

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BOXES 50 ml/100 ml/250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norflunix 50 mg/ml solution for injection for pigs
Flunixin meglumine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance:

Flunixin	50 mg
(equivalent to Flunixin meglumine)	82.9 mg)

Excipients:

Phenol	5 mg
Sodium formaldehyde sulfoxylate dihydrate	2.5 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

The veterinary medicinal product should be administered at a dosage rate of 2.2 mg flunixin/kg bodyweight (2 ml/45 kg) by deep intramuscular injection. Flunixin should not be injected in adipose tissue. One or two injections can be administered separate by a 12 hour interval.

The number of treatments to be administered (one or two) will be according to clinical response.

The volume administered per injection site should not exceed 3ml.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat: 24 days

9. SPECIAL WARNING(S), IF NECESSARY

Do not use during the whole or part of the pregnancy.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products

Do not administer other non-steroidal anti-inflammatory drug (NSAID) concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

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

In case of accidental spillage onto skin, wash immediately with water.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

People with known hypersensitivity to non-steroidal anti-inflammatory products should avoid contact with the veterinary medicinal product.

10. EXPIRY DATE

EXP {month/year}

Once opened use by 28 days.

11. SPECIAL STORAGE CONDITIONS

Store below 25°C. Protect from light.

Avoid introduction of contamination.

Discard unused product.

12. SPECIFIC 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. 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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE IMMEDIATE LABEL

VIAL 100 ml/250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norflunix 50 mg/ml solution for injection for pigs
Flunixin meglumine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Active substance	
Flunixin	50 mg
(equivalent to Flunixin meglumine)	82.9 mg)

Excipients:

Phenol	5 mg
Sodium formaldehyde sulfoxylate dihydrate	2.5 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100ml
250ml

5. TARGET SPECIES

Pigs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.

The veterinary medicinal product should be administered at a dosage rate of 2.2 mg flunixin/kg bodyweight (2 ml / 45 kg) by deep intramuscular injection. Flunixin should not be injected in adipose tissue. One or two injections can be administered separated by a 12 hour interval.

The number of treatments administered (one or two) will be according to clinical response.

The volume administered per injection site should not exceed 3ml.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat: 24 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use by 28 days.

11. SPECIAL STORAGE CONDITIONS

Store below 25°C. Protect from light.

12. SPECIFIC 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. 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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norflunix 50 mg/ml solution for injection for pigs
Flunixin meglumine

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains:

Active substance:

Flunixin	50 mg
(equivalent to Flunixin meglumine)	82.9 mg)

Excipients:

Phenol	5 mg
Sodium formaldehyde sulphonylate dihydrate	2.5 mg

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular use.

5. WITHDRAWAL PERIOD

Meat: 24 days

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP {month/year}

Once opened, use by 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.