# MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels.

#### PRINTED AEROSOL CAN

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

# 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

### MA holder

Bayer plc, 400 South Oak Way, Green Park, Reading, Berkshire, RG2 6AD United Kingdom. Tel 0118 206 3000

# Manufacturer

Bayer AG, Leverkusen.

# 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bolfo 0.25% Flea Spray

#### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Contains 0.25% w/w propoxur. Does not contain CFC propellants

#### 4. PHARMACEUTICAL FORM

#### 5. PACKAGE SIZE

Contains minimum 225 ml.

# 6. INDICATION(S)

FOR THE CONTROL OF FLEAS ON DOGS AND CATS.

#### 7. CONTRAINDICATIONS

Do not use any other insecticide concurrently or within 7 days of last use.

Do not use more often than weekly.

Do not use on puppies and kittens under 12 weeks of age.

Do not use if you pet is unwell or recovering from an illness.

#### 8. ADVERSE REACTIONS

#### 9. TARGET SPECIES

Dogs and cats.

# 10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

**Small Dogs** (up to 9 kg e.g. Terriers) - spray for 3 seconds

and Cats

**Medium Dogs** (9.1 – 18 kg e.g. Collies) - spray for 5 seconds

**Large Dogs** (over 18 kg e.g. German - spray for 10 seconds.

Shepherds)

#### 11. ADVICE ON CORRECT ADMINISTRATION

#### Directions for use

Spray the whole surface of the animal avoiding the mouth and eyes. Ruffle the coat and spray against the direction of the hair.

Some cats dislike aerosols and might be better treated by another method.

#### 12. WITHDRAWAL PERIOD

#### 13. SPECIAL STORAGE PRECAUTIONS



# HIGHLY FLAMMABLE.

Pressurised container. Protect from sunlight. Do not expose to temperatures exceeding 50°C. DO NOT STORE ABOVE 25°C. STORE IN A DRY PLACE.

# 14. SPECIAL WARNING(S)

FOR EXTERNAL USE ONLY.

### **OPERATOR WARNINGS**

Propoxur is a cholinesterase inhibitor. DO NOT USE if under medical advice not to work with ANTICHOLINESTERASES.

Avoid contact with the eyes. If sprayed in the eyes, wash the eyes thoroughly with plenty of clean running water and seek medical advice. Do not breath the spray mist. Use in a well-ventilated area.

Treated animals should not be allowed to sleep with people, particularly children.

Do not smoke whilst using the spray. Do not spray on a naked flame or any incandescent material. Keep treated animals away from fire and other sources of heat for at least 30 minutes following spraying and until the fur it totally dry. Do not pierce or burn, even when empty.

Keep away from food and drink. Wash hands after use.

Do not use on pregnant animals. Do not use on nursing female pets. Remove fleas from young animals and nursing females by careful use of a flea comb.

DANGEROUS TO FISH AND OTHER AQUATIC LIFE. Do not contaminate aquaria, fish bowls etc. with the product. Do not contaminate ponds or streams with product or used container. DO NOT ALLOW FRESHLY TREATED (within 24 hours) ANIMALS TO SWIM IN SUCH WATER.

If signs of disease persist or appear, consult your Veterinary Surgeon.

#### **15. EXPIRY DATE**

Expiry date: {month/year}

# 16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of empty container in household refuse.

#### 17. DATE ON WHICH THE LABEL WAS LAST APPROVED

# 18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.

**AVM-GSL** 

UK Authorised Veterinary Medicinal Product.

#### 19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF REACH OF CHILDREN.

# 20. MARKETING AUTHORISATION NUMBER(S)

Vm 00010/4091

# 21. MANUFACTURER'S BATCH NUMBER

Batch No. : {number}

# 22. OTHER INFORMATION

**FURTHER INFORMATION** 

To help prevent further re-infestation, the animal's bedding, basket and regular resting areas, including carpets and soft furnishings should be treated with a suitable insecticide and vacuumed regularly.

Approved: 01/08/2017