

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Folliplan, 4 mg/ml oral solution for pigs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active ingredient:

Altrenogest 4.0 mg

Excipients:

Butylhydroxytoluene (E321) 0.07 mg

Butylhydroxyanisole (E320) 0.07 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution.

Clear, yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Pig (sexually mature gilts)

4.2 Indications for use, specifying the target species

For the synchronisation and control of oestrus in cycling gilts.

4.3 Contraindications

Do not use in male pigs.

Do not administer to pregnant sows or those suffering from uterine infection.

Do not use in case of hypersensitivity to the active substance.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

To use only in sexually mature gilts who had already presented one oestrus.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

- Women who are, or may be 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. Absorption through the skin 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 the eyes, rinse thoroughly with water for 15 minutes. Seek medical advice.
- 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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Do not administer during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Add the veterinary medicinal product to the feed immediately before feeding.

5 ml (20 mg altrenogest) per animal during 18 days.

Remove the screw cap and the obturator and measure the clinical dose of 5 ml using the dosing cup provided, pour the dose on the feed and close the bottle with the obturator and the screw cap after each use.

It should be ensured that all medicated feed is consumed.

Ensure the correct dose is administered daily as under dosing can lead to the formation of cystic follicles.

When the occasion arises of any uneaten or partly consumed medicated feed, this feed should be safely discarded and not given to any other animal.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No information available.

4.11 Withdrawal Period(s)

Meat and offal: 9 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sex hormones and modulators of the genital system: Progestogens

ATCvet code: QG03DX90

5.1 Pharmacodynamic properties

Altrenogest prevents oestrus and ovulation by inhibiting the release of the gonadotropins LH and FSH from the pituitary. After the end of treatment physiological oestrus (ovulation) occurs after 4 - 8 days.

5.2 Pharmacokinetic properties

Altrenogest is well and rapidly absorbed. It is distributed in the organs, muscle, fat, liver and kidney tissue. After 48 hours altrenogest is still present in the blood, but only just above the detection limit. The highest concentrations are found in the liver and kidneys. The liver is the main organ involved in the metabolism of altrenogest and the excretion occurs via the faeces and urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene (E321)
Butylhydroxyanisole (E320)
Soybean oil

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf-life of the bottle as packaged for sale: 3 years
Shelf life after first opening of the immediate packaging (bottle): 90 days

6.4 Special precautions for storage

Does not require any special storage conditions

6.5 Nature and composition of immediate packaging

540 ml and 1 L aluminium bottle with a low density polyethylene obturator and a polypropylene screw cap. A dosing cup is included with the 540 ml and 1 L presentation sizes.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

The veterinary medicinal product 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.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park
Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/275/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 28th April 2017

10 DATE OF REVISION OF THE TEXT