



HUNGARY
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Rue de l'Aviation
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EUROPEAN BATCH RELEASE PROTOCOL

PRODUCT: **DINDORAL**

MEMBER STATE SPECIFIC INFORMATION

Batch number of finished product: L424463

Release date of finished product: 20-Jul-2015

Marketing authorisation number: 169/95

Issued by: HUNGARY

Target species: PHEASANTS/TURKEYS

Total number of containers in this batch: 520 boxes of 10 units

Number of containers the release is applied for: 520 boxes of 10 units

Number of doses per container: Bottle of 1000 doses

Number of samples for the competent authority: Available upon request

Date of expiry: 16-Mar-2017

Name and Address of Marketing Authorisation Holder:

MERIAL
29, avenue Tony Garnier
69007 LYON
France



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SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Trade name: DINDORAL

INN / PE name / common name of product: Haemorrhagic enteritis (live) vaccine

Batch number of:

Finished product:	Final batch:	Final bulk:
L424463	15DDL3721	15DDL0720

Pharmaceutical form of finished product: Lyophilisate for oral suspension

Type of final container: Bottle of glass

Date of start of period of validity: 16-Mar-2015

Storage: 2°C-8°C

Name and address of manufacturer:

MERIAL
Lentilly
1, chemin de Cruzols
69210 Lentilly
FRANCE

Name and address of the batch release site :

MERIAL
Lyon Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
FRANCE

COMMENT: 3DMH6R34 - Tech 15251: This result complies with the product specifications according to QA retest procedure.

CERTIFICATION BY THE MANUFACTURER

I herewith certify that batch DINDORAL n° L424463 was manufactured and tested according to the procedures approved by the competent authorities and complies with the quality requirement and that all measures have been taken to demonstrate compliance with Directive 2001/82/EC as amended by Directive 2004/28/EC.

Date: 22-Jul-2015

Signature

Dr Olivier MONTET
Pharmacien Adjoint
MERIAL Lyon Porte des Alpes