

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

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## AHAGLOW S FACE WASH

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### 1. Generic Name

Salicylic acid with Glycolic Acid Foaming Face wash

### 2. Qualitative and quantitative composition

Key Ingredients:

Aloe extract.....5% w/v

Salicylic acid....2% w/v

Glycolic acid.....1% w/v

Ingredients:

Sodium laureth sulfate, Cocamidopropyl betaine, Glycol distearate, Glycerin, PEG-8 & Carbomer, PEG-12 Dimethicone, Trometamol, Citric acid, Fragrance, Purified Water.

### 3. Dosage form and strength

**Dosage form:** Face wash

**Strength:** Aloe extract.....5% w/v, Salicylic acid....2% w/v, Glycolic acid.....1% w/v

### 4. Clinical particulars

#### 4.1 Therapeutic indication

It is indicated in acne management or adjuvant treatment in acne management.

#### 4.2 Posology and method of administration

Ahaglow S facewash use twice daily. For gentle cleansing keep maximum up to 30 seconds on face. Not to be used in children below 3 years

#### 4.3 Contraindications

Aloe Vera: Contraindicated in cases of known allergy to plants in the liliaceae family  
Salicylic acid: Salicylic acid is contra-indicated in persons with sensitivity to salicylic acid.  
Alpha hydroxy acid: Contraindications have not yet been identified

#### 4.4 Special warnings and precautions for use

##### Aloe Vera

Pregnancy and breastfeeding: Oral aloe is not recommended during pregnancy due to

Theoretical stimulation of uterine contractions, and in breastfeeding mothers, it may Sometime causes gastrointestinal distress in the nursing infant.

##### Salicylic acid

For external use only. Avoid contact with the mouth, eyes and other mucous membranes to avoid irritation. As with other topical preparations containing salicylic acid, excessive prolonged use may result in symptoms of salicylism.

### **Alpha hydroxy acid**

This may increase skin's sensitivity to the sun and particularly the possibility of sunburn.

### **4.5 Drugs interactions**

#### **Aloe Vera**

Application of aloe to skin may increase the absorption of steroid creams such as hydrocortisone. It reduces the effectiveness and may increase the adverse effects of digoxin and digitoxin, due to its potassium lowering effect. Combined use of Aloe vera and furosemide may increase the risk of potassium depletion. It decreases the blood sugar levels and thus may interact with oral hypoglycemic drugs and insulin.

Thus, though Aloe vera has wide spectrum of the properties and uses, some of them could be myths and some of them could be real magic. In future, controlled studies are required to prove the effectiveness of Aloe vera under various conditions.

#### **Salicylic acid**

None known.

#### **Alpha Hydroxy Acids**

We currently have no information for alpha hydroxy acids Interactions.

### **4.6 Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)**

#### **Aloe Vera**

Pregnancy and breastfeeding:

Oral aloe is not recommended during pregnancy due to theoretical stimulation of uterine contractions, and in breastfeeding mothers, it may sometime cause gastrointestinal distress in the nursing infant.

#### **Salicylic acid**

Whilst there are no known contra-indications to use of Salicylic acid during pregnancy and lactation, the safety has not been established. Salicylic acid should therefore be used with caution or following professional advice.

#### **Alpha Hydroxy Acids**

Not recommended in pregnancy and breastfeeding;

### **4.7 Effects on ability to drive and use machines**

Not available

### **4.8 Undesirable effects**

Aloe vera

Topical: It may cause redness, burning, stinging sensation and rarely generalized dermatitis in sensitive individuals. Allergic reactions are mostly due to anthraquinones, such as aloin and barbaloin. It is best to apply it to a small area first to test for possible allergic reaction. Oral: Abdominal cramps, diarrhea, red urine, hepatitis, dependency or worsening of constipation. Prolonged use has been reported to increase the risk of colorectal cancer. Laxative effect may cause electrolyte imbalances (low potassium levels).

## **Salicylic acid**

Salicylic acid is a mild irritant and may cause skin irritation. If undue skin irritation develops or increases adjust the usage schedule or consult your physician.

## **Alpha hydroxy acid**

No specific warnings and precaution identified for this.

### **4.9 Overdose**

Aloe vera and Alpha hydroxy acid: Overdose has not yet been identified. Salicylic acid Symptoms of systemic salicylate poisoning 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. Salicylism is unlikely to occur if salicylic acid is used as indicated

## **5. Pharmacological properties**

### **5.1 Mechanism of Action**

#### **Aloe Vera**

Aloe Vera Healing properties Glucomannan, a mannose-rich polysaccharide, and gibberellin, a growth hormone, interacts with growth factor receptors on the fibroblast, thereby stimulating its activity and proliferation, which in turn significantly increases collagen synthesis after topical and oral Aloe vera.

