

# NEW ZEALAND DATA SHEET

## 1. HAEMOROL™

Phenol BP 5% w/v

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

HAEMOROL™ contains 5% w/v Phenol BP.

### Excipients with known effect:

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Injection.

HAEMOROL™ is a clear, yellowish, viscous solution containing 5% w/v of Phenol BP in almond oil.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

HAEMOROL™ is indicated for the sclerotherapy of haemorrhoids.

### 4.2 Dose and method of administration

HAEMOROL™ is for submucosal injection only ie. local administration only (see Precautions).

HAEMOROL™ is administered by submucosal injection of 2 to 5 mL. It may be injected into the submucosal space above each of the three principle haemorrhoids.

A maximum of 10 mL should be injected in any one treatment.

It is preferable that only sterile glass syringes be used for injecting this product, to minimise the possibility of absorption or extraction from plastic syringe components. However, plastic syringes with needles with plastic hubs may be used if the injection is to be administered immediately.

HAEMOROL™ is contraindicated for use in neonates or children (see Warnings and Precautions).

### 4.3 Contraindications

HAEMOROL™ is contraindicated:

- in patients who are hypersensitive to phenol or almond oil;
- in neonates and children (see Precautions);
- for use over large areas, since sufficient amounts may be absorbed to give rise to toxic symptoms.

### 4.4 Special warnings and precautions for use

For submucosal injection only. Not for intrathecal use.

Complications of therapy can include local ulceration and sterile abscess formation. These complications may be serious following a misplaced injection (eg prostatic abscess). Care in choosing the correct site of injection is mandatory. Solutions containing phenol should not be applied to large areas of skin or large wounds since sufficient phenol may be absorbed to give rise to toxic symptoms. Toxic symptoms may also arise through absorption of phenol vapour by the skin and lungs.

#### *Use in Children*

Significant absorption of phenol can occur in neonates. Toxic effects have been observed from other phenol formulations, and therefore HAEMOROL™ is contraindicated for use in neonates or children.

#### **4.5 Interaction with other medicines and other forms of interaction**

No significant drug interactions involving phenol are known.

#### Effects on Laboratory Tests

Absorbed phenol can interfere with the following laboratory tests:

- plasma adrenaline (epinephrine) and noradrenaline (norepinephrine) estimation (trihydroxyindole method);
- ferric chloride test for ketones or salicylates in urine (but not the Phenistix test);
- test for ionised calcium in serum;
- measurement of sulfonamides in serum;
- Benedict test for glycosuria.

#### **4.6 Fertility, pregnancy and lactation**

##### *Use in Pregnancy*

No teratogenic effects were observed at doses up to 280 mg/kg in CD1 mice and 120 mg/kg in CD rats. The highest doses were maternotoxic in mice but not in rats. In both species phenol produced a dose-related decrease in average live foetal body weights, but no other significant adverse effects in the foetuses. A developmental study in rats found that doses of up to 53 mg/kg/day phenol administered orally to rats produced kinked tails in two pups, as well as reduced litter sizes and pup weights but these effects were only seen in pups from females which showed toxic effects from the phenol administration. Phenol has been rated as having a low potential for developmental toxicity.

The significance of the oral rat studies to human submucosal administration of phenol is unknown. However, safety in pregnancy has not been established. The effects on the foetus are unknown, therefore HAEMOROL™ is not recommended for use during pregnancy.

##### *Use in Lactation*

It is not known whether phenol is excreted into breast milk. Since safety in infants has not been established, HAEMOROL is not recommended for use while breast-feeding.

##### *Carcinogenicity, Mutagenicity, Impairment of Fertility*

The mutagenic potential of phenol has been assessed in numerous mutation assay systems including in vitro tests (eg Ames test) and in vivo tests (eg the mouse micronucleus test). The results of these tests indicate that phenol is considered to have mutagenic potential.

Phenol is not carcinogenic in mice or rats of either sex, at doses up to 5000 ppm in drinking water. The carcinogenic potential of phenol in humans is unknown.

The clinical relevance of these data to the submucosal administration of HAEMOROL™ is unknown.

The effects of HAEMOROL™ on fertility and reproduction are not known.

#### **4.7 Effects on ability to drive and use machines**

Presumed to be safe or unlikely to produce an effect on the ability to drive or use machinery.

#### **4.8 Undesirable effects**

##### *More Common Reactions*

A high incidence of pain has been reported after submucosal administration of phenol. Discomfort and giddiness has also been reported. Local ulceration and sterile abscess formation may also occur.

##### *Less common reactions*

The following reactions have been reported rarely after injection of phenol, generally as a result of misplaced injection: dysuria, transient incontinence, pyrexia, impotence, prostatic abscess.

##### *Life threatening reactions*

A case of necrotising fasciitis has been reported after injection sclerotherapy of haemorrhoids with 5% phenol in almond oil.

