SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Oily Phenol Injection BP 5%w/v

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Phenol BP 5.00 % WV

3 PHARMACEUTICAL FORM

Sterile solution intended for parenteral use

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Scleropathy of haemorrhoids

4.2 Posology and method of administration

Injected into sub-mucosal layer at the base of the haemorrhoid

ADULTS

2-3 ml of oily phenol injection into the sub-mucosal layer at the base of the pile; Several injections may be given at different sites but not more than a total volume of 10 ml should be used at any one time.

CHILDREN

Use of this product is not advised

ELDERLY

No alternative dosage schedules have been suggested.

4.3 Contraindications

Oily Phenol Injection, BP is contraindicated in patients who are hypersensitive to phenol, nuts and in particular almond oil or any component of the product. It should not be used over large areas, since sufficient amounts may be

absorbed to give rise to toxic symptoms. Oily Phenol Injection, BP is also contraindicated in neonates and children.

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.

4.5 Interaction with other medicinal products and other forms of interaction

None stated

4.6 Fertility, Pregnancy and lactation

Safety in pregnancy has not been established. The effects on the foetus are unknown, therefore Oily Phenol is not recommended for use during pregnancy.

It is not known whether Oily Phenol is excreted in breast milk. Since safety in infants has not been established, Oily Phenol injection is not recommended for use whilst breast-feeding.

4.7 Effects on ability to drive and use machines

Effects of phenol oily injection are not likely to affect the patient's ability to drive and use machinery.

4.8 Undesirable effects

General disorders and administration site conditions:

Pyrexia

Pain

Discomfort

Ulcer

Immune system disorders:

Hypersensitivity

Nervous system disorders:
Dizziness

Hepatobiliary disorders:
Hepatitis

Infections and infestations:
Abscess
Prostatic abscess
Necrotizing fasciitis
Retroperitoneal sepsis

Renal and urinary disorders:
Dysuria
Urinary incontinence

Reproductive system and breast disorders:
Impotence

4.9 Overdose

Symptoms:

The symptoms of overdosage after submucosal injection of Oily 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, haemoglobinurea, 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Oily phenol injection acts as an analgesic and thrombotic agent by numbing the sensory nerve endings and precipitating proteins.

5.2 Pharmacokinetic properties

Phenol is absorbed from the gastro-intestinal tract and through skin and mucous membranes. It is metabolised to phenylglucoronide and phenylsulphate and small amounts are oxidised to catechol and quinol which are mainly conjugated. The metabolites are excreted in the urine; on oxidation to quinones they may tint the urine green.

5.3 Preclinical safety data

No data available

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Almond oil

6.2 Incompatibilities

Incompatible with alkaline salts, acetanilide, phenazone, piperazine, quinine salts, phenacetin and iron salts. Phenol coagulates albumin and gelatinises collodion.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

5 ml neutral glass (type 1) ampoules supplied in cartons of 10.

6.6 Special precautions for disposal

None stated

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs
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8 MARKETING AUTHORISATION NUMBER(S)

PL 35104/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20 March 1987 / 21 December 2002

10 DATE OF REVISION OF THE TEXT

21/03/2014