

8X Shampoo (Ciclopirox + Zinc pyrithione)

Composition

8X Shampoo

Ciclopirox, BP1.0% w/v

Zinc pyrithione, (ZPTO).....1.0% w/v

Shampoo base.....q.s.

Dosage Form

Shampoo

Pharmacology

Pharmacodynamics

Ciclopirox is a hydroxypyridone antifungal agent, although the relevance of this property for the indication of seborrhoeic dermatitis is not known. Ciclopirox acts by chelation of polyvalent cations (Fe^{3+} or Al^{3+}), resulting in the inhibition of the metal-dependent enzymes that are responsible for the degradation of peroxides within the fungal cell. Zinc pyrithione is known to have both a non-specific keratolytic and antifungal activities. Thus it is effective in the treatment of seborrhoeic dermatitis and dandruff. Ciclopirox/zinc pyrithione combination has a synergistic effect on the growth control and the reduction of *Malassezia* population. Aloe vera acts as a natural conditioner.

Pharmacokinetics

In a study in patients with seborrhoeic dermatitis of the scalp, application of 5 mL ciclopirox shampoo 1% twice weekly for 4 weeks, with an exposure time of 3 minutes per application, resulted in detectable serum concentrations of ciclopirox in 6 out of 18 patients. The serum concentrations measured throughout the dosing interval on days 1 and 29 ranged from 10.3 ng/mL to 13.2 ng/mL. Total urinary excretion of ciclopirox was less than 0.5% of the administered dose.

Indications

8X Shampoo is indicated for the topical treatment of seborrhoeic dermatitis of the scalp in adults.

Dosage and Administration

Wet hair and apply approximately 1 teaspoon (5 mL) of **8X Shampoo** onto the scalp. Up to 2 teaspoons (10 mL) may be used for long hair. Lather and leave on hair and scalp for 3 minutes. Avoid contact with eyes. Rinse off. Treatment should be repeated twice per week for 4 weeks, with a minimum of 3 days between applications.

If a patient with seborrhoeic dermatitis shows no clinical improvement after 4 weeks of treatment with **8X Shampoo**, the diagnosis should be reviewed.

Contraindications

8X Shampoo is contraindicated in individuals who have shown hypersensitivity to any of its components.

Warnings and Precautions

Local Effects

If a reaction suggesting sensitivity or irritation should occur with the use of **8X Shampoo**, treatment should be discontinued and appropriate therapy instituted.

Contact of **8X Shampoo** with the eyes should be avoided. If contact occurs, rinse thoroughly with water.

In patients with lighter hair color, hair discoloration has been rarely reported.

Drug Interactions

No clinically significant drug interactions.

Pregnancy

Pregnancy Category B

There are no adequate or well-controlled studies of topically applied ciclopirox in pregnant women. Therefore, **8X Shampoo** should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when **8X Shampoo** is administered to a lactating woman.

Paediatric Use

No clinical trials have been conducted in subjects younger than 16 years.

Geriatric Use

In clinical studies, the safety and tolerability of ciclopirox shampoo in the population aged 65 years and older was comparable to that of younger subjects. Other reported clinical experiences have not identified differences in responses between the elderly and younger subjects, but greater sensitivity to adverse effects in some elderly individuals cannot be ruled out.

Undesirable Effects

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In 626 subjects treated with ciclopirox shampoo twice weekly in the two pivotal clinical trials, the most frequent adverse events were increased itching in 1% of subjects, and application site reactions, such as burning, erythema, and itching, also in 1% of subjects.

Post Marketing Experience

The following adverse reactions have been identified during post approval use of ciclopirox shampoo: hair discoloration and abnormal hair texture, alopecia, irritation and rash. Because these events are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

If you experience any side effects, talk to your doctor or pharmacist or write to drugsafety@cipa.com. You can also report side effects directly via the national pharmacovigilance program of India by calling on 1800 180 3024.

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

Shelf-Life

2 years

Storage and Handling Instructions

Store in a cool, dry place.

Protect from light.

Packaging Information

8X Shampoo.....bottle of 100 mL

How to use 8x?

1. Shake **8X Shampoo** bottle well.
2. Wet the hair and scalp thoroughly. For short hair, apply 5 mL of **8X Shampoo** and for longer hair (below the shoulder), use 10 mL of **8X Shampoo**. Massage into the scalp.
3. Allow shampoo to remain on the scalp for 3 minutes. (Note: It is important to keep the shampoo on for 3 minutes for effective treatment).
4. Rinse thoroughly with water.
5. Additional conditioner is not necessary as **8X Shampoo** contains conditioner.
6. Treatment should be repeated twice per week for 4 weeks, with a minimum of 3 days between applications.

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