[Version 8.2,01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bolfo Gold 80 mg Spot-On solution for Large Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each pipette of 0.8 ml contains:

Active substance:
Imidacloprid 80 mg

Excipient(s):
Butylhydroxytoluene (E 321) 0.8 mg
Benzyl alcohol (E 1519) 665.6 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Spot-on solution
Clear yellow to slightly brownish solution

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

For the prevention and treatment of flea infestations on cats of 4 kg body weight and greater.
For cats of less than 4 kg body weight use Bolfo Gold 40 mg Spot-On solution for Small Cats.
Fleas on cats are killed within one day following treatment. One treatment prevents further flea infestation for three to four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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.
Avoid overdose in sick or debilitated kittens.
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.

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

People with known hypersensitivity to imidacloprid should avoid contact with the product.
This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).
Avoid contact between the product and skin, 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.
If the product gets into eyes, the eyes should be thoroughly flushed with water.
If skin or eye irritation persists, obtain medical attention.
If the product is accidentally swallowed, obtain medical attention immediately.
After application, do not stroke or groom animals until application site is dry.
Wash hands thoroughly after use.

Other precautions

The solvent in this product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

4.6 Adverse reactions (frequency and seriousness)

The product is bitter tasting and salivation may occasionally occur if the cat licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment (see also section 4.9 *Amounts to be administered and administration route*).
On very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation has also been reported. On exceptional occasions, excessive salivation and nervous signs such as incoordination, tremors and depression have been reported.
Oral ingestion may result in other gastro-intestinal signs (vomiting and diarrhoea) which have been observed very rarely based on post marketing data.

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)

4.7 Use during pregnancy, lactation or lay

No reproductive toxic effects have been observed in rats and no primary embryotoxic or teratogenic toxic effects have been observed during the studies 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.

4.8 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.

4.9 Amounts to be administered and administration route

Dosage and Treatment Schedule

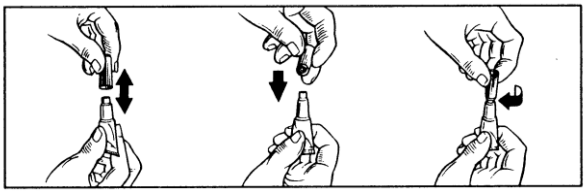
Cat (kg bw)	Product	Number of Pipettes	Imidacloprid (mg/kg bw)
< 4 kg	Bolfo Gold 40 mg Spot-On solution for Small Cats	1 x 0.4 ml	minimum of 10
≥ 4kg	Bolfo Gold 80 mg Spot-On solution for Large Cats	1 x 0.8 ml	minimum of 10

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 in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended.

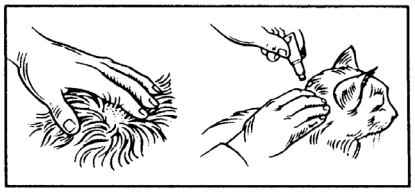
The product remains effective if the animal becomes wet, for example after exposure to heavy rain. However, re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not re-treat more frequently than once weekly.

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 sign of intoxication 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. Do not allow recently treated animals to groom each other.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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, tremors, ataxia, mydriasis, miosis, lethargy) can occur.

Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiparasitic agent
ATCvet code: QP53AX17

5.1 Pharmacodynamic properties

Imidacloprid, 1-(6-Chloro-3-pyridylmethyl)-N-nitro-imidazolidin-2-ylideneamine is an ectoparasiticide belonging to a group of chloronicotinyl compounds. Chemically, it is more accurately described as a chloronicotinyl nitroguanidine.

The substance has a high affinity for the nicotinergic acetylcholine receptors in the post-synaptic region of the central nervous system (CNS). The ensuing inhibition of cholinergic transmission in insects results in paralysis and death. Due to the weak nature of the interaction with mammalian nicotinergic receptor sites and the postulated poor penetration through the blood/brain barrier in mammals, it has virtually no effect on the mammalian CNS. The minimal pharmacological activity in mammals is supported by safety studies involving systemic administration of sub-lethal doses to rabbits, mice and rats.

