PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphacort Q 0.2% w/v Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

A sterile solution for injection containing Dexamethasone Sodium Phosphate 2mg per ml, and Benzyl Alcohol 20mg per ml as preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50ml

5. TARGET SPECIES

Horses
Cattle
Dogs
Cats

6. INDICATION(S)

Dexamethasone is a synthetic corticosteroid with a potent anti-inflammatory action: Duphacort Q can be used for:

(1) Intravenous therapy in cases where emergency treatment is indicated, particularly shock and circulatory collapse, fog fever, acute mastitis and burns.
(2) Acetonaemia (ketosis) in cattle. Duphacort Q has a marked glucogenic action.
(3) Inflammatory conditions in all species: Duphacort Q will suppress inflammation and is indicated in the treatment of arthritis, laminitis (excluding horses), dermatitis, etc.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

By intravenous or intramuscular injection.
Normal aseptic precautions should be observed.

Dosage:

Horses and cattle:	1 ml per 25 kg bodyweight		
Dogs and cats:	1 ml per 10 kg bodyweight		
e.g.			
Horses	500 kg	-	20 ml
Cattle	400 kg	-	16 ml
Dogs	10 kg	-	1 ml
Cats	5 kg	-	0.5 ml

To ensure accuracy of dosing, a suitably graduated syringe should be used when treating small animals.

8. WITHDRAWAL PERIODS

Cattle must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 21 days from the last treatment.
Milk for human consumption must not be taken from a cow during treatment Milk for human consumption may be taken from cows only from 84 hours after the last treatment.
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Systemic corticosteroid therapy is generally contra-indicated in patients with renal disease and diabetes mellitus.

Anti-inflammatory corticosteroids, such as dexamethasone, are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.

Steroids themselves, during treatment, may cause Cushingoid symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result. During therapy effective doses suppress the Hypothalamo-Pituitreal-Adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocorticol atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g. a gradual reduction of dosage (for further discussion see standard texts).

Systemically acting corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use.

Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).

Corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, anti-bacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in corticosteroid-treated animals with spinal cord trauma. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

In very rare cases, hypersensitivity reactions might occur.

The frequency of adverse reactions is defined using the following convention:
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Use of the product in horses could induce laminitis and therefore careful observations during treatment should be made.

During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

Operator warnings: Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the doctor. Pregnant women should not handle this veterinary medicinal product.
Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash the area thoroughly with clean running water. This product contains dexamethasone which can cause allergic reactions in some people. People with known hypersensitivity to dexamethasone should avoid contact with the veterinary medicinal product. Wash hands after use.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C.
Once a vial has been broached, the contents should be used within 28 days.
Discard any unused material.
Keep vials in outer container.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

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

FOR ANIMAL TREATMENT ONLY

POM-V	To be supplied only on a 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
Newry, BT35 6JP
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4255

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphacort Q 0.2% w/v Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
2 mg Dexamethasone Sodium Phosphate, and Benzyl Alcohol 20 mg/ml as preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Horses
Cattle
Dogs
Cats

6. INDICATION(S)

Duphacort Q is indicated for the treatment of inflammatory conditions, bovine ketosis and shock. Dexamethasone is a synthetic corticosteroid with a potent anti-inflammatory action.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous or intramuscular injection in horses, cattle, dogs and cats.

8. WITHDRAWAL PERIODS

Cattle (meat): 21 days.
Cattle must not be slaughtered for human consumption during treatment.
Cattle (milk): 84 hours.
Milk for human consumption must not be taken from a cow during treatment.
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the carton to the physician. Pregnant women should not handle this veterinary medicinal product. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash the area thoroughly with clean running water. This product contains dexamethasone which can cause allergic reactions in some people. People with known hypersensitivity to dexamethasone should avoid contact with the veterinary medicinal product. Wash hands after use.

10. EXPIRY DATE

Exp.: dd/mm/yy
Once broached use by: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Following withdrawal of the first dose, use the product within 28 days.
Keep the vials in the outer carton.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable [*Distribution category]*

FOR ANIMAL TREATMENT ONLY.

POM-V

To be supplied only by 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
Newry
Co. Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 02000/4255

17. MANUFACTURER'S BATCH NUMBER

B.N.:
D.O.M.:

PACKAGE LEAFLET FOR:

Duphacort Q 0.2% w/v Solution for Injection

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

Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duphacort Q 0.2% w/v Solution for Injection.

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

A sterile solution for injection containing Dexamethasone Sodium Phosphate 0.2% w/v, and Benzyl Alcohol 2% w/v as preservative.

4. INDICATION(S)

Dexamethasone is a synthetic corticosteroid with a potent anti-inflammatory action: Duphacort Q can be used for:

(1) Intravenous therapy in cases where emergency treatment is indicated, particularly shock and circulatory collapse, fog fever, acute mastitis and burns.
(2) Acetonaemia (ketosis) in cattle. Duphacort Q has a marked glucogenic action.
(3) Inflammatory conditions in all species: Duphacort Q will suppress inflammation and is indicated in the treatment of arthritis, laminitis (excluding horses), dermatitis, etc.

5. CONTRAINDICATIONS

Systemic corticosteroid therapy is generally contra-indicated in patients with renal disease and diabetes mellitus.

6. ADVERSE REACTIONS

Anti-inflammatory corticosteroids, such as dexamethasone, are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.

Steroids themselves, during treatment, may cause Cushingoid symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g.

redistribution of body fat, muscle weakness and wastage and osteoporosis may result. During therapy effective doses suppress the Hypothalamo-Pituitreal-Adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocorticol atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g. a gradual reduction of dosage (for further discussion see standard texts).

Systemically acting corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use.

Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).

In very rare cases, hypersensitivity reactions might occur.

The frequency of adverse reactions is defined using the following convention:
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Horses, cattle, dogs and cats

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

By intravenous or intramuscular injection.
Normal aseptic precautions should be observed.

Recommended Dosage Schedule:

Horses and cattle:	1 ml per 25 kg bodyweight		
Dogs and cats:	1 ml per 10 kg bodyweight		
e.g.			
Horses	500 kg	-	20 ml
Cattle	400 kg	-	16 ml
Dogs	10 kg	-	1 ml
Cats	5 kg	-	0.5 ml

9. ADVICE ON CORRECT ADMINISTRATION

To ensure accuracy of dosing, a suitably graduated syringe should be used when treating small animals.

10. WITHDRAWAL PERIOD(S)

Cattle must not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only after 21 days from the last treatment.
Milk for human consumption must not be taken from a cow during treatment.

Milk for human consumption may be taken from cows only from 84 hours after the last treatment.
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Once a vial has been broached, the contents should be used within 28 days.
Discard any unused material.
Keep the vials in outer container.
When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL WARNINGS

Operator warnings: Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician. Pregnant women should not handle this veterinary medicinal product. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash the area thoroughly with clean running water. This product contains dexamethasone which can cause allergic reactions in some people. People with known hypersensitivity to dexamethasone should avoid contact with the veterinary medicinal product Wash hands after use.

For Animal Treatment Only.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 02000/4255

Approved 25 March 2022