



**PERMIT TO ALLOW SUPPLY AND MINOR USE
OF AN UNREGISTERED VETERINARY CHEMICAL PRODUCT**

PERMIT NUMBER -PER11774

This permit is issued to the Permit Holder in response to an application granted by the APVMA under section 112 of the Agvet Codes of the jurisdictions set out below. This permit allows a Supplier (as indicated) to possess the product for the purposes of supply and to supply the product to a person who can use the product under permit. This permit also allows a person, as stipulated below, to use the product in the manner specified in this permit in the designated jurisdictions. This permit also allows the Permit Holder, the Supplier (if not one and the same) and any person stipulated below to claim that the product can be used in the manner specified in this permit.

THIS PERMIT IS IN FORCE FROM 01 OCTOBER 2009 TO 30 SEPTEMBER 2010 .

Permit Holder and Supplier:

**DAVAL (AUSTRALIA) PTY LTD
45 STEVEDORE STREET
WILLIAMSTOWN VIC 3016**

Permit Coordinator:

Dr Craig Cunningham
CPC Veterinary Consulting Pty Limited
32 Macedon Avenue
Dromana VIC 3936

Persons who can use the product under this permit:

Registered veterinarians for use in animals under their care, as permitted under State legislation in the jurisdiction in which they practice their profession.

CONDITIONS OF SUPPLY

Product to be used:

CEREMBEN

Containing:

4.50 mg/mL PURIFIED HYPERIMMUNE CAPRINE SERUM as the only active constituent.

Directions for Use:

Use as directed by the prescribing veterinarian to provide alternative or adjunctive for the treatment and prevention of endotoxaemia in horses. The prescribing veterinarian is responsible for safe and effective use of this unregistered product.

Permit holder suggestions are based on information from the following references: Sykes BW and Furr MO. (2005). Equine endotoxaemia – A state of the art review. AVJ. 83: 45-50.

Kelmer G. (2009). Update on treatments for endotoxaemia. Veterinary Clinics of North America Equine Practice. 25: 259-270.

Menzies-Gow et al. (2004). Endotoxin-induced digital vasoconstriction in horses: associated change in plasma concentrations of vasoconstrictor mediators. EVJ. 36 (3): 273-278.

Critical Use Comments:

Storage: Store product at minus 18 degrees C (deep freeze).

Expiry date: 12 months from date of manufacture

Withholding Period:

DO NOT USE in horses intended for human consumption

Jurisdiction:

ALL States

Additional Conditions:

- 1 The product must only be supplied to and used by, registered veterinarians
- 2 A copy of this permit must be provided to each participating veterinarian
- 3 The product can only be advertised to registered veterinarians.
- 4 The supplier/permit coordinator must supply product in a container that complies with the requirements of section 18(1) of the Agricultural and Veterinary Chemicals Code Regulations.
- 5 Attached to that container must be a label that is consistent in content and format to that which is attached to this permit at Attachment 1
- 6 The Permit Holder or Permit Coordinator must record the names of each veterinarian to whom product is supplied together with the date, quantity and batch numbers of product supplied as per the form at Attachment 2. This information must be made available to the State Government Chemical Coordinators or the APVMA on request;
- 7 The prescribing veterinarian must maintain a register of all treatments recording the date, amount and batch number of product, the patient and client details (name, address, phone contact) as per Attachment 2.
- 8 The prescribing veterinarian must immediately report all adverse experiences associated with the use of the product, in writing, to the Permit Coordinator

- 9 The Permit Coordinator must immediately report any adverse experiences to the APVMA
- 10 The default shelf life for this product is 12 months from the date of manufacture. The appropriate expiry date must appear on the label.
- 11 Upon application for renewal or extension of this permit, the following information must be submitted with the renewal application:
 - 11.1 copies of all completed request forms (Attachment 2);
 - 11.2 a list sorted by veterinarian names and the quantity supplied;
 - 11.3 the amount of product supplied during the period this permit was in force;
 - 11.4 justification for permit renewal instead of product registration;
 - 11.5 any application for renewal must be made three (3) months prior to expiry date of this permit to allow for continuity of supply.
- 12 This permit remains valid only while there is no suitable registered product available for this purpose

Issued by

Delegated Officer

**ATTACHMENT 1
PRODUCT LABELS AND LEAFLET**

Text Label Leaflet

**KEEP OUT OF REACH OF CHILDREN
FOR ANIMAL TREATMENT ONLY
CEREMBEN**

ACTIVE CONSTITUENT:

4.5mg/mL Purified Hyperimmune Caprine Serum

1mL

This product is NOT registered and is only available under APVMA Permit Number 11774 to registered veterinarians for use in the treatment and prevention of endotoxaemia in horses under relevant state prescribing laws
READ PERMIT BEFORE USE.

