### 1. Name of the medicinal product

# **Muposan Powder**

# 2. Qualitative and quantitative composition

Sorbitol 5g

#### 3. Pharmaceutical form

Powder

#### 4. Clinical particulars

#### 4.1 Therapeutic indications

Sorbitol is used to relieve occasional constipation and irregularity

# 4.2 Posology and method of administration

Adult and Pediatric Dosage Forms and Strengths

Irrigation solution

3 g/100mL (3%)

Oral solution

• 70%

#### Dosage Considerations - Should be Given as Follows:

#### Constipation

- Adult, Oral: 30-150 mL (70% solution) once
- Adult, <u>Rectal enema</u>: 120 mL of 25-30% solution once
- Children under 2 years: Safety and efficacy not established
- Children 2-11 years:
- Oral: 2 mL/kg (as 70% solution) once
- o Rectal enema: 30-60 mL as 25-30% solution
- Children 12 years and older:
- o Oral: 30-150 mL (70% solution) once
- Rectal enema: 120 mL of 25-30% solution once

# 4.3 Contraindications

• Anuria, <u>acute abdominal pain</u>, nausea, vomiting, or other symptoms of <u>appendicitis</u> or undiagnosed abdominal <u>pain</u> Do not take sorbitol if you are allergic to sorbitol or any ingredients contained in this drug.

#### 4.4. Interaction with other medicinal products and other forms of interaction

- Sorbitol has no known severe interactions with other drugs.
- Serious Interactions of sorbitol include:
- o sodium polystyrene sulfonate
- Moderate Interactions of sorbitol include:
- o deflazacort
- dichlorphenamide
- Sorbitol has no known mild interactions with other drugs.
- 4.5 Fertility, pregnancy and lactation
- Use sorbitol with caution during pregnancy if the benefits outweigh the risks. Animal studies <u>show</u> risk and human studies are not available or neither animal nor human studies were done.
- Use caution with the use of sorbitol if <u>breastfeeding</u>. Consult your doctor.

#### 4.8 Undesirable effects

- Abdominal discomfort
- Dehydration
- Diarrhea
- Dry mouth
- Excessive bowel activity
- Fluid and electrolyte losses
- High blood sugar (hyperglycemia)
- Lactic acidosis
- Nausea
- Swelling (<u>edema</u>)
- Vomiting

# 5. Mechanim of action

Sorbitol exerts its **laxative effect by drawing water into the large intestine**, thereby stimulating bowel movements. Sorbitol will either be excreted in the urine by the kidneys, or metabolized to carbon dioxide and dextrose.

# 6. Pharmaceutical particulars

# 6.1 Incompatibilities

Not applicable.

# 6.2 Shelf life

4 years

#### 6.3 Special precautions for storage

Do not store above 30°C.

# 6.4 Nature and contents of container Packed in sachets as 5g x20

# 7. Marketing authorisation holder

Smart way Pharma Ltd

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