PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARTON (containing bottle pack type)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Porcine 0.4% w/v Oral Solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Solution of 0.4 % w/v Altrenogest
Sufficient for a course of 6 gilts or 36 sows
Sufficient for a course of 11 gilts or 66 sows

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

540 ml
1000 ml

5. TARGET SPECIES

<Pictogram of a pig> Pigs.

6. INDICATION(S)

For the synchronisation of oestrus and improvement of farrowing rate and litter size in sows.

For the synchronisation of oestrus and improvement of litter size in sexually mature gilts.

Uses
Uses, dosage, administration, contraindications and warnings, **read label on enclosed container**.

Uses, dosage, administration, contraindications and warnings, see label on enclosed container.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration
Add to feed immediately before administration.
Discard any remaining medicated feed.

8. WITHDRAWAL PERIOD

Withdrawal period
Animals must not be slaughtered for human consumption during treatment or during a period of 9 days following the last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings
Women who are pregnant, or suspected to be pregnant, should not use the product. Women of childbearing age should handle the product with extreme care. The 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 accidental contact with the eyes rinse abundantly with water. 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.

When spreading manure from treated animals, the minimum distance to surface water as defined in the national or local regulations has to be strictly respected, because the manure may contain altrenogest which could cause adverse effects in the aquatic environment.

10. EXPIRY DATE

Expiry end of:
Once broached, use within 90 days.
Date to be discarded after first opening:

11. SPECIAL STORAGE CONDITIONS

The product does not need special storage temperature conditions.
Keep the container in the outer carton.

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

Regumate Porcine, 0.4% w/v oral solution should not enter water courses as this may be dangerous for fish and other aquatic organisms.

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-V

To be supplied by veterinary prescription only.
See container for further information.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4443

17. MANUFACTURER'S BATCH NUMBER

Batch no.:

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET,
540 ml Bottle Fix-a-form label
1000 ml Bottle label

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
MK7 7AJ

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Regumate Porcine 0.4% w/v Oral Solution

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

Solution of 0.4 % w/v Altrenogest
Sufficient for a course of 6 gilts or 36 sows
Sufficient for a course of 11 gilts or 66 sows

4. PHARMACEUTICAL FORM

Oral Solution

5. PACKAGE SIZE

540 ml
1000 ml

6. INDICATION(S)

For the synchronisation of oestrus and improvement of farrowing rate and litter size in sows.
For the synchronisation of oestrus and improvement of litter size in sexually mature gilts.

7. CONTRAINDICATIONS

Contra-indications and warnings
Not to be administered to male animals.
Not to be administered to pregnant sows or to those suffering from uterine infection.
Part consumed feed must be disposed of with other waste feed and not given to any other animals.
Ensure that the correct dose is administered daily as underdosing can lead to the formation of cystic follicles.

8. ADVERSE REACTIONS

9. TARGET SPECIES

<Pictogram of a pig> Pigs.

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

Add to feed immediately before administration.
Dosage and administration
Gilts: One dose of 5 ml per gilt per day for 18 consecutive days given orally on feed for immediate consumption.
Sows: One dose of 5 ml per sow per day for 3 consecutive days given orally on feed for immediate consumption.
Treatment should start on the day of weaning.
It is recommended that the animals to be treated are trough fed.

Individual or group feeding in troughs
Allow the animals to start feeding, then add Regumate Porcine as a top dressing on the feed in front of each pig.
Group feeding on the floor
Feed should be presented in such a manner that each pig is allowed sufficient floor space to get equal access to the feed. Once the animals have started feeding, dispense one dose of Regumate Porcine as a top dressing on to the feed in front of each pig.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Withdrawal period
Animals must not be slaughtered for human consumption during treatment or during a period of 9 days following the last treatment.

13. SPECIAL STORAGE PRECAUTIONS

The product does not need special storage temperature conditions.
Keep the container in the outer carton.

14. SPECIAL WARNING(S)

User warnings
Women who are pregnant, or suspected to be pregnant, should not use the product. Women of childbearing age should handle the product with extreme care. The 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 accidental contact with the eyes rinse abundantly with water. 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.

Other precautions regarding impact on the environment
When spreading manure from treated animals, the minimum distance to surface water as defined in the national or local regulations has to be strictly respected, because the manure may contain altrenogest which could cause adverse effects in the aquatic environment.

15. EXPIRY DATE

Expiry end of:
Once broached, use within 90 days.
Date to be discarded after first opening:

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

Regumate Porcine, 0.4% w/v oral solution should not enter water courses as this may be dangerous for fish and other aquatic organisms.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

March 2021

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V

To be supplied by veterinary prescription only.

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

Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4443

21. MANUFACTURER'S BATCH NUMBER

Batch no.

Approved 12 March 2021