



REPUBLIC OF ESTONIA  
AGENCY OF MEDICINES

Interchemie Werken De Adelaar Eesti aktsiaselts  
Vanapere tee 14, Püüsi küla  
74013 Viimsi vald  
Harju maakond  
EESTI

29.02.2024 nr JV-2/754

**Certificate of manufacturing and marketing  
(Certificate of Pharmaceutical Product CoPP)**

**Certifying country:** Estonia  
**Certifying authority:** State Agency of Medicines

**Name and dosage form of the veterinary medicinal product**

**Macrotil solution for injection**

**Active ingredient(s) and amount(s) per unit dose:**

1 ml of solution contains:

Tilmicosin 300 mg

**For complete composition including excipients**

1 ml of solution contains:

Propylene glycol 250.0 mg

Phosphoric acid, concentrated qs pH 6.0

Water for injection ad 1 ml

**Is this product licensed / authorized to be placed on the market in the certifying country?**

Yes

**Marketing authorization**

Number: 2156

Date of issue: 02.04.2019, valid until: unlimited

**Marketing authorisation holder**

Interchemie Werken De Adelaar Eesti aktsiaselts

Vanapere tee 14, Püüsi küla, 74013 Viimsi vald, Harju maakond, Eesti

**Manufacturer**

Interchemie Werken De Adelaar Eesti aktsiaselts

Vanapere tee 14, Püüsi küla, 74013 Viimsi vald, Harju maakond, Eesti

**Manufacturing licence**

Number 513 (no time limit for validity / no expiry date)

**Do the facilities and operations conform to GMP as recommended by the European Union?**

Yes

Macrotil is commercially available in Estonia under the condition of the subsection 1 of the paragraph 63 of the Medicinal Product Act.



Aet Viispert

Head of Department of Marketing Authorisations



Kairi Kasemets

Inspector, Department of Supervision