

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis AE 1143

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Avian Encephalomyelitis virus (strain Calnek 1143) > 103.0 EID50

3. PHARMACEUTICAL FORM

Lyophilisate for suspension.

4. PACKAGE SIZE

5. TARGET SPECIES

Chickens (breeding stock)

6. INDICATION(S)

For active immunisation of breeding chickens to reduce vertical transmission and the adverse effects on egg lay and hatchability due to Avian Encephalopathy and to induce passive immunity against infection with Avian Encephalomyelitis (Epidemic tremor) in the progeny in the critical first few weeks of their life.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

In drinking water

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal
treatment only

POM-VPS

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4281

17. MANUFACTURER'S BATCH NUMBER

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {NATURE/TYPE}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis AE 1143

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Avian Encephalomyelitis virus (strain Calnek 1143) > 103.0 EID50

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4. ROUTE(S) OF ADMINISTRATION

In drinking water

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET FOR:

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE
FOR BATCH RELEASE, IF DIFFERENT**

Marketing Authorisation Holder and manufacturer responsible for batch release:

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nobilis AE 1143

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Avian Encephalomyelitis virus (strain Calnek 1143) > 103.0 EID50

4. INDICATION(S)

For active immunisation of breeding chickens to reduce vertical transmission and the adverse effects on egg lay and hatchability due to Avian Encephalopathy and to induce passive immunity against infection with Avian Encephalomyelitis (Epidemic tremor) in the progeny in the critical first few weeks of their life.

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Chickens (breeding stock)

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

In drinking water

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

12. SPECIAL WARNING(S)

<User Warnings>

For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

POM - VPS

Vm 01708/4281