PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON, 250 ml and 1 Litre

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Swish, Pour-on Suspension 7.5 mg/ml
Deltamethrin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of Butox Swish contains 7.5 mg of deltamethrin in an aqueous suspension.

3. PHARMACEUTICAL FORM

Pour-on suspension

4. PACKAGE SIZE

250 ml
1 Litre

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

For the control of biting and nuisance flies, biting and sucking lice of cattle.
Long acting, ready-to-use topical ectoparasiticide.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration and dosage
Read the package leaflet before use.
For external use only.
The required volume of Butox Swish should be applied along the midline of the animal's back, starting between the shoulders using the pour-on procedure.
The following treatment schedule should be followed:

Indications	Dose rate
Flies Control of biting and nuisance flies	up to 100 kg : 10 ml 100 – 300 kg : 20 ml over 300 kg : 30 ml
Lice: Control of biting and sucking lice	10 ml per animal irrespective of bodyweight.

Treatment for fly control in cattle should be repeated within 8-10 weeks depending on the weather and the fly species. A single application is sufficient against lice.

Method of use:

[Fig 1]

Remove cap no 2 from the dose reservoir of the Butox Swish bottle. Keep cap no. 1 closed at all times.

[Fig 2]

Attach the applicator to the dose reservoir.

[Fig 3]

Fill the dose reservoir by squeezing the container.

Important:

[Fig 4]

Hold the container on the applicator side. After inverting the bottle and during application ensure that the applicator is kept below the dose reservoir *(see diagram above)*. Apply the dose by pouring it along the animal's spine from the base of the head to the tail, while pressing lightly on the container. *(Repeat the procedure to treat flies on animals weighing more than 100 kg who need a larger than 10 ml dose).*

[Fig 5]

Ensure that the complete dose has been applied to the animal's back.

[Fig 6]

When all animals have been treated, remove the applicator before recapping the bottle.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 20 days
Milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
User warnings:
Personal protective equipment consisting of waterproof apron and boots and impervious gloves should be worn when either applying or handling the veterinary medicinal product or recently treated animals.
Wash hands and exposed skin after handling this product and before meals.
For full user warnings read the package leaflet before use.

Information for doctors:
Advice on clinical management is available from the National Poisons Information Service.

10. EXPIRY DATE

EXP END OF:

11. SPECIAL STORAGE CONDITIONS

Protect from direct sunlight.
Keep away from food, drink and animal feeding stuffs.
Keep the container in the outer carton.

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

Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used containers.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

[Distribution category]

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

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

MA holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4495

17. MANUFACTURER’S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Label (Front and Back labels, 250 ml and 1 Litre)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Swish, Pour-on Suspension 7.5 mg/ml
Deltamethrin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of Butox Swish contains 7.5 mg of deltamethrin in an aqueous suspension.

3. PHARMACEUTICAL FORM

Pour-on suspension

4. PACKAGE SIZE

250 ml
1 Litre

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

For the control of biting and nuisance flies, biting and sucking lice of cattle.
Long acting, ready-to-use topical ectoparasiticide.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administration and dosage
For external use only.
Read the package leaflet before use.
The required volume of Butox Swish should be applied along the midline of the animal's back, starting between the shoulders using the pour-on procedure.
The following treatment schedule should be followed:

Indications	**Dose rate**
Flies Control of biting and nuisance flies	up to 100 kg : 10 ml 100 – 300 kg : 20 ml over 300 kg : 30 ml
Lice: Control of biting and sucking lice	10 ml per animal irrespective of bodyweight.

Treatment for fly control in cattle should be repeated within 8-10 weeks (depending on the weather and the fly species). A single application is sufficient against lice.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 20 days
Milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP END OF:

11. SPECIAL STORAGE CONDITIONS

Storage: Protect from direct sunlight.
Keep away from food, drink and animal feeding stuffs.
Keep the container in the outer carton.

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

Disposal: Read the package leaflet.

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

[Distribution category]

For animal treatment only. To be supplied only on veterinary prescription.

POM-VPS

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

MA holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4495

17. MANUFACTURER'S BATCH NUMBER

BN:

PACKAGE LEAFLET FOR:

Butox Swish, Pour-on Suspension 7.5 mg/ml

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet Productions
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Swish, Pour-on Suspension 7.5 mg/ml
Deltamethrin

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

Each ml of Butox Swish contains 7.5 mg of deltamethrin in an aqueous suspension.
Off-white homogenous suspension.

4. INDICATION(S)

Long-acting, ready-to-use topical ectoparasiticide.

Control of biting and nuisance flies of cattle, including *Haematobia irritans*, *Hippobosca equina*, *Stomoxys calcitrans*, *Musca autumnalis* and *Musca domestica*.
Control of biting and sucking lice of cattle, including *Damalinia bovis*, *Haematpoinus eurysternus*, and *Linognathus vituli*.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use on animals with major skin lesions.

6. ADVERSE REACTIONS

Application site reactions including erythema and pruritus, hyperactivity, anxiety and hypersensitivity have been reported in very rare cases in post-marketing experience.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) 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).