DIRECTIONS FOR USE:

Use as directed by the prescribing veterinarian to provide alternative or adjunctive treatment and prevention of endotoxaemia in horses. The prescribing veterinarian is responsible for safe and effective use of this unregistered product.

Permit holder suggestions are based on information from the following references:

Sykes BW and Furr MO. (2005). Equine endotoxaemia – A state of the art review. AVJ. 83: 45-50.

Kelmer G. (2009). Update on treatments for endotoxaemia. Veterinary Clinics of North America Equine Practice. 25: 259-270.

Menzies-Gow et al. (2004). Endotoxin-induced digital vasoconstriction in horses: associated change in plasma concentrations of vasoconstrictor mediators. EVJ. 36 (3): 273-278.

WITHHOLDING PERIOD: DO NOT USE in horses intended for human consumption.

FIRST AID:

If poisoning occurs, contact a doctor or Poisons Information Centre (Phone 13 11 26).

Dispose of empty container by wrapping with paper and putting in garbage.

Store below -18°C (Deep freeze).

Manufactured by:

Sypharma Pty Ltd

27 Healey Road

Dandenong VIC 3175

Phone: +61 3 9706 4913

Fax: +61 3 9706 4914

Text 15x1mL Carton

FOR ANIMAL TREATMENT ONLY
CEREMBEN

ACTIVE CONSTITUENT:

4.5mg/mL Purified Hyperimmune Caprine Serum

Contents: 15 x 1mL vials.

This product is NOT registered and is available under APVMA Permit Number 11774.

READ PERMIT BEFORE USE.

READ ENCLOSED LEAFLET BEFORE USING THIS PRODUCT

WITHHOLDING PERIOD: NIL

Store below -18°C (Deep freeze).

B:

EXP:

Text Immediate Container

FOR ANIMAL TREATMENT ONLY
CEREMBEN

ACTIVE CONSTITUENT:

4.5mg/mL Purified Hyperimmune Caprine Serum

1mL

READ ENCLOSED LEAFLET BEFORE USING THIS PRODUCT

Store below -18°C (Deep freeze).

B:

EXP:

ATTACHMENT 2

APVMA REQUEST FORMS FOR THE SUPPLY OF UNREGISTERED PRODUCT TO REGISTERED VETERINARIANS.

PRODUCT NAME: CEREMBEN PURIFIED HYPERIMMUNE CAPRINE SERUM

PERMIT NUMBER: PER 11774

Part 1

COMPANY AND PRODUCT DETAILS	
Manufacturer	Sypharma Pty Limited 27 Healy Street Dandenong VIC 3175
Product name	CEREMBEN Purified Hyperimmune Caprine Serum
APVMA Permit Number	PER 11774
Proposed use	Endotoxaemia in horses

Part 2

TO BE COMPLETED BY THE SUPPLIER AND/OR PERMIT COORDINATOR	
Name of Veterinarian supplied	
Address of Veterinarian supplied	
Date Supplied	
Quantity Supplied	
Batch Number	
Signature of Permit Coordinator/Supplier	

Part 3

TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN The supplier and the prescribing Veterinarians must keep copies of this record	
Name of prescribing Veterinarian	
Veterinarian Registration Number	
Veterinary Practice or Trading Name	
Street Address	
Postal Address	
Date of request	
Quantity and batch number supplied	
Signature of Prescribing Veterinarian	

Part 4

PATIENT DETAILS TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN These details are to be made available to AVPMA or State Coordinators on request	
Date of use	
Quantity used	
Batch Number	
Name and address of client	
Identity of horse treated	
Name and signature of the prescribing Veterinarian	