PARTICULARS TO APPEAR ON <THE OUTER PACKAGE>

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexadreson 2 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Dexamethasone 2 mg/ml
as dexamethasone sodium phosphate 2.63 mg/ml
Preservative Benzyl alcohol 15.6 mg

3. PHARMACEUTICAL FORM

Aqueous solution for injection.

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Horses, cattle, pigs 1.5 ml/50 kg
Dog, cat 0.5 ml/10 kg

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read leaflet for directions and warnings before use.
Dosage:
Horses, cattle, pigs 1.5 ml/50 kg, Dog, cat 0.5 ml/10 kg

Administer by intramuscular injection. In horses intravenous or intra-articular routes can be used.

8. WITHDRAWAL PERIOD

Withdrawal periods:
Meat and offal Cattle: 8 days; Milk: 72 hours
Meat and offal Pigs: 2 days
Meat and offal Horses: 8 days
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read leaflet for directions and warnings before use.

Do not store above 25°C. Protect from light.

<User Warnings>
Take care to avoid accidental self-injection.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Keep container in the outer carton.

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

Following withdrawal of the first dose use the product within 28 days.
Discard unused material.

Dispose of any empty packaging and any remaining product in the household refuse.

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

FOR ANIMAL TREATMENT ONLY

[Distribution category]

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF REACH AND SIGHT 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

Licensed distributor in N. Ireland:
Intervet Ireland Ltd., Magna Drive, Magna Business Park, Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4323

17. MANUFACTURER’S BATCH NUMBER

Batch No.: / Expiry end of:

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexadreson 2 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Dexamethasone 2 mg/ml as dexamethasone sodium phosphate 2.63 mg/ml
Preservative Benzyl alcohol 15.6 mg.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

For administration to cattle, pigs, horses, cats and dogs by i.m. injection. In horses i.a. and i.v. routes can be used.

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For administration to cattle, pigs, horses, cats and dogs by i.m. injection. In horses i.a. and i.v. routes can be used.

8. WITHDRAWAL PERIOD

Withdrawal periods:
Meat and offal Cattle: 8 days; Milk: 72 hours
Meat and offal Pigs: 2 days

Meat and offal Horses: 8 days
Not authorised for use in horses producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet for directions and warnings before use.

10. EXPIRY DATE

Once broached, use by:

Expiry end of:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light. Keep container in outer carton.

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

Once vial is broached use within 28 days.

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

FOR ANIMAL TREATMENT ONLY

[Distribution category]

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF REACH AND SIGHT 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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4323

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

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

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

Manufacturer responsible for batch release:
Intervet International GmbH
Feldstrasse 1a
D-85716
Unterschleissheim
Germany

Licensed distributor in N. Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
Citywest Road
Dublin 24

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexadreson 2 mg/ml solution for injection

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

Each ml contains 2 mg Dexamethasone (as 2.63 mg dexamethasone sodium phosphate). Benzyl alcohol 15.6 mg is included as a preservative.

4. INDICATION(S)

This preparation contains the sodium phosphate ester of dexamethasone, a fluoro-methyl derivative of prednisolone, which is a potent glucocorticoid with

minimal mineralocorticoid activity. Dexamethasone has ten to twenty times the anti-inflammatory activity of prednisolone.

Following intramuscular injection this soluble ester of dexamethasone is rapidly absorbed and hydrolysed to the parent alcohol giving a prompt response which is maintained for approximately 48 hours.

Dexadreson may be used whenever a parenteral corticosteroid preparation giving a medium duration of activity is indicated.

It can be used as an anti-inflammatory and anti-allergic agent in horses, cattle, pigs, dogs and cats and for the treatment of primary ketosis in cattle. The product can also be used to induce parturition in cattle. Dexadreson is suitable for intravenous use in the horse and is thus of particular benefit in cases needing emergency treatment.

5. CONTRAINDICATIONS

Contra-indications:

Except in emergency situations the product should not be used in animals suffering from diabetes, chronic nephritis, renal disease, congestive heart failure, osteoporosis and in viral infections during the viraemic stage.

