological classification
5. Pharmacological action
(Pharmacokinetics, pharmacodynamics and summary of clinical studies, where applicable)
6. Indications
7. Contra-indications
8. Warnings
9. Interactions
10. Pregnancy and lactation
11. Dosage and directions for use
12. Side effects and special precautions
13. Known symptoms of overdosage and particulars of its treatment
14. Identification
15. Presentation
16. Storage instructions
17. Registration number
18. Name and business address of the holder of the certificate of registration
19. Date of publication of the package insert

Current reviewed
Not yet submitted
to MCC

Type A Amendment

Date of Implementation: 7/03/2017

Signature: *Flambusch*

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PROPOSED PACKAGED INSERT:

<p>1. Scheduling status</p> <p>Not Scheduled</p>											
<p>2. Proprietary name and dosage form</p> <p>VIRALGUARD THROAT SPRAY</p>											
<p>3. Composition</p> <p>VIRALGUARD THROAT SPRAY contains:</p> <table border="1" data-bbox="172 846 1010 1256"> <thead> <tr> <th data-bbox="172 846 719 913">Ingredient</th> <th data-bbox="719 846 1010 913">Per 1 ml</th> </tr> </thead> <tbody> <tr> <td data-bbox="172 913 719 981">Elderberry Extract (<i>Sambucus Nigra</i>)</td> <td data-bbox="719 913 1010 981">250 mg</td> </tr> <tr> <td data-bbox="172 981 719 1122">Pelargonium Extract (<i>Pelargonium Sidoides</i> 12,5 %)</td> <td data-bbox="719 981 1010 1122">136 mg</td> </tr> <tr> <td data-bbox="172 1122 719 1189">Peppermint Oil (<i>Mentha Piperita</i>)</td> <td data-bbox="719 1122 1010 1189">10 mg</td> </tr> <tr> <td data-bbox="172 1189 719 1256">Zinc (as zinc lactate)</td> <td data-bbox="719 1189 1010 1256">1 mg</td> </tr> </tbody> </table> <p>The other ingredients of the spray are:</p> <ul data-bbox="159 1328 446 1429" style="list-style-type: none"> • Cremaphor CO 40 • Flavour Peppermint <p>Contains sugar (Puratex)</p>	Ingredient	Per 1 ml	Elderberry Extract (<i>Sambucus Nigra</i>)	250 mg	Pelargonium Extract (<i>Pelargonium Sidoides</i> 12,5 %)	136 mg	Peppermint Oil (<i>Mentha Piperita</i>)	10 mg	Zinc (as zinc lactate)	1 mg	
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Elderberry Extract (<i>Sambucus Nigra</i>)	250 mg										
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Peppermint Oil (<i>Mentha Piperita</i>)	10 mg										
Zinc (as zinc lactate)	1 mg										
<p>4. Pharmacological classification</p> <p>D.32 Other substances or agents</p>											
<p>5. Pharmacological action</p> <p>ViralGuard Throat Spray targets the sensitive membrane deep in the oral cavity and throat, where the first signs of cold and flu symptoms appear.</p> <p>ViralGuard Throat Spray contains herbal extracts and zinc to assist in the protection of the body against potential unwanted organisms associated with</p>											

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<p>colds and flu. Its soothing, protecting action provides a feeling of relief to sore and irritated throats.</p>	
<p>6. Indications</p> <p>ViralGuard Throat Spray is indicated for periods of illness when the symptoms of cold and flu appear.</p> <p>Start using when the first signs and symptoms of colds and flu appear. For the best results, continue use for 3 days after symptoms improve.</p>	
<p>7. Contraindications</p> <p>ViralGuard Throat Spray is contraindicated in persons who are hypersensitive to any of the ingredients.</p>	
<p>8. Warnings</p> <p>ViralGuard Throat Spray contains sugar (Puratex) which may have an effect on the glycaemic control of patients with diabetes mellitus.</p> <p>Spray nozzle can detach from the main part of the spray bottle. Take care. This can present a choking hazard. To be used under adult supervision.</p> <p>If symptoms worsen, please consult your healthcare professional.</p> <p>Avoid accidental contact with your eyes.</p> <p>For oral use only.</p> <p>This medicine has not been evaluated by the Medicines Control Council. This product is not intended to diagnose, treat, cure or prevent any disease.</p>	
<p>9. Interactions</p> <p>None known.</p>	

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<p>10. Pregnancy and lactation</p> <p>Safety in pregnancy and during breastfeeding has not been established.</p>	
<p>11. Dosage and directions for use</p> <p>Shake well before use.</p> <p>Remove the cap cover from the screw cap. Insert the nozzle onto the screw cap. Ensure that the nozzle is tightly fitted by spraying it in the air before use. This action must be repeated before each use, i.e. check that the nozzle is tightly fitted and spray once into the air before spraying into the throat.</p> <p>Children older than 3 years: Spray 2 to 4 squirts into the mouth 5 times per day</p> <p>Adults: Spray 4 to 6 squirts into the back of your throat 6 times a day as required</p>	
<p>12. Side effects and special precautions</p> <p>None recorded.</p>	
<p>13. Known symptoms of overdosage and particulars of its treatment</p> <p>No known symptoms of overdosage recorded.</p>	
<p>14. Identification</p> <p>Characteristic peppermint scented, light brown liquid.</p>	
<p>15. Presentation</p> <p>30 ml amber coloured bottle with a white screw cap and detachable cap cover and nozzle.</p>	
<p>16. Storage instructions</p> <p>Store in a cool and dry place at or below 25 °C.</p> <p>KEEP OUT OF REACH OF CHILDREN.</p>	
<p>17. Registration number</p> <p>To be allocated.</p>	

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<p>18. Name and business address of the holder of the certificate of registration</p> <p>Adcock Ingram Limited</p> <p>1 New Road</p> <p>Erand Gardens</p> <p>Midrand</p> <p>1685</p> <p>Gauteng</p> <p>South Africa</p> <p>Private Bag X69</p> <p>Bryanston, 2021</p> <p>www.adcock.com</p>	
<p>19. Date of publication of the package insert</p> <p>November 2012</p>	

References

1. Natural Medicines Comprehensive Database. Therapeutic Research Faculty (www.naturaldatabase.com). "Elderberry" (1995 – 2011) (Page 2)
2. Natural Medicines Comprehensive Database. Therapeutic Research Faculty (www.naturaldatabase.com). "Rose Geranium Oil" (1995 – 2011) (Page 1 and 2)
3. Alankar S. A Review on Peppermint Oil. Asian Journal of Pharmaceutical and Clinical Research. Volume 2, Issue 2. (2009) (Page 27-31)
4. Natural Medicines Comprehensive Database. Therapeutic Reserach Faculty (www.naturaldatabase.com). "Zinc" (1995 – 2011)