[Version 8.1,01/2017]

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Dixie Permethrin 715 mg Spot-On solution for Dog.

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

Marketing authorisation holder and manufacturer responsible for batch release:

QUIMICA DE MUNGUÍA S.A.
Derio Bidea, 51
48100 Munguía- Vizcaya
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PT, IT, FR, HE, UK, SP: Dixie Permethrin 715 mg Spot On solution for dogs
PL: Dixie Permethrin Quimunsa 715 mg Spot On solution for dogs

Permethrin

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

Each pipette of 1ml contains:
Active substance:
Permethrin (40:60)…….715 mg
Excipient:
Non-aqueous vehicle…….q.s. 1 ml

Yellow solution

4. INDICATION(S)

'Treatment and prevention of external parasites infestations in dogs caused by fleas (*Ctenocephalides canis, Ctenocephalides felis*) and ticks (*Rhipicephalus sanguineus*). The veterinary medicinal product prevents infestations for up to 4 weeks following administration.
One treatment provides an insecticidal effect for 3 weeks against mosquitoes (*Aedes aegypti*).
One treatment provides a repellent effect for one week against sand flies (*Phlebotomus perniciosus*).

5. CONTRAINDICATIONS


Do not use in cats. **This product is extremely poisonous to cats and could kill them**.
The administration in cats can cause serious adverse reactions and even death could occur.
Do not use in dogs less than 2 weeks old.
Do not use in case of hypersensitivity to the active substance or excipients.
Do not use in case of extended cutaneous injuries.

6. ADVERSE REACTIONS

Signs of lethargy, pruritus, erythema, rash and hair loss in the point of application have been described in treated dogs.

Exceptionally, skin sensitivity reactions have been reported. If occurs, withdrawal the treatment, bath the animal and consult your veterinary surgeon.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

Spot-on use
The recommended dose is 1 ml of the product for dogs weighing less than 15 kg.
Dogs up to 15 Kg bw:
-Apply the content of the 1 ml single-dose pipette between the shoulders blade.

For dermal use only. Apply only to undamaged skin.
Depending on the intensity of the infestation, the responsible veterinary surgeon may recommend repeating the treatment.

The veterinary medicinal product can be safely applied at intervals of not less than seven days.

9. ADVICE ON CORRECT ADMINISTRATION

Method of administration:

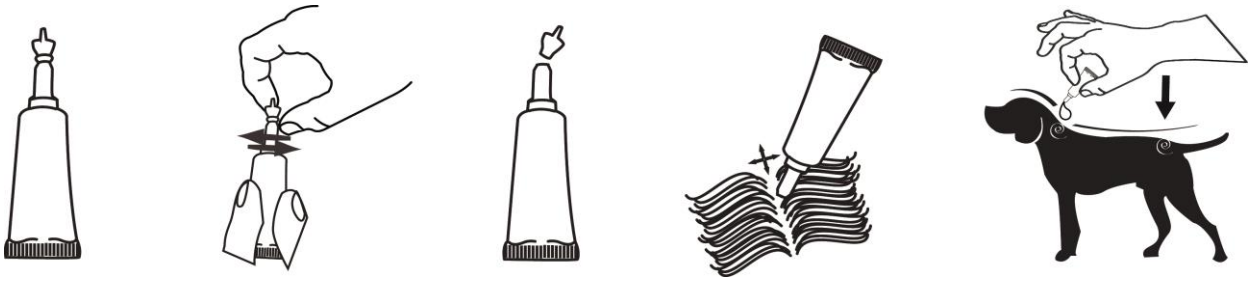
Remove one pipette from the package.

Step 1: The dog should be standing for easy application.

Hold upright. Tap the narrow part of the pipette to ensure the contents are within the main body of the pipette. Break back the snap-off top from the spot-on pipette along the scored line.

