# Preparation and Evaluation of Anti-viral Topical Gel Formulations Containing Salicylic Acid for the Treatment of Common Warts

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## Abstract:

In this study, we developed a new product for assessing antiviral activity for treatment the human wart, this product include gel containing a salicylic acid with oxidant agent. Thirty patients were treated. The treatment involved application of the gel each day by the patients. Every 1-2 weeks under the supervision of Dermatologist, the percentage of patients cleared of warts is 100%.

**الخلاصة :**

في هذه الدراسة تم تطوير مستحضر ذي فعالية عالية ضد فيروسية لعلاج الثآليل التي تصيب الانسان . يتضمن هذا المستحضر هلاماً يحتوي حامض السليسليك ومادة مؤكسدة. تم اختبار الهلام المحضر على ثلاثون حالة مرضية مصابة بأنواع مختلفة من الثآليل وتحت أشراف اختصاص أمراض جلدية وكانت طريقة وضع العلاج على المنطقة المصابة كل يوم ولفترة زمنية تتراوح بين1 -2 أسبوع وكانت نسبة الشفاء 100% .

## Introduction:

Wide varieties of warts are found on human skin and are caused by the human papilloma virus (HPV) [1]. For example, the following types of warts are found on human skin and are caused by the human papilloma virus (HPV): common warts (verruca vulgaris), plantar warts, palmar warts, planar warts (verruca plana), mosaic warts, and venereal warts (condyloma accuminatum) [2]. These skin growths are unsightly, irritating, and potentially oncogenic (carcinogenic), and their removal is desired. .

Throughout the years a number of therapies have been developed for treating warts, and these therapies can be categorized in the following seven categories: locally destructive chemicals[3]; surgically destructive methods[4]; blister-producing methods[5]; cellular inhibition[6]; altering the cutaneous environment[7]; immune stimulation[8]; and miscellaneous methods[9].

Treatment methods using locally destructive chemicals include using the following chemicals: salicylic acid (in films, plasters, pads, and tapes); lactic acid; trichloracetic acid (TCA); bichloroaceticacid (BCA); nitric acid and glacial acetic acid [10].

Surgically destructive methods include the following techniques: excision; electrocautery; electro desiccation; curettage; blunt dissection; and laser vaporization or coagulation [11].

Blister-producing methods include the following techniques: liquid nitrogen cry therapy; carbon dioxide cry therapy; and cantharidin [12] .Cellular inhibition methods include use of the following agents: podophyllin and podophyllotoxin; 5-fluorouracil; bleomycin; colchicines; interferon local injections; and radiation [13].

## Materials and Methods:

### Materials:

The chemicals used in this study supplied by several sources, hydroxyl ethyl cellulose, propylene glycol , polyethylene glycol (PEG 400)were provided by Sigma-Aldrich Company(Germany) , ethanol , salicylic acid , oxidant agent ,were provided by Fluka Company (Germany), distilled water was used throughout the study .

### Methods:

Into a clean one liter glass beaker, the gel formulation was prepared by firstly combining 30 grams of Propylene glycol with 20 grams of Ethanol and continually mixed with the use of a magnetic stirrer. Hydroxyethylcellulose was subsequently weighed that corresponded to 8.0% w/w of the total solution (w/w). Whilst the co-solvent mix was agitating vigorously (with sealed using Para-film to stop any solvent evaporation) and left continually stirring at room temperature over night. The active materials was prepared as following : into clean beaker added 3ml paraffin oil to 20 grams salicylic acid and mixed with a spatula , and the resulting mixture is homogenized at low speed then to another beaker was slowly added 10g oxidant agent to 20 grams polyethylene glycol and mix well. The gel formulation was placed onto active materials and mix well to allow the gel network to form .A resultant homogenous batch gel formulation was obtained. A gel formulation consisting of 30:20:20:20:10 % of Propylene Glycol, Ethanol, PEG 400: salicylic acid, oxidant agent mix.

### Efficacy of Composition:

In the experiment treatment a total of 30 patients with warts were evaluated in the study. The size of each wart is measured and each wart is photographed before treatment begins. Each of the patients is instructed to topically apply a skin gel of the study over the warts, replacing the old patch with a new one every 24 hours. The patients return to the clinic every three days, when each wart is again measured and photographed. It is found that most of the warts are significantly reduced in size after one week and that most have entirely regressed after tow weeks of treatment, with no scarring, pigmentation changes, or other undesirable side effects.

## Results and Discussions :

As stated above, warts are caused by the human papilloma virus (HPV). There are findings reported in the literature that human papilloma virus may be implicated in certain forms of cancer. In view of the link between the human papilloma virus and cancer, the prompt and effective treatment and destruction of warts is strongly indicated[(14)]salicylic acid is used with tape or film occlusion for treating warts, the range of salicylic acid is in a range of 17% to 40%[(15)]. Accordingly, it is an object of this product to provide a method of treating warts that employs the use of a salicylic acid with oxidant agent. The product is an aqueous pharmaceutical formulation for topical administration, which formulation contains water and antiwart agent at a concentration effective to reduce the number and/or size of virally induced lesions, such as warts . Preferably, the pharmaceutical composition contains a gelling or thickening agent. The concentration of water in the composition is at least that which will provide an enhancement in epithelial penetration, such as skin or mucosal surface penetration, compared to a comparable composition that is substantially free of water. If desired, known penetration enhancing agents such as poly ethylene glycol, sodium lauryl sulfate, may optionally be included in the composition. Polyethylene glycol 400, also known as liquid macrogol, PEG 400 is also known in topical formulations to improve drug solubility within the formulation.