If you notice any side effects, even those not listed in this package leaflet or if you think this medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

For external use only.

The required volume of Butox Swish should be applied along the midline of the animal's back, starting between the shoulders using the pour-on procedure.
The following treatment schedule should be followed:

Indications	**Dose rate**
Flies: Control of biting and nuisance flies	up to 100 kg : 10 ml 100 – 300 kg : 20 ml over 300 kg : 30 ml
Lice: Control of biting and sucking lice	10 ml per animal irrespective of bodyweight.

Flies: a single application provides protection against flies for 8-10 weeks depending on the infestation degree, fly species and weather conditions.
Treatment should be repeated within 8-10 weeks depending on the weather and the fly species.

Lice*:* a single application provides protection against lice for 8-10 weeks. All in contact animals must be treated at the same time. A single application is sufficient against lice.

9. ADVICE ON CORRECT ADMINISTRATION

Refer to Section 8.

10. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 20 days
Milk: Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Protect from direct sunlight.
Keep away from food, drink and animal feeding stuffs.
Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle. The product will reduce the number of flies resting directly on the animal, but it is not expected to eliminate all flies on a farm. Therefore, the use of this product should be based on local (regional and farm) epidemiological information about susceptibility of parasites, and used in association with other pest management methods.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of ectoparasiticides from the same class over an extended period of time;
- underdosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device.
If clinical signs do not resolve following treatment, the diagnosis should be revised.

Special precautions for use in animals:
Do not apply on or near the animal’s eyes and mucous membranes.
Care should be taken to prevent the animal licking the product. Avoid use of the product during extremely hot weather and ensure animals have adequate access to water. The product should only be administered onto undamaged skin as toxicity is possible due to absorption from major skin lesions. However, signs of local irritation may occur after treatment as skin may already be affected by infestation.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to deltamethrin should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of waterproof apron and boots and impervious gloves should be worn when either applying or handling the veterinary medicinal product or recently treated animals.
Remove heavily contaminated clothing immediately and wash before re-use. Wash splashes from skin immediately with soap and plenty of water. Wash hands and exposed skin after handling this product and before meals.
In case of contact with eyes, rinse immediately with plenty of clean, running water and seek medical advice.
In case of accidental ingestion, wash out mouth immediately with plenty of water and seek medical advice.
Do not eat, drink or smoke while handling the product.
This product contains deltamethrin, which may produce tingling, itching and blotchy redness on exposed skin. Irritation, sensitisation and adverse effects on the neuronal system might occur. If you feel unwell after working with this product, seek medical advice immediately and show the package leaflet or the label to the physician.
Information for doctors: Advice on clinical management is available from the National Poisons Information Service.

Pregnancy and lactation:
No restrictions apply for use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Some organo-phosphorous insecticides can reduce metabolism rate and thus enhance deltamethrin toxicity. Therefore, avoid the use of such organo-phosphorous insecticides (consult the supplier).

Overdose (symptoms, emergency procedures, antidotes):
Overdose of twice the level of recommended treatments does not induce any adverse effects.

Other precautions:
Deltamethrin is very toxic to dung fauna and aquatic organisms.
The risk to dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle, e.g., by using only a single treatment per season on the same pasture.

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

Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used 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

March 2023

15. OTHER INFORMATION

Environmental properties
Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees. It is persistent in soils and may accumulate in sediments.
Deltamethrin has the potential to adversely affect non-target organisms, both in water and in dung. Following treatment, excretion of deltamethrin levels potentially toxic to dung fauna may take place over a period of 2 to 4 weeks. Faeces containing deltamethrin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

For animal treatment only.

Pack sizes: 250 ml, 1 Litre and 2.5 Litre.
Not all pack sizes may be marketed.

Legal category: POM-VPS To be supplied only on veterinary prescription.

Vm 01708/4495

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE, 2.5 Litre

{CONCERTINA LABEL – Base Label and Top Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Swish, Pour-on Suspension 7.5 mg/ml
Deltamethrin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of Butox Swish contains 7.5 mg of deltamethrin in an aqueous suspension.

3. PHARMACEUTICAL FORM

Pour-on suspension

4. PACKAGE SIZE

2.5 Litre

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

Read the package leaflet before use.

For the control of biting and nuisance flies, biting and sucking lice of cattle.
Long acting, ready-to-use topical ectoparasiticide.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Meat and offal: 20 days
Milk: Zero hours

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP END OF:

11. SPECIAL STORAGE CONDITIONS

Protect from direct sunlight. Keep away from food, drink and animal feeding stuffs.

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

Read the package leaflet before use.

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

For animal treatment only.

POM-VPS To be supplied only on veterinary prescription.

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

MA holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER (S)

Vm 01708/4495

17. MANUFACTURER'S BATCH NUMBER

BN:

PACKAGE LEAFLET:
Butox Swish, Pour-on Suspension 7.5 mg/ml

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet Productions
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Butox Swish, Pour-on Suspension 7.5 mg/ml
Deltamethrin

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

Each ml of Butox Swish contains 7.5 mg of deltamethrin in an aqueous suspension.
Off-white homogenous suspension.

