

Important Information. Please read carefully.

Pristine™

ketoconazole 20mg/gm

SHAMPOO

洗髮液

Composition: Contains Ketoconazole 2%w/w in shampoo base.
5-Bromo-5-Nitro-1,3-Dioxane 0.2%w/w as preservative.

Properties: Ketoconazole is an imidazole antifungal agent that impairs the synthesis of ergosterol, which is a vital component of fungal cell membrane and therefore alters the permeability of the cell membrane of the following common dermatophytes and yeast. Dermatophytes: *Trichophyton rubrum*, *T. mentagrophytes*, *T. tonsurans*, *Microsporum canis*, *M. audouinii*, *M. gypseum* and *Epidermophyton floccosum*; Yeast: *Candida albicans*, *Malassezia ovale* (*Pityrosporum ovale*) and *C. tropicalis*; and the common organism responsible for tinea versicolor, *Malassezia furfur* (*Pityrosporum orbiculare*).

Indications: Pristine shampoo is used for the treatment and prophylaxis of infections such as pityriasis capitis (dandruff), seborrhoeic dermatitis and pityriasis versicolor (white spots).

Directions for Use:

- ◆ Use this product as directed by your doctor.
- ◆ The affected area should be washed with the shampoo. Leave it on for about 3-5 minutes before rinsing (ketoconazole absorption takes place during this period).
- ◆ For treatment of:
 - Seborrhoeic Dermatitis and Pityriasis Capitis (dandruff): twice weekly for 2 to 4 weeks.
 - Pityriasis Versicolor: once daily for 5 days.
- ◆ For prophylaxis of:
 - Seborrhoeic Dermatitis and Pityriasis Capitis (dandruff): once every one to two weeks.
 - Pityriasis Versicolor: once daily for 3 days before exposure to sunshine.

Side Effects / Adverse Reactions: After topical administration of Ketoconazole, irritation, dermatitis, or a burning sensation may occur. Abnormal hair text, scalp, pustules, mild dryness of the skin and itching may also occur.

Contraindications: Known sensitivity to ketoconazole or the excipients.

Interactions: Systemic absorption following topical application in healthy subjects is minimal.

Precautions / Warning: Irritation may occur if used immediately after prolong treatment with topical corticosteroids. Therefore, recommend to wait about 2 weeks before using the shampoo.

Carcinogenicity:

A long term feeding study in Swiss albino mice and Wistar rats has shown no evidence in carcinogenicity.

Mutagenicity:

The dominant lethal mutation test in male and female mice given oral ketoconazole, has shown no mutation at any stage of germ cell development.

Breast-feeding:

No systemic absorption was detected following a single application to the chest, back, and arms of healthy volunteers. Therefore, topical ketoconazole is unlikely to be excreted in breast milk in significant amounts, or to cause adverse effects in the nursing infant.

Overdosage and Treatment: Ketoconazole is for External Use Only. In the event of accidental ingestion, supportive measures should be carried out.

Storage: Store below 30°C, away from light. Keep container well closed.

KEEP OUT OF REACH OF CHILDREN

JAUHI DARI KANAK-KANAK

Shelf-life: The expiry date is indicated on the packaging.

Presentation: Red colour in shampoo base. In plastic containers of 120 ml.

List of Excipients: Citric Acid, Ammonium Laureth Sulfate, Ammonium Lauryl Sulfate, Cocamidopropyl Betaine, Polyquarternium 47, PEG-7-Glycerol Cocoate, 5-Bromo-5-Nitro-1,3-Dioxane, Triethanolamine, PEG-120 Methyl Glucose Diolate, Colour Powder Eurocert Red 2G, Perfume Compound, Purified Water.

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Manufactured and Marketed by:

Xepa-Soul Pattinson (Malaysia) Sdn Bhd

1-5 Cheng Industrial Estate, 75250 Melaka, Malaysia.

成份：含 Ketoconazole 2%w/w

保存劑：5-Bromo-5-Nitro-1,3-Dioxane 0.2%w/w

藥性及功能：Ketoconazole 是由其主化學物質 imidazole 抗真菌類衍化而成的有效物質成份。它能抑制及破壞麥角甾醇(ergosterol)的合成。麥角甾醇是構成頭皮芽胞菌 (*Pityrosporum ovale*) 細胞膜的主要物質。Ketoconazole 能抑制及破壞此細胞膜的生成，從而消除引致頭皮受微生物感染，使頭皮屑問題得以治療與預防。

一般真菌可分為二類：皮膚菌(Dermatophytes)與酵母菌(Yeast)。頭皮屑的 *Pityrosporum ovale* 是屬於酵母菌的一種。

主治：治療與預防頭皮屑，皮膚腺炎與汗斑。

用法：

頭屑：治療性用法，每周使用二次，持續二至四周；預防性用法，每一或二周，洗滌一次。洗髮時，將洗髮液倒在掌中，在頭髮與頭皮上輕輕按摩，讓洗髮液在頭髮與頭皮上，停留約三至五分鐘後才沖洗乾淨，以便讓 Ketoconazole 能充份發揮其最佳藥性功效。

汗斑：治療性用法，每日一次，每次洗滌數分鐘，連續五日；預防性用法，在接觸陽光前使用，每日洗滌一次，連續三日。

皮脂腺炎：其治療與預防的使用方法，與頭屑相同。

禁忌：舉凡對 Ketoconazole 過敏者。

警語：此洗髮液所含的 Ketoconazole 成份，滲入人體血液的機會非常低。因此外敷 Ketoconazole 不太可能大量滲入母乳，對嬰兒造成不良影響的可能性極低。

過量使用：此產品只用于外敷。倘若誤食，應依照其產生的症狀，給予治療。

貯存：儲存於溫度 30°C 以下，遠離陽光，將瓶蓋旋緊。將此產品放置在兒童不能觸及的地方。

貯存期：有效日期備注于包裝外。

包裝：紅色液體，裝置于120毫升瓶里。

有關其他詳細資料，請參閱英文說明書。

