Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedalin 7 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains:

Active substance

Acepromazine Maleate BP (Vet) equivalent to 7 mg acepromazine in a formulation also containing titanium dioxide, propylene glycol, indigotine 1 and eudragit RL 30D.

For a full list of excipients see 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Cat and Dog.

4.2 Indications for use, specifying the target species

Sedation: elimination of defensive reactions during fixation or examination of an animal, nervousness, stress situations and transport.

Anaesthetic pre-medication and symptomatical therapy of vomiting and motion sickness during long lasting journeys under sedation of several hours duration.

4.3 Contraindications

Shock (hypovolaemia)
Very excited animals
Spasmophilia
Status epilepticus
Pregnant animals

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precaution(s) for use in animals

Refer to information outlined under 4.3 above.

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

Persons who are sensitive to chlorpromazine should avoid direct skin contact with uncoated tablets.

The active substance in Sedalin 7mg is a phenothiazine derivate. Another substance of this group, chlorpromazine causes photosensitization in some humans (photo-allergy), which can last over years. The symptoms are severe redness, swelling or vesication of the skin after exposure to sun or light.

The phenothiazine which is included in Sedalin 7mg is probably not relevant as a first trigger of a photo-allergy, but in persons who already suffer from such a sensitivity to chlorpromazine, it may cause above mentioned skin-reactions in exposed parts of the body (so-called cross allergy).

4.6 Adverse reactions (frequency and seriousness)

Acepromazine induces a transient hypotension.

By inhibition of temperature regulation acepromazine may cause hypothermia.

Paradoxical excitation symptoms.

Reversible decrease in haematocrit and hemoglobin, in number of erythrocytes, leukocytes and thrombocytes.

By increasing the release of prolactin acepromazine may cause disturbance of fertility.

4.7 Use during pregnancy, lactation or lay

Sedalin 7mg should not be used in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

Acepromazine potentiates the action of central inhibiting pharmaca.

For acepromazine reduces sympathicotonia it potentiates the effect of hypotensive agents.

Simultaneous administration of organic phosphoric esters increase the toxicity of acepromazine.

4.9 Amounts to be administered and administration route

Sedalin 7mg is intended for oral administration.

Guide dose for sedation, pre-medication and symptomatical therapy:

- 1.5 - 3.0 mg acepromazine/kg bw

cat:		1-2 film-coated tablets, equivalent to 7-14mg acepromazine
small dog of:	5kg	1-2 film-coated tablets, equivalent to 7-14mg acepromazine
	10kg	2-4 film-coated tablets, equivalent to 14-28mg acepromazine

Single administration approx. 30-60 minutes before action is desired. Depending on the intended effect this dosage regimen can be varied. The effect lasts for approx. 4h.

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

None known.

4.11 Withdrawal Period(s)

Not for use in animals intended for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Sedalin 7mg contains the neuroleptic acepromazine. By its centrally psychomotoric inhibition it leads to a diminished excitation (sedation) and to a diminished motoricity (hypokinesia) with relaxation of the musculature which does not essentially impair consciousness. This state of relative indifference to the environment leads to apathic listlessness with reduced pain sensation which makes manipulations at and with the animal possible without trouble. Psychic irritability, aggressions, anxiety and defence reactions are inhibited. The sedative effect occurs 30-60 minutes after administration of the tablets. Peak plasma levels are also measured at this time. The duration of the sedative effects continues under the required dose 4 hours, on the average. Increasing the recommended dosage prolongs but does not intensify the action.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients

Lactose
Wheat Starch
Microcrystalline Cellulose
Methylhydroxyethylcellulose
Colloidal Anhydrous Silica
Magnesium Stearate

Tablet Coating

Talc
Titanium Dioxide (E171)
Propylene Glycol
Polyethylene Glycol 6000
Eudragit RL 30D
Sicovit indigotine lake (E132)

6.2 Incompatibilities

None known

6.3 Shelf-life

4 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place.

6.5 Nature and composition of immediate packaging

Base layer foil of PVC/PVDC, push through foil of aluminium.
Each blister strip contains 20 tablets.
Folding cartons with 2 blister strips (40 tablets), 5 blister strips (100 tablets) 12 blister strips (240 tablets) and 25 blister strips (500 tablets).

6.6 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

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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10966/25/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12th January 2001