

Material Safety Data Sheet

Prednicare 1mg and 5mg tablets

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s):	Prednicare 1mg and 5mg tablets
Product code(s):	XVD 481 (500 tablets of 1mg prednisolone) XVD 482 (1000 tablets of 1mg prednisolone) XVD 483 (500 tablets of 5mg prednisolone) XVD 484 (1000 tablets of 5mg prednisolone)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses:	Veterinary medicinal product
Uses advised against:	Not for human use. Refer to the product information leaflet
Reasons why uses advised against:	Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name:	Animalcare Limited
Address:	10 Great Northway York Business Park Nether Poppleton York YO26 6RB United Kingdom

1.4 Emergency telephone number

Daytime:	+44 (0) 1904 487687
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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008	This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.
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2.2 Label elements

Labelling according to Regulation (EC) 1272/2008	This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.
Hazard pictograms:	Not applicable
Signal word:	Not applicable
Hazard statements:	Not applicable
Precautionary statements:	Not applicable
Supplemental information:	Not applicable

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC)	None known
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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
Prednisolone	[50-24-8]	1 – 5 mg/tablet
Lactose Monohydrate	[5989-81-1]	Proprietary
Maize Starch	[9005-25-8]	Proprietary
Dextrin	[9004-53-9]	Proprietary
Stearic Acid	[57-11-4]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes:	In case of eye contact Rinse abundantly with fresh water
Skin:	Wash with soap and water and seek medical advice
Ingestion:	Drink plenty of water and seek medical advice
Inhalation:	Remove to fresh air. Seek medical advice for discomfort

4.2 Most important symptoms and effects, both acute and delayed

May cause water retention with oedema and hypertension
Prolonged absorption or ingestion or large doses may produce hirsutism, moon face, flushing, increased bruising, acne and a possibility of fully developed Cushing's syndrome

4.3 Indication of any immediate medical attention and special treatment needed

See patient package insert in shipping carton for complete information.
No specific measures identified. Seek medical advice if required

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
Unsuitable extinguishing media:	None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:	Not flammable or combustible
Hazardous combustion products:	Decomposition products may include the following materials: Carbon oxides (CO _x), nitrogen oxides (NO _x)

5.3 Advice for fire-fighters

Special protective equipment for firefighters:	Use personal protective equipment
Further information:	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel:	Refer to protective measures listed in sections 7 and 8
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Advice for emergency responders: If specialised clothing is required to deal with the spillage, take note of any information in section 8 on suitable and unsuitable materials

6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Small spills: Wear recommended personal protective equipment (see section 8- Exposure controls/personal Protection). Use absorbent towels or brooms to clean up spill. Wipe surface area clean with soap and water

Large spills: Dike spilled material or otherwise contain material to ensure runoff does not reach a waterway

6.4 Reference to other sections

See Section 1 for emergency contact information
See section 8 for personal protection
See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling: Avoid breathing dust and contact with skin, eyes and clothing. Use techniques that keep dust to a minimum

Hygiene measures: Wash thoroughly after handling

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep out of reach of children. Keep in the original packaging. Keep container tightly closed

Storage temperature: Store below 25 °C

Further information on storage conditions: Keep in a dry, cool and well-ventilated place

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. At this time, none of the other constituents have known exposure limits

8.2 Exposure controls

Engineering measures: Good general ventilation should be sufficient to control worker exposure to airborne contaminants

Individual protection measures:

Hygiene measures: No specific measures identified

Eye/face protection: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent)

Skin/body protection: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent)

Hand protection:	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent)
Environmental exposure controls:	Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Solid tablet
Colour:	White
Odour:	None
Odour threshold:	No data available
pH:	No data available
Density:	No data available
Melting point:	No data available
Boiling point:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability:	No data available
Water solubility:	Soluble
Partition coefficient:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Explosive properties:	No data available
Oxidizing properties:	The substance or mixture is not classified as oxidizing

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

None Known

10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Prednisolone LD ₅₀ 1680 mg/kg (Mouse, oral) Prednisolone LD ₅₀ 147 mg/kg (Rat, subcutaneous) Prednisolone LD ₅₀ 120 mg/kg (Rat, intravenous)
Chronic toxicity:	No data available
Skin irritation/sensitization:	No data available
Reproductive toxicity:	No data available
Carcinogenicity:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related carcinogenic/tumorigenic effects based on animal data
Mutagenicity:	No data available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

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