

TA-TAR shampoo

1. NAME OF THE MEDICINAL PRODUCT

TA-TAR (20%w/v) shampoo

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

TA-TAR (20% w/v) shampoo: Each 1 mL of shampoo contains 0.2 g of coal tar topical solution

3. PHARMACEUTICAL FORM

Shampoo with yellowish brown liquid with characteristic odor

4. CLINICAL PARTICULARS

4.1 Therapeutic indications [1, 4.1 Therapeutic indications, p. 1]

TA-TAR (20% w/v) shampoo is used as a shampoo for the treatment of psoriasis of the scalp.

4.2 Posology and method of administration [1, 4.2 Posology and method of administration, p. 1]

For adults, children and the elderly

Use as a shampoo, daily if necessary, reducing the frequency of use to once or twice a week as the condition improves. Thereafter, occasional use may be necessary.

Wet the hair thoroughly. Apply a small amount of the shampoo to the scalp (approximately a quantity the size of a ten baht coin for short hair, adjusting up depending on length/thickness of hair), and massage gently until a rich lather has been generated. Retain on the scalp for a few minutes. Remove excess lather with the hands before rinsing with warm water. If necessary, repeat the above procedure.

4.3 Contraindications [1, 4.3 Contraindications, p. 1]

- Not to be used for acute, sore or pustular psoriasis or in the presence of infection.

- Not to be used in cases of sensitivity to any of the ingredients.

4.4 Special warnings and precautions for use [1, 4.4 Special warnings and precautions for use, p. 1]

- Keep away from the eyes and mucous membranes.

- Replace cap after use.

- Avoid spillage.

- If there is no improvement after 4 weeks, or the scalp condition seems to look or feel worse, discontinue treatment and tell your doctor, pharmacist or nurse.

4.5 Interaction with other medicinal products and other forms of interaction

[1, 4.5 Interaction with other medicinal products and other forms of interaction, p. 1]

None known.

4.6 Fertility, pregnancy and lactation [1, 4.6 Fertility, pregnancy and lactation, p. 1]

No special precautions.

4.7 Effects on ability to drive and use machines [1, 4.7 Effects on ability to drive

and use machines, p. 1]

None known.

4.8 Undesirable effects [1, 4.8 Undesirable effects, p. 1-2]

Local side-effects do not normally occur. In rare cases of skin irritation, acne-like eruptions or photosensitivity, discontinue treatment. Rarely, TA-TAR (20% w/v) shampoo may stain skin, hair or fabric.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via <http://www.fda.moph.go.th>.

4.9 Overdose [1, 4.9 Overdose, p. 2]

There are no known toxic effects resulting from excessive use of TA-TAR (20% w/v) shampoo.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties [2, 5.1 Pharmacodynamic properties, p. 2], [3,

5.1 Pharmacodynamic properties, p. 2]

TA-TAR (20%w/v) shampoo contains coal tar, an antipruritic and keratoplastic. It is used in eczema, psoriasis and other skin conditions. [2, 5.1 Pharmacodynamic properties, p. 2] The precise mechanism of action of coal tar is not understood,

largely as a result of it comprising up to 10,000 components. There is evidence that topical application of coal tar improves psoriasis by reducing the excessive rate of mitotic epidermal cell division. [3, 5.1 Pharmacodynamic properties, p. 2] Tar acids have also been shown to have disinfectant properties. TA-TAR (20%w/v) shampoo may be used alone, or as part of a more extensive treatment regimen. [2, 5.1 Pharmacodynamic properties, p. 2]

5.2 Pharmacokinetic properties [1, 5.2 Pharmacokinetic properties, p. 2]

Not applicable.

5.3 Preclinical safety data [1, 5.3 Preclinical safety data, p. 2]

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

salicylic acid, sodium lauryl sulfate, methylcellulose, glycerin, polyethylene glycol, cocamide DEA, polysorbate 20, sorbitan laurate and purified water

6.2 Incompatibilities. [1, 6.2 Incompatibilities, p. 2]

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

- Do not store above 30°C
- Store in the original container
- Keep out of reach of children

6.5 Nature and contents of container

Each box contains one 150 mL brown opaque high-density polyethylene (HDPE) bottle.

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

Not applicable.

7. MARKETING AUTHORISATION HOLDER

The Government Pharmaceutical Organization 75/1 Rama VI Road, Ratchathewi,
Bangkok, 10400, Thailand

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT

19 April 2022

References:

1. Dermal Laboratories Limited, Psoriderm Scalp Lotion Shampoo, in Summary of Product Characteristics, Dermal Laboratories Limited, Herts, UK, Revised: Mar 2020.
2. Teva UK Limited, Coal Tar (Exorex) Lotion, in Summary of Product Characteristics, Teva UK Limited, East Sussex, UK, Revised: June 2020.
3. Dermal Laboratories Limited, Psoriderm Cream, in Summary of Product Characteristics, Dermal Laboratories Limited, Herts, UK, Revised: Jan 2020.