Step 2: Part the coat between the shoulder blades until the skin is visible

Step 3 (dogs < 15 kg bw): Place the tip of the pipette on the skin and squeeze gently applying the entire content directly onto the skin in one point between the shoulders.
Step 3 (dogs from 15 to 30kg bw): Use two pipettes. Place the entire content of one pipette directly onto the skin in one point between the shoulders. Place the entire content of the second pipette directly onto the skin in one point at the base of the tail.



10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25 C
Do not use this veterinary medicinal product after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species:

There may be an attachment of single ticks or bites by single sand-flies or mosquitoes. For this reason, the transmission of infectious diseases by these parasites cannot be excluded if conditions are unfavourable.

For optimal control of flea infestation in multi-pet household, all dogs and cats in the household should be treated with a suitable insecticide.

Fleas from pets often infest the animal´s basket, bedding and regular resting areas such as carpets and soft furnishings which should be treated, in cases of massive infestation and at the beginning of the control measures, with a suitable insecticide and vacuumed regularly.

In the case that the treated dog is widely wet (for example, if a dog requires a shampoo, etc.), the protection period could be reduced.

Parasite resistance to an ectoparasiticide may develop following frequent, repeated use of this ectoparasiticide or another one of the same chemical class.

Special precautions for use in animals:

Care should be taken to avoid the content of the pipette coming into contact with the eyes or mouth of the dogs. In particular oral uptake due to the licking of the application site by treated or in-contact animals should be avoided.

To prevent cats from being accidentally exposed to the product keep treated dogs away from cats for 72 hours after the treatment. It is important to ensure that cats do not groom the site of application of a dog that has been treated with this product. See veterinary advice immediately if this occurs.

This product is extremely poisonous to cats and could be fatal due to the unique physiology of cats which is unable to metabolise permethrin. In case of accidental dermal exposure, wash the cat with shampoo or soap, and seek veterinary advice rapidly. To prevent cats from being accidentally exposed to the product, keep treated dogs away from cats after treatment until the application site is dry.

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

This product can cause transient skin and eye irritation.
Avoid contact between the product and skin, eyes or mouth.
People with known skin hypersensitivity to pyrethroids should avoid contact with the veterinary medicinal product.
Treated dogs should not be handled especially by children until the application site is dry. Therefore, animals should not be treated during the day, but should be treated in the early evening. Recently treated dogs should not be allowed to sleep with their owner, especially children.
Do not eat, drink or smoke during application.
Wash hands thoroughly after use.
In case of accidental spillage onto skin, wash off immediately with soap and water.
If the product gets accidentally into the eyes, they should be thoroughly rinsed with water.
If skin or eye irritation persists, or if the product is accidentally swallowed, obtain medical attention immediately and show the package leaflet to the physician.
Keep stored pipettes in the original packaging until ready to use. In order to prevent children from getting access to used pipettes, dispose of used pipettes immediately in a proper way.

Pregnancy and lactation:

Laboratory studies in rats, mice and rabbits with permethrin have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects. The safety of the product has not been established in pregnant and lactating bitches. Use only accordingly to the benefit/risk assessment by the responsible veterinarian

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with other insecticides like other pyrethroids, organophosphorus compounds or carbamates.

Overdose (symptoms, emergency procedures, antidotes):

The risk of experiencing adverse reactions (see section 6) may however increase with overdosing, so animals should always be treated with correct pipette size according to bodyweight.

In case of oral ingestion (very high doses), excitation and convulsions that can progress to paralysis and muscular fibrillation which may even lead to death by respiratory failure have been reported. Saline cathartic or active carbon suspension may be administered.

If nervous system signs occur, treatment with anticonvulsants should be considered.

Do not administer oils and fats that promote absorption in the intestine.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

- Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

- The product should not enter water courses as this may be dangerous for fish and other aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes: 1, 2, 3, 4, 5, 6, 8, 10, 12, 24, 30, 60, 90, 120 or 150 pipettes in carton box.
Not all pack sizes may be marketed. Each pipette is protected in a heat-sealed aluminium sachet.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.