National Food Chain Safety Office (NÉBIH)

Veterinary Medicinal Products Directorate

Marketing Authorization / Registration Certificate

Product Family: Viroplazin (capsules and powder for oral solution)
Holder: BioTecton Ltd., 1098 Budapest, Epreserdő u. 24. Building 3, 2nd floor, Apt. 11.
Representative: Dr. Szilvia Speidl, sole proprietor, 7768 Kistótfalu, Kossuth Lajos u. 35.

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1. Decision

The registration certificates for the veterinary medicinal products listed below are hereby **amended and renewed**.

2. Registered Products and Authorization Numbers

Product Name	Strength / Form	Pack size	Registration Number
Viroplazin capsule	25 mg	10 capsules	1387/1/2019 NÉBIH ÁTI
Viroplazin capsule	25 mg	20 capsules	1387/2/2019 NÉBIH ÁTI
Viroplazin capsule	50 mg	10 capsules	1388/1/2019 NÉBIH ÁTI
Viroplazin capsule	50 mg	20 capsules	1388/2/2019 NÉBIH ÁTI
Viroplazin capsule	100 mg	10 capsules	1389/1/2019 NÉBIH ÁTI
Viroplazin capsule	100 mg	20 capsules	1389/2/2019 NÉBIH ÁTI
Viroplazin capsule	200 mg	10 capsules	1595/1/NM/2020 NÉBIH ÁTI

Viroplazin capsule	200 mg	20 capsules	1595/2/NM/2020 NÉBIH ÁTI
Viroplazin powder for oral solution	20 g	–	1390/1/2019 NÉBIH ÁTI
Viroplazin powder for oral solution	500 g	–	1390/2/2019 NÉBIH ÁTI

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3. Conditions of the Authorization

- The amended product information (SmPC) and labeling texts approved by this decision are available in the official electronic database of NÉBIH: https://atiportal.nebih.gov.hu.
- The authority has entered the amendment into the official register.
- A **6-month transition period** is granted for the implementation of label and product information changes.
- Certificates issued before **23 June 2025** are no longer valid.
- The registration certificate is valid **for an indefinite period**.
- Products remain subject to inspection by the Veterinary Medicinal Products Directorate of NÉBIH.

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4. Administrative Details

- Administrative service fee: HUF 100,000 (paid on 11 January 2025).
- This decision is final upon notification.

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5. Legal Remedies

An administrative lawsuit may be filed against this decision.

- The statement of claim must be submitted to **NÉBIH** and addressed to the **Budapest-Capital Regional Court**within 30 days of notification.
- Business entities registered in Hungary and parties represented by legal counsel must file electronically via the http://anyk.nebih.gov.hu platform.
- Filing does not suspend enforcement of this decision.

Issued by:

Dr. Imre Nemes
President, National Food Chain Safety Office (NÉBIH)

on behalf and by authorization

Márta Reining
Head of Department

Recipients:

1. Dr. Szilvia Speidl, sole proprietor (via Client Portal)
2. Archives