

**Material Safety Data Sheet****Fungiconazol 200/400 mg Tablets for Dogs****SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING****1.1 Product identification**

Product name(s):	Fungiconazol 200/400 mg Tablets for Dogs
Product code(s):	XVD 162 200mg XVD 172 400mg

**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:	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not eat, drink or smoke when using this product
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>% [weight]</i>
Ketoconazole	65277-42-1	200 - 400 mg
Microcrystalline cellulose	9004-34-6	Proprietary
Sodium starch glycolate, Type A	9063-38-1	Proprietary
Sodium lauryl sulphate	151-21-3	Proprietary
Silica, colloidal anhydrous	7631-6-9	Proprietary
Magnesium stearate	557-04-0	Proprietary
Dried yeast	n.a.	Proprietary
Chicken Flavour	n.a.	Proprietary

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

<b>Eyes:</b>	In case of eye contact Rinse with water and maintain the eyelids open. In case of irritation consult with an ophthalmologist
<b>Skin:</b>	In case of skin contact Rinse with water
<b>Ingestion:</b>	Rinse mouth. Get medical attention if symptoms occur
<b>Inhalation:</b>	This route of exposure is unlikely. Get medical attention if symptoms occur

### 4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more information on health effects and symptoms

### 4.3 Indication of any immediate medical attention and special treatment needed

No specific measures identified. Seek medical advice if required

## SECTION 5: FIRE- FIGHTING MEASURES

### 5.1 Extinguishing media

<b>Suitable extinguishing media:</b>	Small fire: Use Dry chemical powder Large fire: Use water spray, fog or foam. Do not use water Jet.
<b>Unsuitable extinguishing media:</b>	Water jet

### 5.2 Special hazards arising from the substance or mixture

<b>Specific hazards during firefighting:</b>	Not flammable or combustible
<b>Hazardous combustion products:</b>	Decomposition products may include the following materials: Carbon oxides (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> )

### 5.3 Advice for fire-fighters

<b>Special protective equipment for fire-fighters:</b>	Wear self- containing breathing apparatus and protective clothing. Use personal protective equipment
<b>Further information:</b>	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

**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

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

**Small spills:** Stop leak if safe to do so. Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13). Flush away traces with water

### 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:** When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist and/or vapours associated with the product.

**Hygiene measures:** None identified

### 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

**Storage temperature:** Store below 25 °C

**Further information on storage conditions:** Protect from direct incidence of light

### 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, the other constituents have no known exposure limits

<i>Substance name in the mixture</i>	<i>Type</i>	<i>Value</i>
Ketoconazole	TWA	0.2 mg/m <sup>3</sup>

## 8.2 Exposure controls

<b>Engineering measures:</b>	If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. Good general ventilation should be sufficient to control worker exposure to airborne contaminants
<b>Individual protection measures:</b>	
<b>Hygiene measures:</b>	No specific measures identified
<b>Eye/face protection:</b>	Safety glasses or goggles recommended.
<b>Skin/body protection:</b>	No specific measures identified
<b>Hand protection:</b>	Disposable latex gloves recommended
<b>Respiratory protection:</b>	None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements (89/656/EEC, 89/686/EEC), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.
<b>Environmental exposure controls:</b>	Consider the provision of containment around storage vessels

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

<b>Appearance</b>	Tablet
<b>Colour:</b>	Brown spiked
<b>Odour:</b>	None
<b>Odour threshold:</b>	No data available
<b>pH:</b>	No data available
<b>Density:</b>	No data available
<b>Melting point:</b>	No data available
<b>Boiling point:</b>	No data available
<b>Flash point:</b>	No data available
<b>Evaporation rate:</b>	No data available
<b>Flammability:</b>	No data available
<b>Water solubility:</b>	No data available
<b>Partition coefficient:</b>	No data available
<b>Auto-ignition temperature:</b>	No data available
<b>Thermal decomposition:</b>	No data available
<b>Viscosity:</b>	No data available
<b>Vapour pressure:</b>	No data available
<b>Vapour density:</b>	No data available
<b>Explosive properties:</b>	No data available
<b>Oxidizing properties:</b>	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

<b>Acute toxicity:</b>	Ketoconazole LD <sub>50</sub> 227 mg/kg (Rat, oral) Ketoconazole LD <sub>50</sub> 702 mg/kg (Mouse, oral) Ketoconazole LD <sub>50</sub> 202 mg/kg (Guinea pig, oral) Ketoconazole LD <sub>50</sub> 780 mg/kg (Dog, oral)
<b>Chronic toxicity:</b>	No data available
<b>Skin irritation/sensitization:</b>	No data available
<b>Reproductive toxicity:</b>	No data available
<b>Carcinogenicity:</b>	This material is not considered to be a carcinogen by IARC, NTP, or OSHA
<b>Mutagenicity:</b>	Negative in Dominant lethal test in mice

## 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 as dangerous goods

## **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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