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

PERMIT NUMBER –PER13488

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. If this permit were not issued, supply of the product as specified below would constitute an offence under section 79 of the Agvet Code.

THIS PERMIT IS IN FORCE FROM: 12 SEPTEMBER 2012 TO 30 SEPTEMBER 2026

Permit Holder:
PHEBRA PTY LTD
19 Orion Road
LANE COVE WEST NSW 2066

Suppliers:
PHEBRA PTY LTD
19 Orion Road
LANE COVE WEST NSW 2066

Persons who can use the product under this permit:
Registered veterinarians for the treatment of animals under their care as permitted in the jurisdiction in which they practice their profession.

Product to be used (the Product):
Methylene Blue 50mg/5mL Injection as approved by the TGA (AUST R 223583)
10 x5mL vials

Directions for Use:
Use only by intravenous injection for the treatment of methaemoglobinemia in dogs.
For use by registered veterinarians for the treatment of dogs under their care as permitted in the jurisdiction in which they practice their profession only.

Critical Use Comments:
For use in dogs only. NOT TO BE USED in food-producing animal species
Withholding Period:
NOT TO BE USED in food-producing animals

Jurisdiction:
ALL States

CONDITIONS

1. The Product supplied must be identical to that registered by the TGA for human use.
2. The product can only be supplied to and used by a registered Veterinarian.
3. Person who wish to use the products for the purpose specified must be supplied with a copy of this permit.
4. The prescribing veterinarian must report all adverse experiences associated with the use of this product in writing to the supplier.
5. The supplier must immediaely report any adverse experiences to the APVMA.

Issued by the Australian Pesticides and Veterinary Medicines Authority
Note: Version 3 issued to extend the expiry date to 30 Sept 2026 and to update product and conditions to reflect TGA approval.