



REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

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

04.03.2024 nr JV-2/817

**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 Oral concentrate for oral solution
(Name used in export: Macrotyl-250 Oral)

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

1 ml of solution contains:
Tilmicosin (as phosphate) 250 mg

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

Yes

Marketing authorization

Number: 2157
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)
www.ravimiamet.ee/en Registers > Activity licences

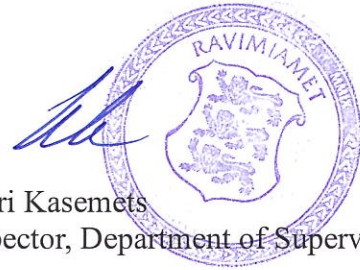
Do the facilities and operations conform to GMP as recommended by the European Union?

Yes

Macrotil Oral 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