#### **Salicylic acid**

Salicylic acid Human comedones, naturally or coal tar induced, are firmly anchored and are dislodged with great difficulty. Most classic "peeling" agents are ineffective: they are merely irritants which cause scaling, creating the illusion of comedolysis. While salicylic acid is an irritant its efficacy is dependent on specific pharmacological effects. It seems to detach horny cells from each other by weakening the intercellular cement. As a result, the comedones tend to undergo disorganisation. The effect is probably a good deal more complex. Salicylic acid penetrates skin readily and increases turnover which also favours exfoliation of the comedo. In concentrations of 0.5 to 2% it significantly reduces the formation of microcomedones, which are the precursors of all other acne lesions.

**Glycolic acid** Glycolic acid reacts with the upper layer of the epidermis, weakening the binding properties of the lipids that hold the dead skin cells together. This allows the stratum corneum to be exfoliated, exposing live skin cells.

### **5.2 Pharmacodynamic properties**

#### **Aloe Vera**

Aloe gel not only increased collagen content of the wound but also changed collagen composition (more type III) and increased the degree of collagen cross linking. Due to this, it accelerated wound contraction and increased the breaking strength of resulting scar tissue. An increased synthesis of hyaluronic acid and dermatan sulfate in the granulation tissue of a healing wound following oral or topical treatment has been reported.

Effects on skin exposure to UV and gamma radiation: Aloe vera gel has been reported to have a protective effect against radiation damage to the skin. Exact role is not known, but following the administration of aloe vera gel, an antioxidant protein, metallothionein, is generated in the skin, which scavenges hydroxyl radicals and prevents suppression of superoxide dismutase and glutathione peroxidase in the skin. It reduces the production and release of skin keratinocyte-

derived immunosuppressive cytokines such as interleukin-10 (IL-10) and hence prevents Induced suppression of delayed type hypersensitivity. Anti-inflammatory action: Aloe vera inhibits the cyclooxygenase pathway and reduces prostaglandin E2 production from arachidonic acid. Recently, the novel anti-inflammatory compound called C-glucosyl pheromone was isolated from gel extracts. Effects on the immune system: Alprogen inhibit calcium influx into mast cells, thereby inhibiting the antigen-antibody-mediated release of histamine and leukotriene from mast cells. In a study on mice that had previously been implanted with murine sarcoma cells, acemannan stimulates the synthesis and release of interleukin-1 (IL-1) and tumor necrosis factor from macrophages in mice, which in turn initiated an immune attack that resulted in necrosis and regression of the cancerous cells. Several low-molecular-weight compounds are also capable of inhibiting the release of reactive oxygen free radicals from activated human Neutrophils Moisturizing and anti-aging effect: Mucopolysaccharides help in binding moisture into the skin. Aloe stimulates fibroblast which produces the collagen and elastin fibers making the skin more elastic and less wrinkled. It also has cohesive effects on the superficial flaking epidermal cells by sticking them together, which softens the skin. The amino acids also soften hardened skin cells and zinc acts as an astringent to tighten pores. Its moisturizing effects has also been studied in treatment of dry skin associated with occupational exposure where aloe vera gel gloves improved the skin integrity, decreases appearance of fine wrinkle and decreases erythema. It also has anti-acne effect. Antiseptic effect:

Aloe vera contains 6 antiseptic agents: Lupeol, salicylic acid, urea nitrogen, cinnamonic acid, phenols and sulfur. They all have inhibitory action on fungi, bacteria and viruses.

**Salicylic acid** The active ingredient, salicylic acid, is a well-established pharmacopoeial substance, which has been used extensively in dermatological therapy for its keratolytic properties. Salicylic acid treats acne by causing skin cells to slough off more readily, preventing pores from clogging up.

When applied topically, and in high enough concentrations, salicylic acid acts by achieving a slow, painless destruction of the thickened stratum corneum. It softens and destroys the thickened stratum corneum of the affected tissue by reducing the adhesiveness of the corneocytes while causing the cornified epithelium to swell, soften, macerate and finally desquamate.

