

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Pentrax 4.3% w/v Shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Fractar 5 7.71% w/v
(equivalent to coal tar 4.3% w/v)

For excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Shampoo

A burgundy-brown liquid of medium viscosity and a coal-tar odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of itching, irritation, redness, flaking and/or scaling due to dandruff, seborrhoeic dermatitis, or psoriasis of the scalp.

4.2 Posology and method of administration

For topical administration.

Adults:

Pentrax Shampoo should be massaged into wet hair and scalp to produce a lather. The hair should be rinsed and the procedure repeated applying a liberal amount of Pentrax and allowing the lather to remain on the hair for up to 10 minutes. Hair should be rinsed thoroughly.

Use at least twice weekly or as directed by a physician.

Children:

As for adults.

Elderly:

As for adults.

4.3 Contraindications

Pentrax Shampoo is contra-indicated in persons with a sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Avoid contact with the eyes. If shampoo gets into the eyes rinse thoroughly with water.

If the condition worsens or does not improve after regular use of the product as directed, consult a physician.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

The safety of Pentrax has not been established.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

There have been no reports of adverse effects following the use of Pentrax Shampoo. However, coal tar may cause irritation to the skin. Erythema and hypersensitivity to coal tar has been reported. Although carcinogenicity of coal tar has been demonstrated in animal studies, no studies demonstrating an increased risk of skin cancer with normal therapeutic use in humans have been reported. There is no unequivocal evidence to link the use of topically applied coal tar products with skin cancer.

4.9 Overdose

There is no evidence of systemic absorption following the use of this shampoo. There are no reports available of its ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Coal tar is an antipruritic, keratolytic and a weak antiseptic.

5.2 Pharmacokinetic properties

There is no evidence of systemic absorption following the use of Pentrax Shampoo.

5.3 Preclinical safety data

Tar preparations have been in wide use for many years. Although coal tar preparations containing polycyclic aromatic hydrocarbons (PAHs) have been demonstrated to be carcinogenic in the skin of experimental animals, present evidence, based upon epidemiology studies in humans and following-up trials, reveals no evidence of increased risk of skin or internal cancer, particularly when the product is used as directed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Diethyl sodium sulphosuccinate
Isopropyl myristate
Sodium lauryl sulphate
Squalane
Laureth-23
Polyethylene glycol 8
Cocamide DEA
Lauramine oxide

6.2 Incompatibilities

None known.

6.3 Shelf life

48 months.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Pentrax Shampoo is supplied in a polyvinylchloride bottle with a polypropylene screw cap with triseal. Each bottle contains either 30ml, 120ml or 240ml of Pentrax Shampoo.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Pentrax SPC Ireland 002

Alliance Pharmaceuticals Limited
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8. MARKETING AUTHORISATION NUMBER

PA 943/10/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 October 1995

Date of last renewal: 26 October 2005

10. DATE OF REVISION OF THE TEXT

April 2006