

PACKAGE INSERT

Brand of Product Name

NW Salicylic Acid 2%w/w Cream

Name and Strength of Active Substance(s)

Salicylic Acid 2%w/w

Product Description

Off-white cream

Pharmacodynamics

Salicylic acid has a potent keratolytic action and a slight antiseptic action when applied topically. It softens and destroys the stratum corneum by increasing endogenous hydration which causes the horny layer of the skin to swell, soften, and then desquamate. At high concentrations, salicylic acid has a caustic effect. It also possesses weak antifungal and antibacterial activity.

Pharmacokinetics

Salicylic acid may be percutaneous absorbed. However, there is no evidence of any systemic absorption from the use of NW Salicylic Acid 2%w/w Cream.

Indication

For treatment of seborrhoeic dermatitis, scalp psoriasis and hyperkeratotic skin conditions.

Recommended dosage

Apply sparingly to the affected area 2-3 times daily.

Contraindication

Contraindicated in patients displaying salicylate hypersensitivity, or sensitivity to any other ingredient in the preparation in NW Salicylic Acid 2%w/w Cream.

Warning and Precautions

For external used only.

Avoid contact with broken or inflamed skin.

Salicylate toxicity may occur if applied to large areas of skin or to the skin of neonates.

Interaction with other medicaments

There are no known interactions when used as indicated. However, topical salicylic acid may increase the absorption of other topically applied medicines.

Concomitant use of NW Salicylic Acid 2%w/w Cream and other topical medicines on the same area of skin should therefore be avoided.

Statement on usage during Pregnancy and Lactation

Whilst there are no known contra-indications to the use of NW Salicylic Acid 2%w/w Cream during pregnancy and lactation, the safety has not been established. NW Salicylic Acid 2%w/w Cream should therefore be used with caution or following professional

advice.

Adverse effect/undesirable effect

Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); skin redness or irritation may occur.

Overdose and Treatment

Symptoms of systemic salicylate poisoning (tinnitus, dizziness and deafness) have been reported after the application of salicylic acid to large areas of skin and for prolonged periods. Salicylism may also occur in the unlikely event of large quantities being ingested. Contact your doctor/pharmacist.

Incompatibilities

No known incompatibilities.

Instructions for use and handling and disposal

Store in the original packaging.

Keep out of reach of children.

Any unused product or waste material should be discarded in accordance with local requirements. No additional environmental precautions for disposal are necessary.

Storage conditions

Store below 30°C. Keep tightly closed.

Keep away from heat, moisture and light.

Do not use after the expiry date.

Shelf life

2 years

Dosage Forms and Packaging Available

10g, 25g, 30g, and 60g in HDPE white bottle with cap

Name and Address of Manufacturer/Marketing Authorization Holder

Natural Wellness Industries Sdn. Bhd.

No: 78, Jalan Kilang Midah, Taman Midah,
56000, Cheras, Kuala Lumpur.

Date of Revision of Package Insert

30/05/2017