**Glycolic acid** reacts with the upper layer of the epidermis, weakening the binding properties of the lipids that hold the dead skin cells together. This allows the stratum corneum to be exfoliated, exposing live skin cells. One theory for the mechanism of action of alphahydroxy acids (AHAs) in exfoliation is: AHAs reduce calcium ion concentration in the epidermis and remove calcium ions from the cell adhesions by chelation; this causes disruption in cell adhesions, and results in desquamation – Glycolic acid can suppress melanin formation by inhibition of tyrosinase activity

### 5.3 Pharmacokinetic properties

**Aloe vera** Aloe vera is best known for its soothing and healing effects on burn and other wounds. Aloe vera when applied to a wound increase both the rate of wound closure and the tensile strength of the wound via the proliferation of cells. It does so by accelerating the flow of blood towards the wounded area. Aloe is the best wound dressing ever discovered. The mechanism explained behind this acceleration is as follows: Aloe vera gel increases the collagen content and extent of collagen cross linking of the wound, resulting in enhanced wound contraction and breakage of scar tissue. also reported the enhancement in content of hyaluronic acid and dermatan sulphate in the granulating tissue of healing wound.<sup>29</sup> A 5.5 kDa

glycoprotein, isolated from Aloe Vera showed an increase in epithelial cell migration and enhanced wound healing process in a human keratinocyte monolayer.

Aloe vera is currently utilized in manufacturing more than 95 % of the dermatologically valuable products. This is because it possesses implausible moisturizing properties. It improves the ability of skin to hydrate itself and help in removal of dead skin cells. It does so, by producing collagen and elastin fibers, making the skin more elastic and less wrinkled, thereby, reversing the degenerative skin changes. It softens the skin, by its cohesive action on superficial flaking epidermal cells and also by the action of amino acids. For such incredible characteristics, Aloe vera is an ideal ingredient in cosmetics and dermatological procedures.

### **Salicylic acid**

The epidermis is the principal barrier to the absorption of many solutes, including salicylic acid. The removal of this barrier allows the kinetics of solute uptake into the dermis and underlying tissues (dermal absorption studies) to be described for defined input conditions. The combination of this kinetics with the penetration fluxes through isolated human epidermis has been used to predict the concentrations in dermis after topical application.

When a solute enters the dermis after topical application, it can either be carried away by the dermal microcirculation or diffuse into underlying tissues, bypassing the dermal blood supply. The relative importance of the diffusion and perfusion processes in the dermis are most easily studied by placing the solute on the dermis in the absence of stratum corneum. Direct deep tissue penetration of salicylic acid was only evident to a depth of 3-4 mm after which most of the observed drug in deeper tissues could be attributed to the systemic blood supply.

### **Glycolic acid**

No reports of human pharmacokinetic studies following topical application – In vitro studies indicate pH and time dependence for glycolic acid penetration of skin: ↓in pH or ↑in time of application enhanced penetration

### **Nonclinical properties**

#### **6.1 Animal Toxicology or Pharmacology**

##### **Aloe vera**

Photo toxicity of aloe-emodin has been demonstrated in animal studies; however, photo toxicity was not observed in several clinical studies in humans using amounts of aloe-emodin that are commonly found in commercially available Aloe vera preparations.

##### **Salicylic acid**

No special information

##### **Glycolic acid**

There is lack of nonclinical data for the evaluation of chronic dermal toxicity and dermal carcinogenic potential of glycolic acid – The available nonclinical data do not raise serious safety concerns about glycolic acid when used topically at low concentrations

## **7. Description**

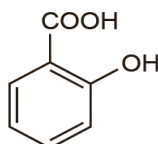
### **Aloe Vera:**

Aloe vera is a natural product that is now a day frequently used in the field of cosmetology. Aloe Vera comprises of more than seventy-five effective components, which includes the twenty amino acids and the eight essential amino acids indispensable for the human body. Besides these, they also contain certain enzymes effective for metabolic health, essential

vitamins, minerals, poly-saccharides that render immune-stimulating properties along with its magical healing touch. The substances in Aloe Vera such as Salicylic Acid, Saponins and Sterols provide its analgesic, anti-inflammatory and antiseptic properties.

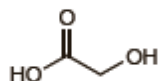
### **Salicylic acid**

White or colourless acicular crystals or a white or almost white, crystalline powder. Slightly soluble in water; freely soluble in alcohol; sparingly soluble in dichloromethane. Protect from light. Its empirical formula is  $C_7H_6O_3$  and molecular weight is 138.1.



### **Alpha hydroxy acid**

Alpha hydroxy acids are a group of natural acids from foods. Some alpha hydroxy acids are gluconolactone; citric, glycolic, lactic, and malic acids and others.



Ahaglow S is a clear, colourless to straw coloured, transparent foaming liquid, filled in transparent plastic bottle with spray pump packed in carton.

## **8. Pharmaceutical particulars**

### 8.1 Incompatibilities

Not Available

### 8.2 Shelf-life

Do not use later than date of expiry

### 8.3 Packaging information

Ahaglow S is available in primary pack of 60 ml and 100 ml.

### 8.4 Storage and handling instructions

Store at a temperature below 30°C, protect from light.