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.

5.2 Pharmacokinetic particulars

The product is indicated for cutaneous administration. Following topical application in cats, the solution is quickly distributed over the animal. Acute dermal studies in the rat and target animal overdose and serum kinetic studies have established that systemic absorption is very low, transient and not relevant for the clinical efficacy. This has been further demonstrated by a study in which fleas were not killed after having fed on previously treated animals once the animal's skin and fur had been cleaned of all active material.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Butylhydroxytoluene E321
Benzyl alcohol
Propylene carbonate

6.2 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Store away from food, drink and animal feeding stuffs.

6.5 Nature and composition of immediate packaging

Pack sizes	0.8 ml solution per pipette Blister pack containing 2, 3, 4, or 6 unit dose pipettes
Container	White polypropylene pipettes with caps

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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.

7. MARKETING AUTHORISATION HOLDER

[to be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[to be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[to be completed in accordance with national requirements after conclusion of the MR phase]

10 DATE OF REVISION OF THE TEXT

[to be completed in accordance with national requirements after conclusion of the MR phase]

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton, pack size of 2, 3, 4 and 6 pipettes.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bolfo Gold 80 mg Spot-On solution for Large Cats
Imidacloprid

2. STATEMENT OF ACTIVE SUBSTANCES

Each 0.8 ml pipette contains:
Active substance: 80 mg imidacloprid;
0.8 mg butylhydroxytoluene.

3. PHARMACEUTICAL FORM

Spot-on solution

4. PACKAGE SIZE

2 pipettes (2x 0.8 ml)
3 pipettes (3x 0.8 ml)
4 pipettes (4x 0.8 ml)
6 pipettes (6x 0.8 ml)

5. TARGET SPECIES

Cats

6. INDICATION(S)

Flea prevention and treatment for cats of 4 kg and greater.
Fleas on cats are killed within one day following treatment. One treatment prevents further flea infestation for three to four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Do not treat unweaned kittens of less than 8 weeks of age.
Keep the blister in the outer carton.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with localrequirements.
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.

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

For animal treatment only.
[Prescription status to be completed nationally; Blue Box]

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

[MAH to be completed nationally]

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

16. MARKETING AUTHORISATION NUMBER(S)

[MAH to be completed nationally]

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

[Pictogram – flea]

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pipette label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bolfo Gold 80 mg Spot-On solution for Large Cats

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

10% imidacloprid(e)

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

0.8 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

[Cat-Pictogram]

≥ 4kg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bolfo Gold 80 mg Spot-On solution for Large Cats

2. NAME OF THE MARKETING AUTHORISATION HOLDER

[to be completed nationally]

3. EXPIRY DATE

4. BATCH NUMBER

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

[Cat-Pictogram]

≥ 4kg

0.8 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bolfo Gold 80 mg Spot-On solution for Large 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:
[to be completed nationally]

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bolfo Gold 40 mg Spot-On solution for Small Cats (NL)
Bolfo Gold 80 mg Spot-On solution for Large Cats (NL)
Imidacloprid

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

Active substance:
10 % (100 mg/ml) Imidacloprid

Excipient(s):
0.1 % (1 mg/ml) Butylhydroxytoluene (E 321)
Benzyl alcohol

Each pipette contains:

	Pipette	**Imidacloprid**	**E321**
Bolfo Gold 40 mg Spot-On solution for Small Cats (< 4 kg)	0.4 ml	40 mg	0.4 mg
Bolfo Gold 80 mg Spot-On solution for Large Cats (≥ 4 kg)	0.8 ml	80 mg	0.8 mg

4. INDICATION(S)

For the prevention and treatment of flea infestations on cats.
Fleas on cats are killed within one day following treatment. One treatment prevents further flea infestation for three to four weeks. The product can be used as part of a treatment strategy for flea allergy dermatitis (FAD).

