ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

NATURE/TYPE: Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4Fleas 11.4 mg tablets for cats & kittens

2. STATEMENT OF ACTIVE SUBSTANCES

Johnson's 4fleas flea tablets for cats and kittens 3 6 tablets each containing 11.4mg Nitenpyram

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

3 treatment pack
6 treatment pack

5. TARGET SPECIES

For cats & kittens over 4 weeks of age between 1-11 kg
Kills fleas on cats & kittens over 4 weeks of age between 1kg (2.2lbs) and 11kg (24.2lbs)
Johnson's 4fleas tablets can be safely used in pregnant or lactating females and breeding cats

6. INDICATION(S)

Starts killing fleas in 15 minutes. Kills fleas on pets in 24 hours.
Why is it so important to kill fleas?
Fleas are a real burden to your pet. In addition to the common nuisance irritations associated with infestations, fleas can be responsible for skin conditions in your pet such as flea dermatitis. Also, fleas transmit other parasites such as intestinal worms. The rapid removal of fleas is therefore important to the comfort and health of your pet, as well as for all members of your family.
Effects on the fleas may be seen as soon as 15 minutes after administration.
Between 95% and 100% efficacy is observed within the first 6 hours after administration and complete efficacy is reached within 24 hours.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Johnson's 4fleas tablets are an easy to use oral treatment to kill adult fleas on cats and kittens over 4 weeks of age, between 1kg (2.2lbs) and 11kg (24.2lbs).

DIRECTIONS FOR USE: Johnson's 4fleas tablets can be given directly into the mouth or may be mixed in a small portion of your pet's favourite food and given immediately.
Administer one tablet on any day when fleas are seen on your pet. Repeat on any subsequent day as necessary. Do not give more than one treatment per day.
Fleas can be detected by parting the pet's coat and examining the skin for signs of flea activity or by combing its coat with a fine toothed flea comb. Frequent scratching or excessive grooming can also be signs of flea infestation.
TO HELP PREVENT RE-INFESTATION: Johnson's 4fleas tablets can only be fully effective as part of a programme to eliminate fleas and their larvae from pets and their surroundings. Pet bedding and regular resting areas e.g. carpets and soft furnishings should be vacuumed regularly and treated periodically with an insecticide suitable for household use, preferably containing an I.G.R (Insect Growth Regulator) to control flea egg development and break the flea life cycle. Wash or change pet bedding regularly. Consult your Veterinary Surgeon if signs of disease persist or appear.

Weight of cat or kitten over 4 weeks of age	**Number of tablets (11.4mg Nitenpyram)**
1 – 11kg (2.2lbs – 24.2lbs)	**1 tablet whenever you see fleas on your pet**

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

CONTRA-INDICATIONS: NONE
ADVERSE REACTIONS: For the first hour after administration, the pet may scratch more than normal. This effect is caused by the fleas reacting to the product. In very rare cases this may present as transient signs of hyperactivity, panting, vocalization and excessive grooming/ licking. Transient neurological signs such as muscle tremors, ataxia and convulsions have also been reported in very rare occasions very rare (less than one animal in 10,000 animals, including isolated reports).. If you notice any serious effects or other effects not mentioned here, please inform your veterinary surgeon.

10. EXPIRY DATE

EXP.END. {month/year}
Do not use the tablets after their expiry date.

11. SPECIAL STORAGE CONDITIONS

STORAGE AND DISPOSAL INSTRUCTIONS: Do not store above 25˚C. Keep container in outer carton.

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

Dispose of empty packaging and any remaining product in the household refuse.

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

For animal treatment only.

AVM-GSL

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

Distributor:
Johnson's Veterinary Products Ltd
Sutton Coldfield, West Midlands B75 7DF UK
Tel: +44 (0)121 378 1684 Email: info@johnsons-vet.com

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4060

17. MANUFACTURER'S BATCH NUMBER

BN. {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE: Blister Foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4Fleas 11.4 mg tablets
Each tablet contains: Nitenpyram 11.4 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd

3. EXPIRY DATE

{month/year}
Do not use after the expiry date

4. BATCH NUMBER

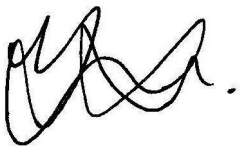
{number}
Keep container in outer carton

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only
For oral use

B. PACKAGE LEAFLET

There is no package leaflet for Johnson's 4Fleas 11.4mg Tablets for Cats and Kittens as all information required is included on the blister foil and cardboard box.



Approved: 22 October 2020