## **9. Patient Counselling Information**

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What AHAGLOW S FACE WASH are and what they are used for
2. Before you take AHAGLOW S FACE WASH
3. How to take AHAGLOW S FACE WASH
4. Possible side effects
5. How to store AHAGLOW S FACE WASH
6. Further information

## **1. WHAT AHAGLOW S FACE WASH ARE AND WHAT THEY ARE USED FOR**

AHAGLOW S FACE WASH contains

### **Aloe Vera:**

Aloe vera is a natural product that is now a day frequently used in the field of cosmetology. Aloe Vera comprises of more than seventy-five effective components, which includes the twenty amino acids and the eight essential amino acids indispensable for the human body. Besides these, they also contain certain enzymes effective for metabolic health, essential vitamins, minerals, poly-saccharides that render immune-stimulating properties along with its magical healing touch. The substances in Aloe Vera such as Salicylic Acid, Saponins and Sterols provide its analgesic, anti-inflammatory and antiseptic properties.

### **Salicylic acid**

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### **Alpha hydroxy acid**

Alpha hydroxy acids are a group of natural acids from foods. Some alpha hydroxy acids are gluconolactone; citric, glycolic, lactic, and malic acids and others

AHAGLOW S FACE WASH used in acne management or adjuvant treatment in acne management.

## **2. BEFORE YOU TAKE AHAGLOW S FACE WASH**

### **Aloe Vera**

Pregnancy and breastfeeding: Oral aloe is not recommended during pregnancy due to theoretical stimulation of uterine contractions, and in breastfeeding mothers, it may sometime cause gastrointestinal distress in the nursing infant.

**Salicylic acid** for external use only. Avoid contact with the mouth, eyes and other mucous membranes to avoid irritation. As with other topical preparations containing salicylic acid, excessive prolonged use may result in symptoms of salicylism.

**Alpha hydroxy acid** this may increase skin's sensitivity to the sun and particularly the possibility of sunburn.

## **3. HOW TO TAKE AHAGLOW S FACE WASH**

### **Directions for use**

- 1) Wet face
- 2) Gentle massage the foam all over the face for 20 to 30 seconds avoiding eyes and

Surrounding areas

3) Rinse thoroughly & pat dry  
Use twice daily  
Not to be used in children below 3 years  
For gentle cleansing keep maximum up to 30 seconds on face.

#### **4. POSSIBLE SIDE EFFECTS**

AHAGLOW S FACE WASH can cause side effects, although not everybody gets them. The side effects described below have been experienced by people using AHAGLOW S FACE WASH.

##### **Aloe vera**

Topical: It may cause redness, burning, stinging sensation and rarely generalized dermatitis in sensitive individuals. Allergic reactions are mostly due to anthraquinones, such as aloin and barbaloin. It is best to apply it to a small area first to test for possible allergic reaction. Oral: Abdominal cramps, diarrhea, red urine, hepatitis, dependency or worsening of constipation. Prolonged use has been reported to increase the risk of colorectal cancer. Laxative effect may cause electrolyte imbalances (low potassium levels).

##### **Salicylic acid**

Salicylic acid is a mild irritant and may cause skin irritation. If undue skin irritation develops or increases adjust the usage schedule or consult your physician.

##### **Alpha hydroxy acid**

No specific warnings and precaution identified for this.

##### **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 any point of contact of Torrent Pharma available at: [http://www.torrentpharma.com/Index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting).

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

#### **5. HOW TO STORE AHAGLOW S FACE WASH**

Store at a temperature below 30°C, protect from light.

#### **6. FURTHER INFORMATION**

##### **What AHAGLOW S FACE WASH contains**

The active substances are Aloe extract 5% w/v, Salicylic acid 2% w/v and Glycolic acid 1% w/v

Other Ingredients are as below:

Sodium laureth sulfate, Cocamidopropyl betaine, Glycol distearate, Glycerin, PEG-8 & Carbomer, PEG-12 Dimethicone, Trometamol, Citric acid, Fragrance, Purified Water.

Ahaglow S is available in primary pack of 60 ml and 100 ml.

##### **10. Details of manufacturer**

Manufactured in India by:  
Aurochem Laboratories (INDIA) Pvt. Ltd.  
2, P.T. Ind. Co-op. Estate Ltd.



Palghar-401404, Maharashtra, India.

**11. Details of permission or licence number with date**

Mfg Lic No. KD/C-390 issued on 11.11.2017.

**12. Date of revision**

**Aug 2019**

**MARKETED BY**



**TORRENT PHARMACEUTICALS LTD.**

Indrad-382721, Dist. Mehsana, INDIA.

**IN/ AHAGLOW S FACE WASH 5 % w/v 2 % w/v and 1 % w/v /SEP-19/02/PI**