1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sumex 10 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Ivermectin 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Glycerol
Glycerol formal

Clear, colourless to slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for the effective treatment of the following harmful parasites of pigs:

Gastrointestinal worms (adult and fourth stage larvae):
Ascaris suum,
Hyostrongylus rubidus,
Oesophagostomum spp.,
Strongyloides ransomi (adult and somatic larval stage)

Lungworms:
Metastrongylus spp. (adult)

Lice:
Haematopinus suis

Mange mites:
Sarcoptes scabiei var. *suis*

3.3 Contraindications

Do not administer by the intravenous or intramuscular route.
Do not use in cases of hypersensitivity to the active substance.
Do not use in cats and dogs as severe adverse reactions may occur.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Parasite resistance to any particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. It is important that the correct dose is given in order to minimise the risk of resistance.
Assess bodyweight as accurately as possible before calculating the dose.

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

Take care to avoid self administration; the veterinary medicinal product may cause local irritation and/or pain at the site of injection.
Do not smoke or eat while handling the veterinary medicinal product.
Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

The veterinary medicinal product has been formulated specifically for use in pigs only. Do not use in cats and dogs. Avermectins may not be well tolerated in all non-target species (cases of intolerance with fatal outcome are reported in dogs - especially Collies, Old English Sheepdogs and related breeds or crosses, and also in turtles/tortoises).

3.6 Adverse events

Pigs:

Undetermined frequency (cannot be estimated from the available data):	Injection site pain[1]

[1] Mild and transient. Disappears without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
As the safety of ivermectin injection has not been demonstrated in sows during early pregnancy, the veterinary medicinal product should not be given to sows in the 1st trimester of pregnancy (Day 1 - 40).

Fertility:
The veterinary medicinal product can be used in breeding sows and boars and will not affect fertility.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product can be used concurrently, without adverse effects, with clostridial vaccine, given at separate injection sites.

3.9 Administration routes and dosage

Subcutaneous use.
The veterinary medicinal product is administered as a single injection. Each ml contains 10 mg of ivermectin sufficient to treat 33 kg of bodyweight of pigs. Massage the injection site after administration of the product.
Injection of wet or dirty animals is not recommended.

Pigs:
In pigs, the recommended dosage level is 300 µg ivermectin per kg bodyweight. This is equivalent to 1 ml per 33 kg bodyweight. The recommended route of administration is by subcutaneous injection into the neck.

Young Pigs:
In young pigs, especially those below 16 kg for which less than 0.5 ml of the product is indicated, dosing accurately is important. The use of a syringe that can accurately deliver as little as 0.1 ml is recommended.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

There is no specific antidote.
A dose of 30 mg ivermectin per kg (100 x the recommended dose of 0.3 mg per kg) injected subcutaneously to pigs caused lethargy, ataxia, bilateral mydriasis, intermittent tremors, laboured breathing and lateral recumbency.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 28 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP54AA01

4.2 Pharmacodynamics

Ivermectin is a member of the avermectin group. Ivermectin is a member of the macrocyclic lactone class of endectocides which have a unique mode of action. Compounds of this class bind selectively and with high affinity to glutamate-gated chloride ion channels which occur in invertebrate nerve and muscle cells. This leads to an increase in the permeability of the cell membrane to chloride ions with hyperpolarization of the nerve or muscle cell, resulting in paralysis and death of the parasite. Compounds of this class may also interact with other ligand-gated chloride channels, such as those gated by the neurotransmitter gamma-aminobutyric acid (GABA).
The margin of safety for compounds of this class is attributable to the fact that mammals do not have glutamate-gated chloride channels, the macrocyclic lactones have a low affinity for other mammalian ligand-gated chloride channels and they do not readily cross the blood-brain barrier.

4.3 Pharmacokinetics

At a dose level of 0.3 mg ivermectin per kg bodyweight, a C_{max} of 6.9 ng/ml was reached at a T_{max} of 3.6 days, and the elimination half-life was 5.5 days.

Billary excretion, followed by elimination in faeces is the major route of ivermectin excretion in pigs. While the major single component excreted was unaltered drug, the main metabolites in swine are 3''-O-desmethyl-H_2B_{1a} and 3''-O-desmethyl-H_2B_{1b}.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf–life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf–life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage precautions.

5.4 Nature and composition of immediate packaging

Multidose high density polyethylene bottles of 50 ml, 250 ml and 500 ml sealed with bromobutyl seals and plain aluminium overseals, containing a clear, colourless sterile solution.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

The veterinary medicinal product should not enter water courses as ivermectin may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10987/151/001

8. DATE OF FIRST AUTHORISATION

28/06/2002

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

14/08/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).