LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
150 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution for horses
Altrenogest

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Altrenogest 2.2 mg/ml, Butylhydroxyanisole (E320), Butylhydroxytoluene (E321), Sorbic acid (E200), Benzyl alcohol

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

150 ml

5. TARGET SPECIES

Horses (mares)

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

8. WITHDRAWAL PERIOD

Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Women of child bearing age should avoid contact with the product.
This product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

10. EXPIRY DATE

<EXP {month /year} >
Once opened, use within 14 days.
Use before:

11. SPECIAL STORAGE CONDITIONS

No special precautions for storage.

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

Disposal: read the package leaflet
Part consumed feed must be safely destroyed and not given to any other animal.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight 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 01708/4503

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
150 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution for horses
Altrenogest

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Altrenogest 2.2 mg/ml

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

150 ml

5. TARGET SPECIES

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

8. WITHDRAWAL PERIOD

Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

<EXP {month /year} >
Once opened, use within 14 days.

11. SPECIAL STORAGE CONDITIONS

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight 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 01708/4503

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
250 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution for horses
Altrenogest

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Altrenogest	2.20 mg
Butylhydroxyanisole (E320)	0.07 mg
Butylhydroxytoluene (E321)	0.07 mg
Sorbic acid (E200)	1.50 mg
Benzyl alcohol	10.00 mg

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Horses (mares)

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

8. WITHDRAWAL PERIOD

Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Women of child bearing age should avoid contact with the product.
This product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

10. EXPIRY DATE

<EXP {month /year} >
Once opened, use within 28 days.
Use before:

11. SPECIAL STORAGE CONDITIONS

No special precautions for storage.

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

Disposal: read the package leaflet
Part consumed feed must be safely destroyed and not given to any other animal.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight 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 01708/4503

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
300 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution for horses
Altrenogest

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Altrenogest		2.20 mg
Butylhydroxyanisole (E320)	0.07 mg	
Butylhydroxytoluene (E321)	0.07 mg	
Sorbic acid (E200)	1.50 mg	
Benzyl alcohol		10.00 mg

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

300 ml

5. TARGET SPECIES

Horses (mares)

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

8. WITHDRAWAL PERIOD

Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Women of child bearing age should avoid contact with the product.
This product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

10. EXPIRY DATE

<EXP {month /year} >
Once opened, use within 28 days.
Use before:

11. SPECIAL STORAGE CONDITIONS

No special precautions for storage.

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

Disposal: read the package leaflet
Part consumed feed must be safely destroyed and not given to any other animal.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight 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 01708/4503

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
1000 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/ml oral solution for horses
Altrenogest

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Altrenogest	2.20 mg
Butylhydroxyanisole (E320)	0.07 mg
Butylhydroxytoluene (E321)	0.07 mg
Sorbic acid (E200)	1.50 mg
Benzyl alcohol	10.00 mg

3. PHARMACEUTICAL FORM

Oral solution.

4. PACKAGE SIZE

1000 ml

5. TARGET SPECIES

Horses (mares)

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.

8. WITHDRAWAL PERIOD

Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Women of child bearing age should avoid contact with the product.
This product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.

10. EXPIRY DATE

<EXP {month /year} >
Once opened, use within 28 days.
Use before:

11. SPECIAL STORAGE CONDITIONS

No special precautions for storage.

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

Disposal: read the package leaflet
Part consumed feed must be safely destroyed and not given to any other animal.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight 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 01708/4503

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Regumate Equine 2.2 mg/mL oral solution for horses

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Manufacturer:
Intervet Productions S.A.
Rue de Lyons
27460 Igoville, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Equine 2.2 mg/mL oral solution for horses
Altrenogest

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

Each ml contains:

Altrenogest		2.20 mg
Butylhydroxyanisole (E320)	0.07 mg	
Butylhydroxytoluene (E321)	0.07 mg	
Sorbic acid (E200)	1.50 mg	
Benzyl alcohol		10.00 mg

Clear, light yellow oily solution.

