

Neutrogena® T/Gel® Shampoo 5 mg/ml Refined Coal Tar

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription.

However you still need to use Neutrogena T/Gel Shampoo carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If irritation occurs, stop using the product and talk to your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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1. What Neutrogena T/Gel Shampoo is and what it is used for

Neutrogena® T/Gel® Shampoo is used to treat dandruff and seborrhoeic dermatitis (dry, flaking, itching scalp).

It contains the active ingredient refined coal tar.

This medicine is for use in adults and children aged over 12 years.

2. Before you use Neutrogena T/Gel Shampoo

This medicine is suitable for most children and adults over the age of 12 years but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

X Do not use this medicine...

- If you have ever had an allergic reaction (e.g. rash, swelling of the face and throat, difficulty breathing) to any of the ingredients. See Section 6.
- In children under 12 years of age.
- If you have inflamed or broken skin.
- If you have a rare and severe form of psoriasis causing redness, inflammation and blistering of the skin (erythrodermic or pustular psoriasis).

! Special warnings about this medicine

- Avoid contact with eyes. If you do get Neutrogena® T/Gel® Shampoo in your eyes, bathe them thoroughly with water. If the eyes become irritated consult your doctor or pharmacist.
- Temporary discoloration of grey, blonde, bleached or tinted hair may occur.

! Pregnancy and breastfeeding

- Do not use if you are pregnant or breast feeding unless recommended by your doctor.

! Some of the ingredients can cause problems

- This medicine contains Methyl (E218) and Propyl (E216) parahydroxybenzoates which may cause allergic reactions (possibly delayed).
- 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.
- 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.

3. How to use Neutrogena T/Gel Shampoo

Adults and children aged 12 years and over.

1. Wet hair thoroughly
2. Apply Neutrogena® T/Gel® Shampoo and massage into the scalp.
3. Leave lather on scalp for several minutes
4. Rinse
5. Repeat steps 2 and 3.
6. Rinse thoroughly

Use once or twice weekly or as recommended by your dermatologist or doctor.

If there is no improvement after 4 weeks consult your doctor or pharmacist.

Do not use the product for more than 4 weeks unless instructed to do so by your doctor.

Neutrogena® T/Gel® Shampoo is for external use only.

If, however, you or your child accidentally swallows Neutrogena® T/Gel® Shampoo seek medical advice right away.

4. Possible side effects

Like all medicines, Neutrogena T/Gel Shampoo can cause side-effects, although not everybody gets them.

Effects which may occur include:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

If you experience any of these symptoms you should seek medical advice immediately.

- Allergic reactions including itchy rash and sensitivity to light.
- Hair loss or changes in hair colour.
- Eye irritation, acne like break outs or rash.

- Application site reactions including skin irritation, burning sensation, itching and dry scalp.

If these side effects occur discontinue use and consult your doctor or pharmacist.

Coal tar has been shown to increase the risk of skin tumours in animals. However, the risk for patients treated with coal tar is unclear. This product should only be used as directed and should not be used for prolonged periods, except under the instruction of your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Neutrogena T/Gel Shampoo

Do not store above 25°C.

Keep out of the sight and reach of children.

Do not use after expiry date which is stated as 'Exp Date' on the carton. The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What is in the medicine?

The active ingredient in Neutrogena® T/Gel® Shampoo is: Refined coal tar 5 mg per ml.

Other ingredients are: Macrogol Lauryl Ether (4), Sodium Lauryl Sulfate, Cocodiethanolamide, Cocamidopropyl Betaine, Imidazolidinyl Urea, Methyl parahydroxybenzoate (E218), Propyl parahydroxybenzoate (E216), Tetrasodium EDTA, Citric Acid anhydrous, Perfume (contains esters of benzoic acid, benzyl benzoate, butylated hydroxytoluene (E321) and other known allergens [refer to section 2]), Sodium Chloride and Purified Water.

What the medicine looks like

Neutrogena® T/Gel® Shampoo is a translucent, amber solution available in 125 ml or 250 ml bottles.

Marketing Authorisation holder:

Johnson & Johnson (Ireland) Ltd., Airton Road, Tallaght, Dublin 24, Ireland.

Manufacturer: McNeil Products Ltd., Foundation Park, Roxborough Way, Maidenhead SL6 3UG, United Kingdom OR Purna Pharmaceuticals NV, Rijksweg 17, 2870 Puurs, Belgium.

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