

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Johnson's Diarrhoea Tablets.

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Calcium carbonate	240.00 mg per tablet
Bismuth subcarbonate	30.00 mg per tablet

For full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Tablet.

Cream, round, shallow convex tablet with half break line.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Dogs and Cats over 12 weeks of age.

#### **4.2 Indications for use, specifying the target species**

An aid in the relief of the symptoms of mild diarrhoeas in dogs, cats, puppies and kittens over 12 weeks of age.

#### **4.3 Contra-Indications**

Do not use on animals under 12 weeks of age.

#### **4.4 Special warnings for each target species**

1. The tablets are an aid to the relief of the symptoms of mild diarrhoeas caused by minor disorders, unsuitable food, change of diet, etc. Withholding food, but not water, for 24 hours from the start of the diarrhoea may also be beneficial.
2. If (a) the diarrhoea is of a watery consistency and/or contains blood, or (b) the dog or cat is lethargic, or (c) the dog or cat is vomiting, or (d) the diarrhoea has not subsided within 24 to 48 hours, then it is important to consult a Veterinary Surgeon promptly. Any of the above signs can indicate a serious condition. If you are unsure of your dog or cat's condition, then consult a Veterinary Surgeon.
3. Consult a Veterinary Surgeon if the puppy or kitten is less than 12 weeks of age.

#### **4.5 Special precautions for use**

- i. Special precautions for use in animals

None.

- ii. Special precautions to be taken by the person administering the medicinal product to animals

Wash hands after use.

#### **4.6 Adverse reactions (frequency and seriousness)**

None reported.

#### **4.7 Use during pregnancy, lactation or lay**

No known contra-indications.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None reported.

#### **4.9 Amounts to be administered and administration route**

Dosage: Dogs:	Under 3.6kg (8lbs)	1 tablet
	3.7 - 11.3kg ( 9 - 25lbs)	2 tablets
	11.4 - 22.6kg (26 - 50lbs)	3 tablets
	22.7kg & over (51lbs & over)	4 tablets
Cats:	Under 2.27kg (5lbs)	½ tablet
	2.28 - 4.54kg (5.1 - 10lbs)	1 tablet

Give the number of tablets shown above twice daily, either whole or crushed and mixed with a little water. Give the tablets for three days. Any part-used tablets should be disposed of in the household refuse.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary**

None stated.

#### **4.11 Withdrawal periods**

Not applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

**ATC Vet code:** QA 07 BB

## 5.1 Pharmacodynamic properties

### Calcium carbonate

Brand et al (1971, 1982) and Jenkins (1988) noted that chalk was the native form of calcium carbonate and was almost insoluble in water. Orally, the antacid effects of carbonates are only temporary, as the carbon dioxide released by the chemical reaction collects in the cardia, distends the stomach before it is released by sphincter relaxation, and in doing so causes a reflex secretion of acid and digestive enzymes: this is the so-called "acid re-bound action". Chalk has a general mechanical gastro-intestinal sedative action by coating the mucous membrane with an inert, protective layer. Calcium, bismuth and aluminium carbonates tend to have an anti-diarrhoeic action (whereas magnesium carbonate is laxative).

Merck (1986) noted that calcium carbonate (>97% of chalk) was one of several compounds used as adsorbents and protectants in the treatment of diarrhoea. These compounds were not absorbed from the gut (or their absorption was very low) and many of them possessed both adsorbent and protective properties.

Murdoch (1979) noted that bone flour, which contains a large proportion of calcium carbonate was a useful addition to the diet as an adsorbent in the treatment of transient diarrhoeas in dogs.

Reynolds (1989) noted in man that chalk was used as an antacid and in the treatment of diarrhoea.

Calcium carbonate is also widely used as a calcium supplement in the diets of dogs and cats. Many commercially prepared dog and cat diets contain approximately 20g calcium/kg dry matter, although this exceeds minimum requirements for calcium by a factor of greater than 3 (Edney, 1988). The daily calcium intake of, for example, a 10kg bodyweight dog given such a commercial diet would be greater than 4g.

### British Veterinary Codex/Pharmacopoeia

The following doses are stated:

	<u>Dogs</u>		<u>Cats</u>	
	<u>1965</u>	<u>1985</u>	<u>1965</u>	<u>1985</u>
Calcium Carbonate	0.5-4.0 g/dog	0.3-0.5 g/kg	0.3-1.5 g/cat	0.3-0.5 g/kg
Bismuth Carbonate (Bismuth oxycarbonate; bismuth subcarbonate)	0.3-2.0 g/dog	-	0.1-0.3 g/cat	-

Note: There appears to be a wide range of doses. Brander and Pugh (1971) suggested that possibly the original doses were determined more by their bulk than their activity.

### Bismuth carbonate

Brander et al (1971, 1982) and Jenkins (1988) noted that bismuth carbonate had an anti-diarrhoeal action, was an antacid, astringent, was used as an absorbent in the treatment of diarrhoea and that the adsorbent effect had been shown against E. coli toxins. These toxins may cause diarrhoea (Brander et al, 1982). The recommended doses of bismuth salts were 0.3 to 2g for dogs and 0.1 to 0.3g for cats.

Merck (1986) noted that bismuth salts were one of several compounds used as adsorbents and protectants in the treatment of diarrhoea. These compounds were not absorbed from the gastro-intestinal tract (or their absorption was very low) and many of them possessed both absorbent and protective properties: the protectants seem to coat the gastro-intestinal epithelium and prevent irritation and erosion; the adsorbents bind chemical compounds which precludes their absorption.

Murdoch (1979) noted that bismuth had been used for decades in the treatment of diarrhoea in the dog.

Reynolds (1989) noted that in man, intoxication by bismuth salts occurs for the soluble salts which are absorbed and bismuth subsequently excreted in the urine. Bismuth carbonate is practically insoluble in water. Recently there has been renewed interest in the use of bismuth salts to treat, in man, gastritis and pyloric ulcers associated with Helicobacter pylori infection (for example, see Heilman and Borchard, 1991).

## **5.2 Pharmacokinetic particulars**

No other information available.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Maltodextrin  
Pregelatinised Starch  
Sodium Starch Glycollate  
Magnesium Stearate

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

### **6.4 Special precautions for storage**

Do not store above 25°C.

## 6.5 Nature and composition of immediate packaging

Pack of 12 cream round, shallow convex tablets with half break-line.

- A) Container: Clear colourless regenerated cellulose/polyurethane/polyethylene laminate strip pack.  
Closure: Heat seal:
- B) Container: Clear colourless polyvinylchloride/polyvinylidene chloride/aluminium foil blister pack.  
Closure: Heat seal.

Secondary packaging: Solid board carton.

## 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Johnson's Veterinary Products Ltd  
5 Reddicap Trading Estate  
Sutton Coldfield  
West Midlands B75 7DF

## 8. MARKETING AUTHORISATION NUMBER(S)

**Vm** 01759/4051

## 9. DATE OF FIRST AUTHORISATION

**Date:** 26 March 1993

## 10. DATE OF REVISION OF THE TEXT

**Date:** September 2011