5. CONTRAINDICATIONS

Do not treat unweaned kittens of less than 8 weeks of age.
Do not use in cases of hypersensitivity to any of the ingredients contained in this product.

6. ADVERSE REACTIONS

The product is bitter tasting and salivation may occasionally occur if the cat licks the application site immediately after treatment. This is not a sign of intoxication and disappears within some minutes without treatment.
On very rare occasions skin reactions such as hair loss, redness, itching and skin lesions may occur. Agitation has also been reported. On exceptional occasions, excessive salivation and nervous signs such as incoordination, tremors and depression have been reported.
Oral ingestion may result in other gastro-intestinal signs (vomiting and diarrhoea) which have been observed very rarely based on post marketing data.

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

Cats

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

Any instructions given by a veterinary surgeon for the use of this product should be followed.

Dosage and Treatment Schedule

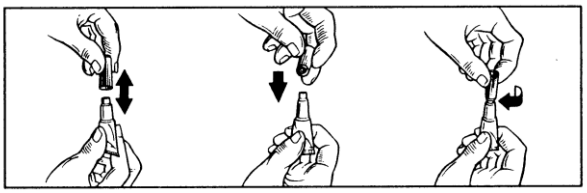
Cat (kg bw)	Product	Number of Pipettes	Imidacloprid (mg/kg bw)
Less than 4 kg	Bolfo Gold 40 mg Spot-On solution for Small Cats	1 x 0.4 ml	minimum of 10
4 kg and greater	Bolfo Gold 80 mg Spot-On solution for Large Cats	1 x 0.8 ml	minimum of 10

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 in environmental challenge, the additional use of a suitable environmental treatment against adult fleas and their developing stages is recommended.

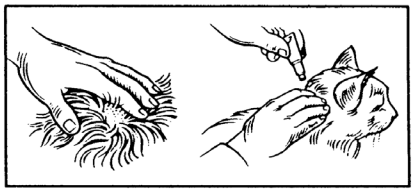
The product remains effective if the animal becomes wet, for example after exposure to heavy rain. However, re-treatment may become necessary, depending on the presence of fleas in the environment. In these cases do not re-treat more frequently than once weekly.

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.



9. ADVICE ON CORRECT ADMINISTRATION

For external use only.
Application at the base of the skull will minimize the opportunity for the cat to lick the product, please also refer to section *Adverse Reactions*.
Apply only to undamaged skin. Do not allow recently treated animals to groom each other.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store away from food, drink and animal feeding stuffs.
Keep the blister in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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.
Avoid overdose in sick or debilitated kittens.

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, tremors, ataxia, mydriasis, miosis, lethargy) can occur.

Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.
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.

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

People with known hypersensitivity to imidacloprid should avoid contact with the product.
This product contains benzyl alcohol and may cause skin sensitisation or transient skin reactions in rare cases (for example, irritation, tingling).
Avoid contact between the product and skin, 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.
If the product gets into eyes, the eyes should be thoroughly flushed with water.
If skin or eye irritation persists, obtain medical attention.
If the product is accidentally swallowed, obtain medical attention immediately.
After application, do not stroke or groom animals until application site is dry.
Wash hands thoroughly after use.

Pregnancy and lactation:

No reproductive toxic effects have been observed in rats and no primary embryotoxic or teratogenic toxic effects have been observed during the studies 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

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, tremors, ataxia, mydriasis, miosis, lethargy) can occur.
Poisoning following inadvertent oral uptake in animals is unlikely. In this event, treatment should be symptomatic under veterinary medical attention. There is no known specific antidote but administration of activated charcoal may be beneficial.

Incompatibilities:

None known.

Other precautions:

The solvent in this product may stain certain materials including leather, fabrics, plastics and finished surfaces. Allow the application site to dry before permitting contact with such materials.

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

[to be adapted nationally, if required]
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product 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

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.

[Further information like prescription status or marketing authorisation numbers to be completed nationally, if required]