Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to Johnson & Johnson Limited on 0808 238 9999.

Neutrogena T/Gel Therapeutic Shampoo Product Information:

Presentation:

A translucent amber solution containing Neutar solubilised coal tar extract 20mg/ml (equivalent to 5mg/ml coal tar).

Uses: Treatment for seborrhoeic dermatitis of the scalp, dandruff and scalp psoriasis. **Dosage:**

For cutaneous use only. Apply liberal amounts of Neutrogena T/Gel Therapeutic Shampoo and massage into wet scalp. Leave on scalp for several minutes, rinse scalp, repeat application, then rinse scalp thoroughly. Neutrogena T/Gel Therapeutic Shampoo should be used two to three times weekly. Treatment usually lasts for 6 weeks. Longer periods of treatment should only take place under the supervision of a doctor. Not recommended for use in children below the age of 12 years.

Contraindications:

Hypersensitivity to coal tar or to any of the excipients. Acutely inflamed or broken skin, erythrodermic or generalized pustular psoriasis.

Precautions:

If irritation develops, discontinue use and consult physician. In rare instances, temporary discolouration of grey, blonde, bleached or tinted hair may occur. Avoid contact with eyes. If contact occurs, rinse thoroughly with water. As coal tar may have a photosensitising action, caution should be exercised in exposing skin to sunlight after use. Contains Methyl (E218) and Propyl (E216) parahydroxybenzoates which can cause allergic reactions (possibly delayed). Esters of benzoic acid, benzyl benzoate and butylated hydroxytoluene (E321) may cause local skin reactions (e.g contact dermatitis), or irritation to the eyes and mucous membranes.

This medicine contains fragrance with the following components which may cause allergic reactions: Alpha-Isomethyl-ionone, Amyl Cinnamal, AmylCinnamyl Alcohol, Benzyl Benzoate, Benzyl Cinnamate, Benzyl Salicylate, Cinnamal, Cinnamyl Alcohol, Citral, Citronellol, Eugenol, Farnesol, Geraniol, Hexyl Cinnamal, Hydroxycitronellal, Isoeugenol, Limonene and Linalool.

Pregnancy and Lactation:

It is recommended that Neutrogena T/Gel Therapeutic Shampoo is not used during pregnancy or while breast-feeding unless the risks and benefits have been evaluated and discussed with a physician.

Side effects:

<u>Not known incidence</u>: Angioedema, hypersensitivity (including urticaria, photosensitization), eye irritation, hair loss, dry hair, rash, hair colour changes, application site reactions (including burning sensation, irritation, pruritus and dry

scalp). Other Adverse Drug reactions identified in published literature include: dermatitis acneiform **RRP (ex VAT)** 125ml - £5.81, 250ml - £9.33 **Legal category:** GSL **PL Holder:** Johnson & Johnson Limited, 50 -100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK. **PL Number(s):** 08874/0014 **Date of preparation:** 26 Sep 2023