PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Outer carton, pack size of 1, 2, 3, 4 and 6 pipettes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4fleas 40 mg Spot-on Solution for Dogs Less than 4 kg
Imidacloprid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 40 mg imidacloprid as active substance

Each 0.4 ml pipette contains 40 mg Imidacloprid as active substance, 0.4 mg butylhydroxytoluene (E 321) and 332.8 mg benzyl alcohol (E1519).

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

1 pipette 1 treatment pack
2 pipettes 2 treatment pack
3 pipettes 3 treatment pack
4 pipettes 4 treatment pack
6 pipettes 6 treatment pack

5. TARGET SPECIES

Puppies and dogs

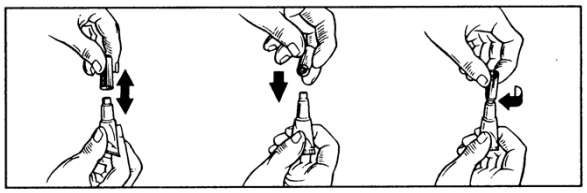
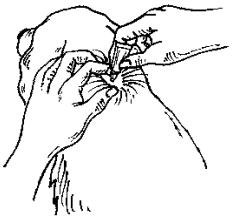
6. INDICATION(S)

For the prevention and treatment of flea infestations and for the treatment of biting lice (*Trichodectes canis*) on dogs over 8 weeks of age and weighing less than 4 kg body weight.
Fleas are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Apply only to undamaged skin.

Read the package leaflet for the full instructions for use.

	
Remove one pipette from the package. Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.	With the dog in the standing position, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S)

User warnings
People with known skin sensitivity to imidacloprid or benzyl alcohol may be particularly sensitive to this product and should avoid contact with the veterinary medicinal product.

This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).

Avoid contact of the product with the eyes or mouth. Do not eat, drink or smoke during application.
Wash off any skin contamination with soap and water.

After application, do not stroke or groom pets until application site is dry.
It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

If the product gets into eyes accidentally, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, obtain medical attention, showing the package leaflet or carton to the physician.

Wash hands thoroughly after use.

In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.
Do not treat unweaned puppies of less than 8 weeks of age.

Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter water courses for 48 hours after treatment.

For the full warnings and precautions, read the package leaflet.

10. EXPIRY DATE

EXP {month/year}
Do not use this veterinary medicinal product after the expiry date.

11. SPECIAL STORAGE CONDITIONS

Please read the package leaflet

Keep the blister in the outer carton. Store away from food, drink and animal feeding stuffs.

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

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.

AVM-GSL

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

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Distributed by:
Johnson's Veterinary Products Ltd.
Sutton Coldfield,
West Midlands
B75 7DF
UK
Tel: 0121 378 1684

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4142

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4fleas for dogs [UK]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Imidacloprid 40 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

0.4 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

[Dog-Pictogram] For animal treatment only

< 4kg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4fleas 40 mg Spot-on Solution for Dogs Less than 4 kg Imidacloprid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Johnson's Veterinary Products Ltd
Vm 00879/4142

AVM-GSL

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

[Dog-Pictogram]

< 4kg

PACKAGE LEAFLET FOR:

Johnson’s 4fleas 40 mg Spot-on Solution for Dogs Less than 4 kg

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

Marketing authorisation holder
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturer responsible for batch release
KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324, 24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson’s 4fleas 40 mg Spot-on Solution for Dogs Less than 4 kg
Imidacloprid

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

Clear yellow to slightly brownish solution.
Each 0.4 ml pipette contains 40 mg imidacloprid as active substance, 0.4 mg butylhydroxytoluene (E321) and 332.8 mg benzyl alcohol (E1519).

4. INDICATION(S)

For the prevention and treatment of flea infestations and for the treatment of biting lice (*Trichodectes canis*) on dogs of less than 4 kg body weight.
Fleas are killed within one day following treatment. One treatment prevents further flea infestation for four weeks.

5. CONTRAINDICATIONS

Do not treat unweaned puppies of less than 8 weeks of age.
Do not use in animals that are known to be hypersensitive to the active substance or any of the excipients

6. ADVERSE REACTIONS

The product is bitter tasting and salivation may occasionally occur if the animal licks the application site immediately after treatment. This is not a cause for concern and disappears within some minutes without treatment (see also section 9 *Advice on correct administration*).
In very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation and disorientation have also been reported. Excessive salivation and nervous signs such as incoordination, tremors and depression have been reported.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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

7. TARGET SPECIES

Dogs

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

Route of administration and dosage

For external use only.
Administer by topical application to the skin according to the bodyweight as follows:

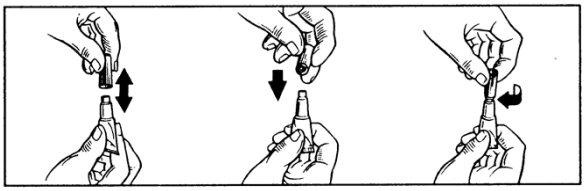
Product	**Dog (kg bw)**	**Number of Pipettes**	**Imidacloprid (mg/kg bw)**
Johnson's 4fleas 40 mg Spot-on Solution for Dogs Less than 4 kg	< 4 kg	1 x 0.4 ml	minimum of 10
Dogs weighing ≥ 4kg bodyweight: use the appropriate Johnson's 4fleas Spot-on solution for dogs			

In case of biting louse infestation, the animal should be re-examined 30 days after treatment as some animals may require a second treatment.

