Summary of Product Characteristics

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Chanoprim Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active Substances

Trimethoprim	40 mg
Sulphadiazine	200 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and pigs

4.2 Indications for use, specifying the target species

Chanoprim Injection is indicated for the treatment of diseases caused by sensitive gram positive and gram-negative organisms.

4.3 Contraindications

This product should not be given by the intravenous route
Do not use in animals with severe liver parenchyma damage or known sulphonamide sensitivity.
Not for use in horses and sheep.
Not for use in animals with severe kidney disease or blood dyscriasis.

4.4 Special warnings for each target species

The maximum dose volume recommended at any one site is:

Cattle	20 ml
Pig	10 ml

4.5 Special precautions for use

Special precautions for use in animals
Fresh, adequate drinking water should be provided during therapy.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Transient local pain and erythema may be observed at the injection site.

4.7 Use during pregnancy, lactation or lay

Potentiated sulphonamides are safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For intramuscular use only.
The recommended dosage is 12 ml per 100 kg bodyweight daily for 3 consecutive days i.e. 24 mg SDZ per kg and 4.8 mg TMP per kg.
To ensure a correct dosage, body weight should be determinated as accurately as possible.

Species	**Dose /bodyweight**
Cattle	12.0 ml/100 kg
Calf	6.0 ml/50 kg
Piglet	0.6 ml/5 kg
Weaner	2.4 ml/20 kg
Fattner/Sow	9.0 ml/75 kg

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

None

4.11 Withdrawal Period(s)

Milk: 72 hours
Meat and offal: 25 days

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, sulfadiazine and trimethoprim.
ATCvet code: QJ01EW10

5.1 Pharmacodynamic properties

Chanoprim solution for injection is used in the treatment of bacterial infections in cattle and pigs that are sensitive to potentiated sulphonamides.

Sulphadiazine
This sulphonamide, sulphadiazine, is one of the more active members of the group and has been used with trimethoprim at the same ratio in a number of products. The dosage rates vary between 1 ml/8 kg and 1 ml/16 kg.

Trimethoprim
Trimethoprim is widely used in human and veterinary medicine to potentiate sulphonamides of which a number may be used. The usual ratio of the combination for therapy if 1:5, trimethoprim: sulphonamide for most products. In turn this gives, in the case of Chanoprim Injection, a peak plasma

ratio of approximately 1:20, TMP: SDZ; this ratio is generally considered optimal for many sensitive bacterial species. This plasma ratio is found also with other sulphonamides.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known.

6.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.3. Special precautions for storage

Do not store above 25°C.
Do not freeze.

6.4 Nature and composition of immediate packaging

100 ml amber, type II glass vial closed with a grey nitryl stopper and aluminium seal.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7. MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,
Loughrea,
Co. Galway,
Ireland.