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Fiproclear 268 mg spot-on solution for large dogs

Authorised

- Fipronil

Product identification

Medicine name:
Fiproclear 268 mg spot-on solution for large dogs

Active substance:
Fipronil

Target species:
Dog

Route of administration:
Spot-on use

Product details

Active substance and strength:
Fipronil
268.00 milligram(s) / 1.00 Pipette

Pharmaceutical form:
Spot-on solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QP53AX15

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Valid

Authorised in:
Ireland

Package description:
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 150 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 120 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 90 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 60 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 30 pipettes

2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 24 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 12 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 8 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 6 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 4 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 3 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 2 pipettes
2.68 ml, pipette moulded from a film composed of 3 layers: a polypropylene/COC/polypropylene, solvent free lacquer laminateand a copolymer of

polyethylene/EVOH/polyethylene. The pipettes are sealed within a child resistant 4-ply foil sachetcomposed of LDPE/nylon/aluminium foil/polyester film and presented in an outer box.Boxes of 1 pipette

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Hybrid application (Article 13(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Norbrook Laboratories (Ireland) Limited

Marketing authorisation date:
17/05/2013

Manufacturing sites for batch release:
Norbrook Manufacturing Limited
Norbrook Laboratories Limited

Responsible authority:
Health Products Regulatory Authority

Authorisation number:
VPA22664/107/003

Date of authorisation status change:
17/05/2013

Reference member state:
Ireland

Procedure number:
IE/V/0306/003

Concerned member states:
Italy United Kingdom (Northern Ireland)

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Combined File of all Documents