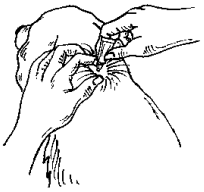
9. ADVICE ON CORRECT ADMINISTRATION

Method of Administration

Remove one pipette from the package. Hold pipette in an upright position, twist and pull off cap. Use reversed cap to twist and remove seal from pipette.



With the dog in the standing position, part the coat between the shoulder blades until the skin is visible. Place the tip of the pipette on the skin and squeeze firmly several times to empty the contents directly onto the skin.



Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog.

The product is bitter tasting and salivation may occasionally occur if the dog licks the application site immediately after treatment. This is not a cause for concern and disappears within some minutes without treatment. Correct application will minimize the opportunity for the dog to lick the product.
Apply only to undamaged skin.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Keep blister in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

For external use only.
For animal treatment only.

Special warnings:
Re-infestation from emergence of new fleas in the environment may continue to occur for six weeks or longer after treatment is initiated. More than one treatment may therefore be required, depending on the level of fleas in the environment. To aid reduction in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended. In order to reduce further the environmental challenge, it is recommended that all dogs, cats and rabbits in the household are treated with a suitable product.

If there are several pets in the household, it is advisable to treat all pets at the same time. Fleas can be detected by parting pet's coat and examining skin for signs of flea activity or by combing coat with a fine-toothed flea comb. Frequent scratching or excessive grooming can also be signs of flea infestation. Fleas from pets often infest pet's basket, bedding and regular resting areas, such as carpets and soft furnishings which 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 help break the flea life cycle. Wash and change pet bedding regularly.

The product remains effective even if your pet becomes wet, e.g. after swimming or exposure to heavy rain. However, in cases of frequent swimming or bathing re-treatment may become necessary, but do not re-treat more frequently than once-weekly.

Special precautions for use in animals:
This product is for topical use and should not be administered orally.
Care should be taken to avoid the contents of the pipette coming into contact with the eyes or mouth of the recipient animal.
Do not allow recently treated animals to groom each other.
Apply only to undamaged skin.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known skin sensitivity to imidacloprid or benzyl alcohol may be particularly sensitive to this product and should avoid contact with the veterinary medicinal product.

This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).

Avoid contact of the product with the eyes or mouth. Do not eat, drink or smoke during application.
Wash off any skin contamination with soap and water.

After application, do not stroke or groom pets until application site is dry.
It is therefore recommended that animals are not treated during the day, but should be treated during the early evening, and that recently treated animals are not allowed to sleep with owners, especially children.

If the product gets into eyes accidentally, the eyes should be thoroughly rinsed with clean water. If skin or eye irritation persists, or the product is accidentally swallowed, obtain medical attention, showing the package leaflet or carton to the physician.

Wash hands thoroughly after use.
In order to prevent children from getting access to pipettes, keep the pipette in the original packaging until ready for use and dispose of used pipettes immediately.

Other precautions
Imidacloprid is toxic to aquatic organisms. To avoid adverse effects on aquatic organisms, treated dogs should not be allowed to enter water courses for 48 hours after treatment.

Keep treated pets away from materials such as leather, soft furnishings, plastics, etc, until site of application is completely dry as contact may damage these surfaces.

Pregnancy and lactation:
No harm to the embryo or its normal development or on normal reproduction has been observed during the studies with imidacloprid on rats and rabbits. Studies on pregnant and lactating bitches together with their offspring are limited. Evidence so far suggests that no adverse effects are to be expected in these animals.

Interaction with other medicinal products and other forms of interaction:
No incompatibility has been observed between this product at twice the recommended dose and the following commonly used veterinary products: fenthion, lufenuron, milbemycin, febantel, pyrantel and praziquantel. The compatibility of the product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

Overdose (symptoms, emergency procedures, antidotes):
No adverse clinical signs were produced by either individual doses of up to 200 mg/kg body weight (five to eight times the therapeutic dose), daily treatments at 100 mg/kg body weight for five consecutive days or weekly treatments at five times the maximum dose rate for eight consecutive weeks.

In rare cases of overdose or licking of treated fur, nervous system disorders (such as twitching, involuntary movements of parts of the body, lack of co-ordination or balance on movement, dilation or constriction of the pupils, tiredness) can occur. Poisoning following inadvertent oral uptake in animals is unlikely. In this event, the animal should be treated for the symptoms under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

Incompatibilities:
None known

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

Imidacloprid may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

15. OTHER INFORMATION

In further studies, in addition to the adulticide flea efficacy of imidacloprid, a larvicidal flea efficacy in the surroundings of the treated pet has been demonstrated. Larval stages in the pet's surroundings are killed following contact with a treated animal.

Pack sizes: Blister pack containing 1, 2, 3, 4, or 6 unit dose pipettes
Not all pack sizes may be marketed.

Vm 00879/4142 AVM-GSL ☐

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

Johnsons Veterinary Products Limited
Sutton Coldfield
West Midlands
B75 7DF
UK
Tel: 0121 378 1684

Approved 02 October 2020