## A. LABELLING

#### PARTICULARS TO APPEAR ON THE OUTER PACKAGE

2 ml pipettes carton boxes

#### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PT, IT, FR, HE, UK, SP: Dixie Permethrin 1430 mg Spot On solution for dogs

PL: Dixie Permethrin Quimunsa 1430 mg Spot On solution for dogs Permethrin

#### 2. STATEMENT OF ACTIVE SUBSTANCES

Permethrin 1430 mg

#### 3. PHARMACEUTICAL FORM

Spot-on solution

Yellow solution

#### 4. PACKAGE SIZE

1,2,3,4,5,6, 8,10, 12, 24, 30, 60, 90, 120, 150 pipettes of 1mL in carton boxes. Each pipette is protected in a heat-sealed aluminium sachet.

### 5. TARGET SPECIES

Dogs

## 6. 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*).

#### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Spot-on use

The recommended dose is:

-1 pipette of 2 ml per dog weighing from 15 – 30 kg

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 from 15-30kg): Use one pipette. The pipette content should be equally divided between two locations from the shoulder to the base of the tail.

#### 8. WITHDRAWAL PERIOD(S)

#### 9. SPECIAL WARNING(S), IF NECESSARY

For dog use only.

Do not use in cats. This product is extremely poisonous to cats and could kill them.

Do not use in dogs less than 2 weeks old.

The product should not be use in dogs weighing less than 15 kg.

Do not use in case of extended cutaneous injuries.

The veterinary medicinal product can be safely applied at intervals of at least seven days. In the case that the treated dogs is widely wet (for example, if a dog requires a shampoo,etc.), the protection period could be reduced.

Keep the product in the sachet until use in order to prevent children from getting access to the product. Avoid contact with skin, mouth and/or eye. Do not contact the application site until it is no longer noticeable.

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

Read package leaflet for full user safety information.

#### 10. EXPIRY DATE

EXP {month/year}

#### 11. SPECIAL STORAGE CONDITIONS

Store below 25 °C

Store in the original package

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

Dispose of waste material in accordance with local requirements.

Disposal: read package leaflet.

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

For animal treatment only.

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

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

QUIMICA DE MUNGUÍA S.A. Derio Bidea, 51 48100 Munguía- Vizcaya SPAIN Telf. +34 946 741 085

e-mail: info@quimunsa.com

## **16.** MARKETING AUTHORISATION NUMBER(S)

## 17. MANUFACTURER'S BATCH NUMBER

<Batch> {number}

MINI UNIT	MUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING S
2 mL	Coex Pipettes
1.	NAME OF THE VETERINARY MEDICINAL PRODUCT
РТ, ІТ	F, FR, HE, UK, SP: Dixie Permethrin 1430 mg Spot On solution for dogs
PL: D Perme	ixie Permethrin Quimunsa 1430 mg Spot On solution for dogs thrin
2.	QUANTITY OF THE ACTIVE SUBSTANCE(S)
	Permethrin 1430 mg
3.	CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES
2ml p	·
4.	ROUTE(S) OF ADMINISTRATION
Spot-o	on
5.	WITHDRAWAL PERIOD(S)
6.	BATCH NUMBER
Batch	{number}
7.	EXPIRY DATE

## 7. EXPIRY DATE

EXP {month/year}

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Aluminium blister	
1. NAME OF THE VETERINARY MEDICINAL PRODUCT	
PT, IT, FR, HE, UK, SP: Dixie Permethrin 1430 mg Spot On solution for dogs	
PL: Dixie Permethrin Quimunsa 1430 mg Spot On solution for dogs Permethrin	
2. NAME OF THE MARKETING AUTHORISATION HOLDER	
QUIMUNSA	
3. EXPIRY DATE	
EXP {month/year}	
4. BATCH NUMBER	
Batch {number}	

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

5.