

Bioveta, a.s. Ivanovice na Hané	Biocan Novel DHPPi, lyophilisate and solvent for suspension for injection for dogs	Ident. kód: BPR00015 Strana: 1 z 16 Počet příloh: 0 Verze: V001 Výtisk číslo:
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### 1. SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Trade name	Biocan Novel DHPPi vakcina A.U.V.
Ph. Eur.	<i>Vaccina ad usum veterinarium.</i>
Nature of product	Vaccine against canine distemper (CDV), inf. hepatitis (CAV-1), inf. laryngotracheitis (CAV-2), parvovirus (CPV-2b), parainfluenza (CPiV-2) vivid.
Target species	Dog
Marketing authorisation number issued by (Member state/EU)	3564/1/14 NÉBIH ÁTI (1 adag)
Batch number(s) of finished product	Biocan Novel DHPPi, 04 53 22
Type of final product	Lyophilisate and solvent for suspension for injection for dogs.
Type of final container	3 ml glass vials
Total number of containers in this batch	11 818 pcs
Number of containers the release is applied for	330 x 10 x 1 dose
Number of doses per container	one dose of 1 ml
Number of samples for the competent authority	-
Date of start of period of validity (start of titration/potency test)	14.11.2014
Date of expiry	26.10.2016
Shelf life	24 months
Storage temperature	Store in a dark and dry place at the temperature between 2 °C and 8 °C. Do not freeze.
Name and address of applicant	Alpha – Vet Animal Health Ltd. Homokosor 7 8000 Székesfehérvár Hungary
Name and address of Marketing Authorisation holder if different Name and address of the batch control site	Bioveta, a.s. Komenského 212 683 23 Ivanovice na Hané, Czech Republic.

Bioveta, a.s. Ivanovice na Hané	Biocan Novel DHPPi, lyophilisate and solvent for suspension for injection for dogs	Ident. kód: BPR00015 Strana: 2 z 16 Počet příloh: 0 Verze: V001 Výtisk číslo:
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**2. PRODUCTION INFORMATION**

Summary information scheme on batch specific production data including data of different production stages, production sites and identification numbers.

**Product name:**

**Biocan Novel DHPPi, lyophilisate and solvent for suspension for injection for dogs.**

**Product batch number: 04 53 22**

Component and ID No.	Site(s) of manufacture	Date of manufacture
DHPPi component 04 60 21 A		
Canine distemper virus 04/2014/CDV	Bioveta, a.s.	27.10.2014
Virus laryngotracheitidis contagiosae canis 73/2014/CAV-2	Bioveta, a.s.	11.2.2014
Parvovirus enteritidis canis, strain 2b 01/2014/CPV-2b	Bioveta, a.s.	11.4.2014
Virus parainfluenzae canis 73/2014/CPV-2	Bioveta, a.s.	20.5.2014
Lyophilisation medium 88 58 21	Bioveta, a.s.	22.8.2014