

1. NAME OF THE MEDICINAL PRODUCT

Compound Benzoin Tincture BP or Friars' Balsam BP.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Benzoin (Ground) 10.0 % w/v
Prepared Storax 10.0% w/v
Aloes 2.0% w/v.

3. PHARMACEUTICAL FORM

Concentrate for inhalation solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

For the relief of colds and laryngitis.

4.2. Posology and method of administration

Adults the elderly and children over 3 months

Add one 5 ml spoonful to a pint of hot, but not boiling, water and inhale the vapour.

Children under 3 months

Not recommended for children under 3 months.

Route of administration

Inhalation of the vapours released by the addition of the product to hot water.

4.3. Contraindications

Apart from the possibility of skin sensitisation (See 4.8 below) in a few persons using the product, no other contraindications have been reported.

4.4. Special warnings and precautions for use

If symptoms persist consult your doctor.

4.5. Interactions with other medicinal products and other forms of interaction

No significant interactions have been reported.

4.6. Pregnancy and lactation

No significant problems have been reported either with pregnant women or with nursing mothers who are breast feeding; However, as with many other medicines, its use, especially in the first three months of pregnancy, is recommended only when the benefits outweigh any risks.

4.7. Effects on ability to drive and use machines

None known.

4.8. Undesirable effects

Skin sensitisation has been reported.

4.9. Overdose

Overdosage is unlikely to present a significant risk but if it does occur then the treatment consists of general supportive therapy and may include gastric lavage.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Benzoin

It is reported to have expectorant properties in the relief of catarrh and congestion of the upper respiratory tract.

Storax (Prepared)

It is reported to have a similar action to Benzoin in the relief of catarrh and congestion of the upper respiratory tract.

Aloes

It is uncertain what pharmacological action it plays when used in Compound Benzoin Tincture B.P. as a treatment for the relief of catarrh and congestion of the upper respiratory tract.

5.2. Pharmacokinetic properties

Benzoin / Storax (Prepared) / Aloes

Little information is available in the literature regarding the pharmacokinetic particulars of these three compounds when administered by nasal inhalation of the vapours released when the product is added to hot water.

5.3. Preclinical safety data

No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Ethanol 96%
Potable water.

6.2. Incompatibilities

No significant major incompatibilities have been reported other than the fact that solid material is precipitated on addition of water.

6.3. Shelf life

60 months.

6.4. Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

Dispensing packs

2000 ml HDPE bottle with plastic screw cap with an aluminium foil lined EPE liner.

500 ml HDPE bottle with a wadless polypropylene cap.

OTC Packs

50 ml and 100 ml amber glass bottles with a plastic Jay cap closure.

Not all pack sizes may be marketed.

6.6. Instruction for use and handling, (and disposal)

None.

7. MARKETING AUTHORISATION HOLDER

Wise Pharmaceuticals Limited
Hani Wells Business Park
Unit 7
Hardicker Street
Manchester
M19 2RB
United Kingdom.

8. MARKETING AUTHORISATION NUMBER

PL 18374/0038

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

14th April 2005

10. DATE OF (PARTIAL) REVISION OF THE TEXT