REPUBLIC OF ESTONIA
AGENCY OF MEDICINES

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

07.02.2024 nr JV-2/497

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

Intermec Plus solution for Injection

Active ingredient(s) and amount(s) per unit dose:
1ml of solution contains:
Ivermectin: 10.0 mg
Clorsulon: 100.0 mg
For complete composition including excipients
1 ml of solution contains:
Glycerol formal: 485.6 mg
Propylene glycol: Ad 1 ml
Target animal species:
Cattle

Package size:
50 ml

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

Marketing authorization
Number: 2099
Date of issue: 29.06.2018, valid until: unlimited

Marketing authorisation holder
Interchemie Werken De Adelaar Eesti aktsiaselts
Vanapere tee 14, Püünsi küla, 74013 Viimsi vald, Harju maakond, Eesti

Manufacturer
Interchemie Werken De Adelaar Eesti aktsiaselts
Vanapere tee 14, Püünsi 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

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

RAVIMIAMET

Aet Viispert
Head of Department of Marketing Authorisations

Kairi Kasemets
Inspector, Department of Supervision