4. INDICATION(S)

Long-acting, ready-to-use topical ectoparasiticide.

Control of biting and nuisance flies of cattle, including *Haematobia irritans*, *Hippobosca equina*, *Stomoxys calcitrans*, *Musca autumnalis* and *Musca domestica*.
Control of biting and sucking lice of cattle, including *Damalinia bovis*, *Haematpoinus eurysternus*, and *Linognathus vituli*.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use on animals with major skin lesions.

6. ADVERSE REACTIONS

Application site reactions including erythema and pruritus, hyperactivity, anxiety and hypersensitivity have been reported in very rare cases in post-marketing experience.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) 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).

If you notice any side effects, even those not listed in this package leaflet or if you think this medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

For external use only.

The required volume of Butox Swish should be applied along the midline of the animal's back, starting between the shoulders using the pour-on procedure.
The following treatment schedule should be followed:

Indications	Dose rate
Flies: Control of biting and nuisance flies	up to 100 kg : 10 ml 100 – 300 kg : 20 ml over 300 kg : 30 ml
Lice: Control of biting and sucking lice	10 ml per animal irrespective of bodyweight.

Flies: a single application provides protection against flies for 8-10 weeks depending on the infestation degree, fly species and weather conditions.
Treatment should be repeated within 8-10 weeks depending on the weather and the fly species.

Lice: a single application provides protection against lice for 8-10 weeks. All in contact animals must be treated at the same time. A single application is sufficient against lice.

9. ADVICE ON CORRECT ADMINISTRATION

Refer to Section 8.

10. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: 20 days
Milk: Zero hours

11. SPECIAL STORAGE PRECAUTIONS

Protect from direct sunlight.
Keep away from food, drink and animal feeding stuffs.
Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Cases of resistance to deltamethrin have been reported in stinging and nuisance flies in cattle. The product will reduce the number of flies resting directly on the animal, but it is not expected to eliminate all flies on a farm. Therefore, the use of this product should be based on local (regional and farm) epidemiological information about susceptibility of parasites, and used in association with other pest management methods.
Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:
- too frequent and repeated use of ectoparasiticides from the same class over an extended period of time;
- underdosing, which may be due to underestimation of bodyweight, misadministration of the product, or lack of calibration of the dosing device.
If clinical signs do not resolve following treatment, the diagnosis should be revised.

Special precautions for use in animals:
Do not apply on or near the animal's eyes and mucous membranes.
Care should be taken to prevent the animal licking the product. Avoid use of the product during extremely hot weather and ensure animals have adequate access to water. The product should only be administered onto undamaged skin as toxicity is possible due to absorption from major skin lesions. However, signs of local irritation may occur after treatment as skin may already be affected by infestation.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to deltamethrin should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of waterproof apron and boots and impervious gloves should be worn when either applying or handling the veterinary medicinal product or recently treated animals.

Remove heavily contaminated clothing immediately and wash before re-use. Wash splashes from skin immediately with soap and plenty of water. Wash hands and exposed skin after handling this product and before meals.
In case of contact with eyes, rinse immediately with plenty of clean, running water and seek medical advice.
In case of accidental ingestion, wash out mouth immediately with plenty of water and seek medical advice.
Do not eat, drink or smoke while handling the product.
This product contains deltamethrin, which may produce tingling, itching and blotchy redness on exposed skin. Irritation, sensitisation and adverse effects on the neuronal system might occur. If you feel unwell after working with this product, seek medical advice immediately and show the package leaflet or the label to the physician.
Information for doctors: Advice on clinical management is available from the National Poisons Information Service.

Pregnancy and lactation:
No restrictions apply for use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Some organo-phosphorous insecticides can reduce metabolism rate and thus enhance deltamethrin toxicity. Therefore, avoid the use of such organo-phosphorous insecticides (consult the supplier).

Overdose (symptoms, emergency procedures, antidotes):
Overdose of twice the level of recommended treatments does not induce any adverse effects.

Other precautions:
Deltamethrin is very toxic to dung fauna and aquatic organisms. The risk to dung fauna can be reduced by avoiding too frequent and repeated use of deltamethrin (and other synthetic pyrethroids) in cattle, e.g., by using only a single treatment per season on the same pasture.

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

Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used 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

March 2023

15. OTHER INFORMATION

Environmental properties
Deltamethrin is very toxic to dung fauna, aquatic organisms and honey bees. It is persistent in soils and may accumulate in sediments.
Deltamethrin has the potential to adversely affect non-target organisms, both in water and in dung. Following treatment, excretion of deltamethrin levels potentially toxic to dung fauna may take place over a period of 2 to 4 weeks. Faeces containing deltamethrin excreted onto pasture by treated animals may reduce the abundance of dung feeding organisms which may impact on the dung degradation.

For animal treatment only.

Pack sizes: 250 ml, 1 Litre and 2.5 Litre.
Not all pack sizes may be marketed.

Legal category: POM-VPS To be supplied only on veterinary prescription.

Vm 01708/4495

Distributor in Northern Ireland
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road, Dublin 24

Approved: 31 March 2023