4. INDICATION(S)

In mares with significant follicular activity during the transitional period between seasonal anoestrus and the breeding season (follicles of at least 20-25 mm present at the beginning of treatment):

- Suppression/prevention of oestrus (usually after 1 to 3 days of treatment) during the prolonged oestrus periods occurring during this period.
- Control of the time of initiation of oestrus (approximately 90% of mares show signs of oestrus within 5 days following the end of treatment) and synchronization of ovulation (60% of mares ovulate between days 11 and 14 following the end of treatment).

5. CONTRAINDICATIONS

Do not use in mares where a uterine infection has been diagnosed.
Do not use in males.

6. ADVERSE REACTIONS

Adverse reactions, such as uterine infection, are extremely rare, as shown by the field clinical trial data. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horse (mare).

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

0.044 mg altrenogest (1 ml per 50 kg bodyweight) per kg bodyweight and per day, for 10 consecutive days.

9. ADVICE ON CORRECT ADMINISTRATION

Carefully withdraw the volume of product corresponding to the mare bodyweight (1 ml per 50 kg bodyweight) and administer this volume via oral route.

- 150, 300 and 1000 ml bottles: Wearing gloves remove the original cap and in its place screw on the luer lock cap. Keeping the bottle upright, screw the luer lock syringe onto the cap orifice, turn the bottle upside down, and carefully withdraw the solution from the bottle using the syringe. Turn the bottle right way up before detaching the syringe. Securely replace the small cap on the luer lock cap. Replace the childproof cap on the bottle until next use.

- 250 ml bottles: Remove the white cap and the aluminium foil seal from the neck of the measuring compartment. Keeping the bottle upright, press the body of the bottle until the required volume of product is accumulated into the measuring compartment. Carefully pour the content of the measuring compartment on the mare feed.

The product should be added to the mare’s feed, at a single feeding per day, or directly administered into the mouth using a syringe.

10. WITHDRAWAL PERIOD

Meat and offal: 9 days.
Not authorised for use in lactating animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
This veterinary medicinal product does not require any special storage precautions
Do not use after the expiry date stated on the carton and bottle.
Shelf life after first opening the container: 14 days for the 150 ml bottle, 28 days for the 250, 300 and 1000 ml bottles. When the container is broached (opened) for the

first time, using this in-use shelf-life, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
Avoid introduction of contamination.

12. SPECIAL WARNING(S)

Special warnings:
- In order to ensure effective use of the product, the presence of follicular activity in mares must be confirmed during the transitional period.
- The medicated feed should be offered to mares being treated as soon as the product has been added, and not stored.
- Griseofulvin may alter the effects of altrenogest if administered concomitantly with this product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- Women who may be, or are pregnant, should not use the product. Women of childbearing age should avoid contact with the product.
- This product should not be handled by persons with known or suspected progesterone-dependent tumours or thrombo-embolic disorders.
- Direct contact with the skin should be avoided. Personal protective clothing (gloves and overalls) must be worn when handling the product. Porous gloves may let this product pass through. Transcutaneous absorption may be even higher when the area is covered by an occlusive material, such as latex or rubber gloves. Accidental spillage on the skin should be washed off immediately with soap and water.
- Wash hands after treatment and before meals.
- In case of incidental contact with eye, rinse thoroughly with water for 15 minutes. Get medical attention.
- Effects of overexposure: repeated accidental absorption could lead to disruption of the menstrual cycle, uterine or abdominal cramping, increased or decreased uterine bleeding, prolongation of pregnancy or headache.

Overdose (symptoms):
- No negative effects have been observed in horses following up to five times the recommended dose of altrenogest for 87 days and at the recommend dose for continuous periods up to 305 days.

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 product should be disposed of in accordance with local requirements.
Part consumed feed must be safely destroyed and not given to any other animals.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

Exists in 150 ml, 250 ml, 300 ml and 1000 ml bottles; not all pack sizes may be marketed.

Approved 14 August 2020