A case of retroperitoneal sepsis has also been reported. This reaction has also been reported rarely with other forms of haemorrhoid treatment, such as rubber band ligation.

##### Phenol-containing preparations:

##### *Less Common Reactions*

These reactions have been observed with topical use of various phenol preparations, although not necessarily phenol itself.

- Body as a whole: pyrexia, allergic reactions.
- Cardiovascular system: cardiac arrhythmia.
- Central Nervous system: dizziness collapse.
- Dermatological: contact urticaria, darkening of skin on hands and face (after prolonged use).
- Ocular: darkening of cornea (after prolonged use).
- Other: Use of this product may result in the urine being tinted green.

##### *Life Threatening Reactions*

Significant absorption of phenol can occur through skin and mucous membranes, resulting in serious, sometimes fatal, toxicity (see Overdosage).

#### **4.9 Overdose**

##### *Symptoms*

The symptoms of overdose after submucosal injection of phenol are not known, but are likely to be similar to symptoms observed after excessive exposure to phenol in other preparations. Absorption of phenol after application of dilute phenol solutions to extensive wounds has resulted

in abdominal pains, dizziness, methaemoglobinaemia, haemoglobinuria, cyanosis, cardiac arrhythmias, ECG abnormalities, and may result in respiratory failure, circulatory failure, coma and death.

### *Treatment*

There is no specific antidote for acute phenol overdose. Treatment of overdose is symptomatic and supportive. Treatment may involve the following measures:

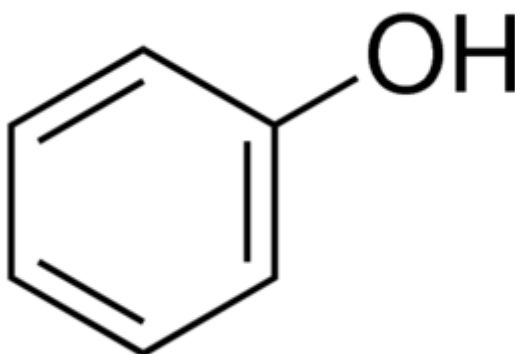
- support of respiratory functions;
- correction of fluid and electrolyte balance.

If spillage onto skin occurs, remove all contaminated clothing, and rub contaminated skin for at least 10 minutes with swabs soaked in glycerol, a liquid macrogol or a mixture of 70% macrogol and 30% methylated spirits. Water can be used initially if these are not available.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

The molecular formula of phenol is  $C_6H_5OH$ . Its molecular weight is 94.1. The CAS Registry number of phenol is 108-95-2. The structural formula of phenol appears below:



Phenol is an antiseptic and disinfectant. It is also corrosive. When applied to mucous membranes, it causes the surface to become white and opaque due to precipitation of proteins, and a slough is formed. When HAEMOROL™ is injected into haemorrhoids, submucosal fibrosis is produced, fixing the mucosa to the underlying muscle

### **5.2 Pharmacokinetic properties**

Phenol is readily absorbed through intact skin, mucous membranes and the gastrointestinal tract. It is metabolised in the liver, mainly via conjugation to phenyl glucuronide and phenyl sulfate, although small amounts are oxidised to catechol and quinol prior to further conjugation. The metabolites are excreted in the urine. Ninety-nine percent of an absorbed dose is excreted in the urine in 24 hours.

The extent of systemic absorption of HAEMOROL™ following submucosal administration (when used in the treatment of haemorrhoids) is not known. Since HAEMOROL™ produces submucosal fibrosis, fixing the mucosa to the underlying muscle, the amount of phenol entering the systemic circulation would be minimal.

### **5.3 Preclinical safety data**

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Not applicable.

### **6.2 Incompatibilities**

Phenol is reported to be incompatible with alkaline salts and non-ionic surfactants. It is also corrosive. It is preferable that only sterile glass syringes be used for injecting this product, to minimise the possibility of absorption or extraction from plastic syringe components. However, plastic syringes with needles with plastic hubs may be used if the injection is to be administered immediately.

### **6.3 Shelf life**

HAEMOROL™ has a shelf life of three years.

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

Store below 30°C. Protect from light.

### **6.5 Nature and contents of container**

Pack size 5 x 5 mL vials. 250 mg phenol in 5 mL

### **6.6 Special precautions for disposal**

No special precautions.

## **7. MEDICINE SCHEDULE**

Prescription medicine.

## **8. SPONSOR**

AFT Pharmaceuticals Ltd  
PO Box 33-203  
Takapuna  
Auckland 0740  
Phone: 0800 423 823  
Email: [customer.service@aftpharm.com](mailto:customer.service@aftpharm.com)

## **9. DATE OF FIRST APPROVAL**

20/02/1986

## **10. DATE OF REVISION OF TEXT**

February 2019

## SUMMARY TABLE OF CHANGES

<b>Date</b>	<b>Section(s) Changed</b>	<b>Change (s)</b>
February 2019	All	Reformat consistent with new Medsafe Data Sheet Template.