IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10835/009/001**
Case No: 7003285

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Novartis Animal Health Ireland Ltd

Industrial Park, **Cork Road**, **Waterford**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

ACP Solution for Injection 10mg/ml

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **11/08/2008** until **30/09/2010**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ACP Solution for Injection 10mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active Substance	
Acepromazine	10 mg
(as Acepromazine Maleate 1.355 %w/v)	
Excipients	
Phenol (preservative)	3 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses declared as not intended for human consumption.

4.2 Indications for use, specifying the target species

Anaesthetic Premedication: Following acepromazine administration, the amount of anaesthetic necessary to induce anaesthesia is considerably reduced. This reduction is approximately one-third of a suitable induction agent.

Tranquillisation: Acepromazine tranquillisation (ataraxy) involves a modification of temperament which is not associated with hypnosis, narcosis or marked sedation. This is achieved with low doses of acepromazine. At low doses, acepromazine reduces anxiety which is beneficial for use in horses prior to shoeing.

Sedation: At higher dose rates acepromazine is an effective sedative, as an adjunct to, or replacement for physical restraint e.g. dentistry, handling and shoeing. The relaxant effects aid examination of the penis in horses and the treatment of tetanus and choke. Acepromazine possesses anti-emetic, anti-convulsant, hypothermic, hypotensive and anti-spasmodic properties, and shows a marked potentiating effect on barbiturate anaesthesia.

4.3 Contraindications

Do not administer to breeding stallions. Paralysis of the retractor penis muscle has been associated with the use of parenterally administered acepromazine in horses.
Do not administer to pregnant mares.

Do not use this product in conjunction with organophosphates and/or procaine hydrochloride, as it may enhance activity and potential toxicity.

Horses should not in any circumstances be ridden within 36 hours of administration of a clinical dose.

4.4 Special warnings for each target species

Duration of action may be prolonged and this should be remembered when riding, as acepromazine may affect performance and appear in drug tests for some time.

4.5 Special precautions for use

Special precautions for use in animals

Situations may arise where general anaesthesia is required in the 4-6 hours following use of the product. In such cases care should be taken to reduce the induction dose of other premedicants and anaesthetic agents, particularly parenteral barbiturates so as to avoid potentiation and additive depressant effects.

Acepromazine has little, if any, analgesic effect so that painful procedures must be avoided, particularly where animals are known to have unpredictable temperaments. Therefore, the usual precautions should be maintained when handling sedated horses.

During sedation, horses will normally retain visual and auditory acuity so that loud sounds and rapid movements may cause arousal from the sedated state. It is therefore important to keep treated horses in a quiet environment and avoid sensory stimulation as far as possible.

Take adequate precautions to maintain sterility.

Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, discard the product.

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

Take precautions to avoid accidental injection or self-administration of this potent drug. Should accidental injection occur, seek medical advice immediately. Symptomatic treatment may be necessary.

4.6 Adverse reactions (frequency and seriousness)

Acepromazine has caused paraphimosis, sometimes as a sequel to priapism. When extrusion of the penis occurs, the owner should be advised to inform his veterinary surgeon if retraction of the penis does not take place within 2-3 hours. Suitable treatments have been described in the veterinary literature. When administered to male horses (geldings or stallions), use the lowest dose recommended to produce the required effect.

Acepromazine is an adrenoceptor blocking drug and this causes hypotension and lowered p.c.v. The product should therefore be administered with great caution and at low dose rates only to debilitated horses and animals in states of hypovolaemia, anaemia and shock, or with cardiovascular disease. Rehydration should precede acepromazine administration.

Accidental intracarotid injection in horses can produce clinical signs ranging from disorientation to convulsive seizures and death.

4.7 Use during pregnancy, lactation or lay

This product is not intended for use in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

Tranquillisers are additive to the actions of other depressants and will potentiate general anaesthesia (see 4.6).

4.9 Amounts to be administered and administration route

By intramuscular injection:
0.03 - 0.10 mg per kg bodyweight. Approximately equivalent to 0.15 - 0.5 ml of 10 mg/ml injection per 50kg (approx. 1 cwt) bodyweight.

By intravenous injection:
As for intramuscular, except that it is recommended the injection is made slowly.

Normally single doses of acepromazine are administered. Long term use is not recommended. On the rare occasions that repeat dosing is required, the dosing interval should be 36-48 hours.

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

Overdosage: Slow intravenous injection of norepinephrine (noradrenaline) should be used whenever a hypertensive agent is required to reverse any fall in blood pressure.

Epinephrine (adrenaline) is contra-indicated in the treatment of acute hypotension produced by overdosage of acepromazine maleate, since further depression of systemic blood pressure can result. Other pressoramines such as norepinephrine or neosynephrine should be administered to reverse hypotensive effects. However, the reversing effect of norepinephrine is likely to be transient and repeated doses will normally be required.

4.11 Withdrawal Period(s)

Treated horses may never be slaughtered for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Ataractic

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium Hydroxide/Maleic Acid
Water for Injections

6.2 Incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

A clear pale yellow, sterile aqueous solution in 20 ml clear glass (Type II) vials, closed with chlorobutyl rubber bungs and aluminium crimped seals.

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

Novartis Animal Health Ireland Ltd.
Industrial Park
Cork Road
Waterford
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10835/009/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2005

10 DATE OF REVISION OF THE TEXT

11th August 2008