

EUROPEAN BATCH RELEASE PROTOCOL

PRODUCT: **DINDORAL SPF**

MEMBER STATE SPECIFIC INFORMATION

Batch number of finished product: L435887

Release date of finished product: 06-Jul-2016

Marketing authorisation number: 2776/1/10 MgSzH ATI

Issued by: HUNGARY

Target species: PHEASANTS/TURKEYS

Total number of containers in this batch: 100 boxes of 10 units

Number of containers the release is applied for: 100 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: 23-Mar-2018

Name and Address of Marketing Authorisation Holder:

MERIAL
29, avenue Tony Garnier
69007 LYON
France

SUMMARY INFORMATION ON THE FINAL BATCH OF FINISHED PRODUCT

Trade name: DINDORAL SPF

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

Batch number of:

Finished product:	Final batch:	Final bulk:
L435887	16DDL3781	16DDL0780

Pharmaceutical form of finished product: Lyophilisate for oral suspension

Type of final container: Bottle of glass

Date of start of period of validity: 23-Mar-2016

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

CERTIFICATION BY THE MANUFACTURER

I herewith certify that batch DINDORAL SPF n° L435887 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: 12-Sep-2016

Signature



Dr. Marc TEICHNER
Deputy Qualified Person
MERIAL LYON