

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10277/084/001

Case No: 7002486

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Schering Plough Limited

Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW, United Kingdom

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Intrac

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **19/12/2006** until .

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Intrac

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients	Quantity/ dose
<i>Bordetella bronchiseptica</i> - strain S55	1 x 10 ⁷ - 5 x 10 ⁸ viable organisms

Diluent	per dose
Purified water Ph. Eur.	1.0 ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder and diluent for intra-nasal solution

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs, from 2 weeks of age

4.2 Indications for use, specifying the target species

For the active immunisation of dogs to reduce clinical signs of tracheobronchitis (kennel cough) caused by *B. bronchiseptica*.

Onset of protection can be expected within 5 days of administration of the initial dose and duration of immunity is at least six months from initial vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Do not vaccinate unhealthy animals.

Dogs being treated with antibiotics that are active against *B. bronchiseptica* should not be vaccinated.

As Intrac is a live vaccine, some spread of the vaccine organism to susceptible contact animals may occur shortly after administration but with no adverse effect.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

Wash hands after using the product.

4.6 Adverse reactions (frequency and seriousness)

Transient coughing may occur in a small number of dogs within a few days of vaccination. Occasional hypersensitivity reactions may occur. In such cases appropriate treatment such as adrenaline should be administered without delay.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

4.9 Amounts to be administered and administration route

Dogs- from 2 weeks of age

Dose- one dose of 1 ml

Dogs should be vaccinated at least 5 days before being exposed to a risk of infection. Dogs may be revaccinated at a frequency of not less than 6 months in preparation for any anticipated future exposure.

Reconstitution: When reconstituting freeze-dried vaccine with diluent, aseptic precautions should be taken. Withdraw 1ml of diluent into a syringe, inject into a vaccine vial, mix in order to reconstitute completely and withdraw back into the syringe. Affix the nasal applicator.

Administration: Intranasal application - in small breeds of dog, 0.5 ml of vaccine may be administered into each nostril. In larger breeds, 1.0 ml may be administered into one nostril.

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

No adverse events other than those referred to in 4.6 above, are expected following administration of an overdose.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against *Bordetella bronchiseptica*.

ATCvet code: QI07AE01

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Casein hydrolysate
Dextran
Gelatin
Lactose monohydrate
Dipotassium hydrogen phosphate
Potassium dihydrogen phosphate
Sodium glutamate
Bovine serum albumin
Glutathione

Diluent

Purified water

6.2 Incompatibilities

Do not mix with other vaccine/immunological product except the diluent provided.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year
Shelf life after reconstitution: Reconstituted vaccine must be used immediately and not stored.

6.4 Special precautions for storage

Store between +2 °C and +8 °C. Protect from light. Transportation should be carried out under the conditions recommended for storage.

6.5 Nature and composition of immediate packaging

Cardboard box with 5 vaccine vials each containing 1 dose, 5 diluent (purified water) vials of 1ml , and 5 nasal applicators.
Vials of type 1 glass, closed with a rubber stopper and sealed with an aluminium cap. Applicator of polypropylene.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Schering-Plough Ltd
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Welwyn Garden City
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10277/84/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th October 2005

10 DATE OF REVISION OF THE TEXT

24th August 2006

22nd September 2006