

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 80 mg Spot-on Solution for Cats
Imidacloprid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 80 mg imidacloprid as active substance

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

Cats
For cats over 8 weeks of age and weighing 4 kg or greater

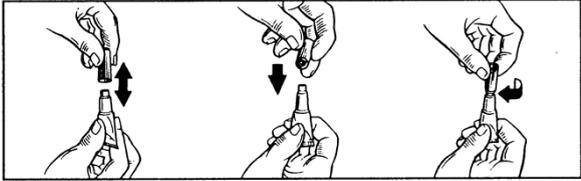
6. INDICATION(S)

For the prevention and treatment of flea (*Ctenocephalides felis*) infestations on cats of 4 kg bodyweight and greater. One treatment prevents further flea infestation for three to 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.

	
<p>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.</p>	<p>Part the hair on the cat's neck at the base of the skull 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. Application at the base of the skull will minimise the opportunity for the cat to lick the product.</p>

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.

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

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 00879/4145

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

18. ADDITIONAL 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.

Dual action

PROTECTS PET AND HOME

- Kills fleas on cats
- Kills flea larvae in the area around your cat
- One treatment gives up to 4 weeks protection

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4fleas for cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Imidacloprid 80mg
Contains 80 mg imidacloprid per 0.4 ml tube

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

0.8 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only
[Cat-Pictogram]



≥ 4kg

9. ADDITIONAL INFORMATION

Keep container in outer carton
Vm 00879/4145

AVM-GSL

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnson's 4fleas 80 mg Spot-on Solution for Cats
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 00879/4145

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

BN {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

[Cat-Pictogram]



≥ 4kg

6. ADDITIONAL INFORMATION

For external use only.
0.8 ml

AVM-GSL

PACKAGE LEAFLET FOR:

Johnsons 4fleas 80 mg Spot-on Solution for Cats

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

Distributed by:

Johnsons Veterinary Products Limited
Sutton Coldfield
West Midlands
B75 7DF
UK

Manufacturer responsible for batch release

KVP Pharma + Veterinär Produkte GmbH
Projensdorfer Str. 324, 24106 Kiel
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Johnsons 4fleas 80 mg Spot-on Solution for Cats
Imidacloprid

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

Appearance: clear yellow to slightly brownish solution.
Each 0.8 ml pipette contains 80 mg imidacloprid as active substance, 0.8 mg butylhydroxytoluene (E321) and 665.6 mg benzyl alcohol (E 1519).

4. INDICATION(S)

For the prevention and treatment of flea (*Ctenocephalides felis*) infestations on cats of 4 kg bodyweight and greater.
One treatment prevents further flea infestation for three to four weeks.

5. CONTRAINDICATIONS

Do not treat unweaned kittens of less than 8 weeks of age.
Do not use in cases of hypersensitivity to the active substance or to 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 (less than 1 animal in 10,000) skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation, excessive salivation and nervous signs such as incoordination, tremors and depression have also been reported.

Oral ingestion may result in other gastrointestinal signs (vomiting and diarrhoea), which have been observed very rarely, in cats, based on post-marketing data.

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

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).

7. TARGET SPECIES

Cats

For cats over 8 weeks of age and weighing 4 kg and greater

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

Route of administration and dosage

For external use only.

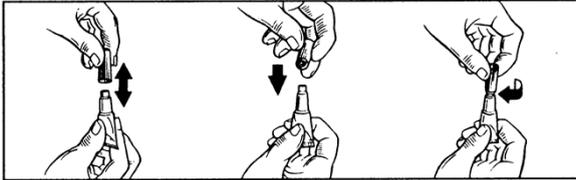
Administer by topical application to the skin according to the bodyweight as follows:

Product	Cat (kg bw)	Number of Pipettes	Imidacloprid (mg/kg bw)
Johnson's 4fleas 80 mg Spot-on Solution for Cats	≥4 kg	1 x 0.8 ml	minimum of 10
Cats weighing less than 4 kg bodyweight: use Johnson's 4fleas 40 mg Spot-on Solution for Kittens and Small Cats			

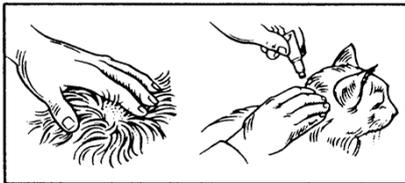
9. ADVICE ON CORRECT ADMINISTRATION

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.



Part the hair on the cat's neck at the base of the skull 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.



The product is bitter tasting and salivation may occasionally occur if the cat licks the application site immediately after treatment. This is not a cause of concern and disappears within some minutes without treatment. Application at the base of the skull will minimize the opportunity for the cat 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 exposure to heavy rain. However, in cases of frequent exposure to heavy rain, 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 use in cases of hypersensitivity to the active substance or to any of the excipients.

Any collar should be removed prior to application of the product. Prior to re-fitting the collar, the treated area should be visually assessed to ensure it is dry.

Do not allow recently treated animals to groom each other.

Apply only to undamaged skin.

If signs of disease persist or appear, consult a veterinary surgeon.

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 massage the application site.

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

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 studies with imidacloprid on rats and rabbits. Studies on pregnant and lactating queens 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: lufenuron, pyrantel and praziquantel. The compatibility of the product was also demonstrated with a wide range of routine treatments under field conditions including vaccination.

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.

Overdose (symptoms, emergency procedures, antidotes):

No adverse clinical signs were produced using doses of five times the therapeutic level weekly 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 pupil, 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 MATERIALS, IF ANY

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

September 2021

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 00879/4145

AVM-GSL

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

Johnsons Veterinary Products Limited
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Approved 30 November 2021

