Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Neutrogena T/Gel Shampoo 5 mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The shampoo contains 5 mg/ml of refined coal tar as the active ingredient.

The shampoo also contains 2.0 mg/ml methyl parahydroxybenzoate (E218) and 0.5 mg/ml propyl parahydroxybenzoate (E216). The constituents of the fragrance include esters of benzoic acid, benzyl benzoate and butylated hydroxytoluene (E321).
For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Shampoo.
A translucent, amber solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As a shampoo in the symptomatic treatment of dandruff and seborrhoeic dermatitis of the scalp.

4.2 Posology and method of administration

For cutaneous use only. Liberal amounts of Neutogena T/Gel Shampoo should be applied and massaged into the wet scalp and left for several minutes. The scalp should be rinsed, the application repeated and then the scalp rinsed thoroughly. Neutrogena T/Gel Shampoo should be used once or twice weekly for the treatment of scalp disorders. Treatment usually lasts 4 weeks, after which improvement should be seen. Longer periods of treatment should only take place under the supervision of a doctor.

4.3 Contraindications

Hypersensitivity to coal tar or to any of the excipients listed in section 6.1.
Acutely inflamed or broken skin, erythrodermic or generalised pustular psoriasis.
Use in children under 12 years of age.

4.4 Special warnings and precautions for use

If irritation develops, use should be discontinued and a physician consulted.
In rare instances, temporary discoloration of grey, blonde, bleached or tinted hair may occur.

Contact with eyes should be avoided. If contact occurs, rinse eyes thoroughly with water.
Coal tar may have a photosensitising action and caution should be exercised in exposing skin to sunlight after applying this product.

Contains Methyl (E218) and Propyl (E216) parahydroxybenzoates which may 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, Anise Alcohol, Benzyl Benzoate, Benzyl Cinnamate, Benzyl Salicylate, Butylphenyl Methylpropional, Cinnamal, Cinnamyl Alcohol, Citral, Citronellol, Coumarin, Eugenol, Evernia Furfuracea (Treemoss) Extract, Evernia Prunastri (Oakmoss) Extract, Farnesol, Geraniol, Hexyl Cinnamal, Hydroxycitronellal, Hydroxyisohexyl-3-Cyclohexene

Carboxaldehyde, Hydroxyisohexyl 3-&4-Cyclohexene Carboxaldehyde (HMPCC), Isoeugenol, Limonene, Linalool and Methyl-2-Octynoate.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There are no data from the use of Neutrogena T/Gel Shampoo in pregnant women or during lactation. Studies in animals have shown fetotoxic and teratogenic effects of coal tar products (see Section 5.3). Neutrogena T/Gel Shampoo should not be used in pregnancy and lactation unless the risks and benefits have been evaluated and discussed with a physician.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

An increased risk of skin cancer in animals exposed to high concentrations treated with coal tar has been reported. However, epidemiological studies in patients are inconclusive. The risk of carcinogenicity should be taken in to account when considering the suitability of this medicinal product for patients (see also Section 5.3).

Adverse drug reactions (ADRs) identified during clinical trials and post-marketing experience with coal tar are listed below by System Organ Class (SOC). The frequencies are provided according, to the following convention:

Very common ≥ 1/10
Common ≥ 1/100 and < 1/10
Uncommon ≥ 1/1,000 and < 1/100
Rare ≥ 1/10,000 and < 1/1,000
Very rare < 1/10,000
Not known - cannot be estimated from the available data

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available, or 2) when incidence cannot be estimated, frequency category is listed as 'Not known'.

System Organ Class (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Immune System Disorders	Not known	Hypersensitivity (including Urticaria, Photosensitization)
Eye Disorders	Not known	Eye irritation
Skin and Subcutaneous Tissue Disorders	Not known	Angioedema Hair colour changes Hair loss Rash
General Disorders and Administrative Site Conditions	Not known	Application site reactions (including burning sensation, irritation, pruritus and dry scalp)

Other Adverse Drug Reactions identified in published literature include:

Skin and subcutaneous tissue disorders

Dermatitis acneiform

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 HPRA Pharmacovigilance, website: www.hpra.ie.

4.9 Overdose

Not applicable.
In the event of oral ingestion, seek immediate medical advice. The use of gastric lavage or activated charcoal is not recommended as coal tar is corrosive. Supportive therapy may be given.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Medicated Shampoo, ATC code: D11 AC 30

Tar preparations have been extensively used in the treatment of various skin diseases for 50 years. The precise mode of action is not known. Tar suppresses DNA synthesis in hyperplastic skin by inhibiting mitotic activity and protein synthesis. It reduces epidermal proliferation and dermal infiltration, thus producing a return to normal hornification. Tar also has (cellular) proliferation-inhibiting, vasoconstrictive, antipruritic and antiseptic properties. This is of significance in the treatment of skin diseases where there is increased cell partition, such as dandruff. Tar preparations are used extensively in preparations intended for use in the treatment of scalp conditions. This form of treatment has proved to be safe and effective.

5.2 Pharmacokinetic properties

Little is known about the percutaneous absorption, residence time and excretion of coal tar, although there is epidermal metabolism of polyaromatic hydrocarbons, and the urine of patients undergoing therapy with high levels of raw coal tar contains substances which apparently originate from the raw coal tars used. The potential for systematic absorption of coal tar from Neutrogena T/Gel Shampoo is extremely low, in particular because it is used as a shampoo that can be washed off after use.

5.3 Preclinical safety data

Certain of the ingredients of coal tar are mutagenic and genotoxic carcinogens. In animal studies, coal tar has been shown to increase the incidence of epidermal carcinomas and self-limiting keratoacanthomas. After dermal application of coal tar products, fetotoxic and teratogenic effects were observed in rats and mice at high doses. However, epidemiological studies with patients are inconclusive. Nevertheless, the possible risk to patients of prolonged treatment should be taken into account when considering usage of this medicinal product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol lauryl ether (4)
Sodium lauryl ether sulfate
Cocodiethanolamide
Cocamidopropyl betaine
Imidazolidinyl urea
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Tetrasodium EDTA
Citric acid anhydrous
Perfume: FUGIO 242156*
Sodium chloride
Purified water
*The constituents of the fragrance include esters of benzoic acid benzyl benzoate, butylated hydroxytoluene (E321) and other allergens (refer to section 4.4).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Clear plastic PET or PETG bottle with cap, or screw cap, containing 15, 125 or 250 ml. Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements

7 MARKETING AUTHORISATION HOLDER

Johnson & Johnson (Ireland) Limited
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0330/014/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First day of authorisation: 09 April 1987
Date of last renewal: 27 December 2006

10 DATE OF REVISION OF THE TEXT

July 2022