General warnings

1. 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 clinical signs.
2. Steroids themselves, during treatment, may cause Cushinoid 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.
3. During therapy effective doses suppress the hypothalamo-pituitreal-adrenal axis. Following cessation of treatment, signs of adrenal insufficiency extending to adrenocortical 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. dosing to coincide with the time of the endogenous cortisol peak (i.e. in the morning with regard to dogs and the evening re cats) and a gradual reduction of dosage (for further information see standard texts).
4. Systemically administered 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)*.
5. Apart from the use of Dexadreson to induce parturition in cattle, 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.

6. If the product is used for induction of parturition in cattle a high incidence of retained placentae may be experienced and possible subsequent metritis and/or subfertility.
7. Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, antibacterial 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.
8. Gastrointestinal ulceration has been reported in animals treated with corticosteroids and g.i.t. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
9. Care should be taken when the product is used for the treatment of laminitis in horses, where there is the possibility that such treatment could worsen the condition. The use of the product in horses for other conditions could induce laminitis and careful observations during the treatment period should be made.
10. Use of the product in lactating cows may cause a reduction in milk yield.
11. During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

6. ADVERSE REACTIONS

In very rare cases, hypersensitivity reactions might occur.

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).

7. TARGET SPECIES

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

Dexadreson may be administered by intravenous or intramuscular injection in horses, and by intramuscular injection in cattle, pigs, dogs and cats. The product may also be given by intra-articular injection in horses.

Normal aseptic technique should be observed. To measure small volumes of less than 1-ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

For the treatment of inflammatory or allergic conditions:

The following average doses are advised. However, the actual dose used should be determined by the severity of the signs and the length of time for which they have been present.

Species	Dosage
Horses, cattle, pigs	1.5 ml/50 kg
Dog, cat	0.5 ml/10 kg

For the treatment of primary ketosis in cattle (acetonaemia):
A dose of 5 -10 ml given by intramuscular injection is advocated dependent on the size of the cow and the duration of the signs. Care should be taken not to overdose Channel Island breeds. Larger doses will be required if the signs have been present for some time or if relapsed animals are being treated.

For the induction of parturition:
To avoid foetal oversize and mammary oedema in cattle. A single intramuscular injection of 10 ml after day 260 of pregnancy. Parturition will normally occur within 48 -72 hours.

For the treatment of arthritis, bursitis or tenosynovitis:
By intra-articular injection in the horse.
Dose 1- 5 ml.
These quantities are not specific and are quoted purely as a guide. Injections into joint spaces or bursae should be preceded by the removal of an equivalent volume of synovial fluid. Strict asepsis is essential.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Cattle:
Meat and offal: 8 days
Milk: 72 Hours
Pigs:
Meat and offal: 2 days
Horses:
Meat and offal: 8 days
Not authorised for use in horses producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Keep container in outer carton. Following withdrawal of the first dose, use the product within 28 days. When the container is broached for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf life of the product is given on this package leaflet. This discard date should be written in the space provided on the label. Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority. Discard unused material.

12. SPECIAL WARNING(S)

User warnings:
The veterinary medicinal product can cause allergic reactions. Persons with known hypersensitivity to the active substance or any of the excipients should avoid contact with the veterinary medicinal product. Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician. To avoid the risk of self-injection, pregnant women should not handle the veterinary medicinal product. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash/irrigate the area with clean running water. Seek medical attention if irritation persists.
Wash hands after use.

In very rare cases, hypersensitivity reactions might occur.

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. Discard unused material.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

15. OTHER INFORMATION

In order to obtain a rapid response in very acute hypersensitivity reactions and anaphylactic conditions it may be necessary to administer antihistamines and/or adrenaline together with the corticosteroid.

When using corticosteroids to treat cases of shock the clinician should also give intravenous fluids to maintain circulating blood volume and take measures to control the acid base balance.

[Distribution category]

POM-V

Vm 01708/4323.

Approved 15 March 2022