ΠΑΡΑΡΤΗΜΑ 1: ΠΕΡΙΛΗΨΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEPAGEN 100 mg/ml solution for injection for cattle, horses, goats, swine and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

2-methyl-2-phenoxy-propionic acid	100 mg
equivalent to 2-methyl-2-phenoxy sodium propionate	112.2 mg

Excipients:

Sodium edetate	0.90 mg
Sodium methyl parahydroxybenzoate (E219)	0.16 mg
Sodium propyl parahydroxybenzoate (E217)	0.08 mg
Water for injections q.s. to 1 ml	

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

4. CLINICAL PARTICULARS

4.1. Target species

Cattle, horses, goats, swine, dogs.

4.2. Indications for use, specifying the target species

In general:

Indigestion - alimentary intoxication - acetonemia - hepatic insufficiency - inappetence - meteorism - coadjuvant in the specific treatment of gastrointestinal parasitosis.

More specifically:

Cattle – Goats: alimentary intoxication, rumen overload, dyspepsia with meteorism, acetonemia (ketosis), complementary treatment in cases of distomatosis and dicrocoeliasis.

Horses: hepatic disorders due to dietary imbalance, hepatic insufficiency also due to piroplasmosis and leptospirosis.

Swine: enterotoxemia, hepatic dystrophy, edema, inappetence and constipation also resulting from farrowing or weaning.

Dogs: jaundice, hepatic insufficiency, coadjuvant treatment in cases of leptospirosis and distemper.

4.3. Contraindications

None.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for use in animals

None.

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

None.

4.6. Adverse reactions (frequency and severity)

No secondary effects are known at the prescribed doses, nor have they been reported following administration of higher doses.

4.7. Use during pregnancy, lactation or lay

It can be used 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

For all animal species for which the product is intended, the posology is 10 mg/kg body weight.

Adult cattle and horses:	up to 300 kg b.w.: 30 ml.
	up to 500 kg b.w.: 40 ml.
	over 500 kg b.w.: 50 ml.
Calves - Foals - Goats - Swine:	5 - 15 ml.
Piglets:	1 ml per 10 kg b.w.
Dogs:	1 ml per 10 kg b.w.

Inject by the deep intramuscular route, by the intraperitoneal route or by the slow intravenous route.

The above-mentioned doses may be repeated every 24 hours, at the discretion of the Veterinary surgeon.

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

No symptoms due to overdose are known.

4.11. Withdrawal periods

Meats: 0 days.
Milk: 0 hours.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: liver therapy
ATCvet Code: QA05BA

5.1. Pharmacodynamic properties

HEPAGEN, an aqueous solution containing 10% phenoxy-2-methyl-2-propionic acid, is characterised by an elective action on the liver, with an increase in bile secretion and consequent activity favouring the performance of digestive functions.
HEPAGEN performs its secretory stimulatory action by acting directly on the glandular system without excitation or depression of the central or autonomous nervous systems.
Owing to its choleretic activity, HEPAGEN is indicated in the treatment of diseases characterised by or accompanied by hepatic insufficiency.

5.2. Pharmacokinetic particulars

Administered by the parenteral route, HEPAGEN is rapidly absorbed and is eliminated via the urine and the faeces, in unmodified form in cattle and partially metabolised in swine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium edetate
Sodium methyl parahydroxybenzoate (E219)
Sodium propyl parahydroxybenzoate (E217)
Water for injections

6.2. Incompatibilities

HEPAGEN is not miscible with calcium salts.
In the absence of compatibility studies, do not mix with other veterinary medicinal products.

6.3. Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 4 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Store protected from light and from sources of heat.

6.5. Nature and composition of immediate packaging

100 ml type II glass bottle, with an elastomer closure and sealed with an aluminium collar, in a cardboard box.

100 ml PET (polyethylene terephthalate) bottle with elastomer cap and sealed with aluminium collar, in a cardboard box.

Not all pack sizes may be marketed.

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

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

FATRO S.p.A. - Via Emilia, 285 - Ozzano Emilia - Bologna - Italy.

8. MARKETING AUTHORISATION NUMBER

10464

9. DATE OF FIRST AUTHORISATION OF THE AUTHORISATION

07/05/1986

10. DATE OF REVISION OF THE TEXT

22/03/2012