The treatment involved application of the gel each day by the patients. Every 1-2 weeks gentle cutting and scraping of the warts were performed in a clinic. There is a disclosure that( salicylic acid 20 % + oxidant agent ) in a gel –based that was used for 1-2 weeks was effective against common warts . More specifically, there were 30 patients treated. After a mean of 7 days of treatment, warts in 13 patients were cleared, and warts in 17 patients persisted. The treatment involved daily application of (20% salicylic acid + oxidant agent ) gel based supplemented by weekly paring (cutting or shaving) of the wart. By having 17 patients out of 30 patients cleared of warts, the percentage of patients cleared of warts is 100%.

A method is provided for treating a patient who has one or more warts. The method includes the steps of (a). applying to a wart an amount of a composition consisting essentially of (20% salicylic acid + oxidant agent ) gel based active ingredient (b). covering the wart and skin area peripheral to the wart with a tape which provides an occluding environment for the wart, and (c). maintaining the tape in position over the wart and peripheral skin area for a predetermined period, the tape providing an occluding environment for the wart for the predetermined period of time. The predetermined period of time can be in a range spanning 1-6 hours. .

Thirty patients having warts have been successfully treated with (20% salicylic acid + oxidant agent) gel based with occlusion conditions under adhesive tape, and some case histories are described as follows:

Patient number one was a 28 year old male who was seen for treatment of mosaic wart virus infection of his right plantar (up surface) foot and right first toe. he had previously been treated with other conventional therapy without clearing of his wart, the patient after consent, started (20% salicylic acid + oxidant agent) gel based product , under occlusion with adhesive tape each night and removal in the morning. This was repeated each night. The patient was seen one week later. The wart on his right first toe was cleared and approximately 10 percent of the wart was left on his right foot. The patient was instructed to use the topical gel for 3 days longer. The patient returned one week later was clinically clear of his wart. Figures(1, 2, 3, 4, 5) .

Patient number two was an 11 year old female who had cluster of warts on her right hand. After parental consent the patient was treated with (20% salicylic acid + oxidant agent ) gel based product with adhesive tape occlusion four hours, for a period of one week, the warts were clinically cleared. Figures(6,7) Patient number three was a 44 year old male who had common warts on the hand was treated with another product . After two applications, the patient had stopped the treatment because he experienced itching and noticed small blisters on the his hand. The hand showed an oozing vesicular dermatitis, the warts being swollen. The eczematous reaction subsided with topical steroid medication in a couple of days. Two weeks after two applications of the gel containing 20%, salicylic acid, and oxidant agent, all warts had completely cleared. Figures(8,9,10).

Patient number four a 36 year old male who was seen for treatment of mosaic wart virus infection of his right knee foot. he had previously been treated with other conventional therapy without clearing of his wart, the patient after consent, started (20% salicylic acid + oxidant agent ) gel based product , under occlusion with adhesive tape each day for four hours. The patient was seen one week later. The wart on his right knee foot was cleared and approximately 10 percent of the wart was left on his right foot. The patient was instructed to use the topical gel for two days longer. The patient returned one week later was clinically clear of his wart. Figures(11,12,13,14).

Patient number five a 18 year old male who was seen for treatment of mosaic wart virus infection of his left arm .The patient after consent, started (20% salicylic acid + oxidant agent) gel based product , under occlusion with adhesive tape each day for four hours. The patient was seen two weeks later. The wart on his left arm was cleared Figures(15,16,17) .

Patient number six was a 15 year old female who had a refractory mosaic wart virus cluster on her left hand. He was treated with surgery .The wart recurred and the patient treated approximately l year later .After consent she was started on topical (20% salicylic acid + oxidant agent ) gel based product under adhesive occlusion four hours each day. she was seen one week later , 95percent of the wart cluster was cleared, she was continued on this therapy another one week his wart on her left hand was cleared. Figures(18,19). For convenience, the results of treating the six patients described above are presented in the following Figures.

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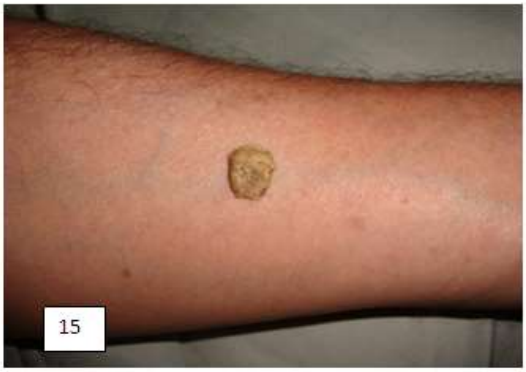
Figures(6,7) Patient number two




Figures (8, 9, 10) Patient number three


Figures (11, 12, 13, 14) Patient number four






Figures(15,16,17) Patient number five



Figures(18,19) Patient number six