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MINISTRY OF HEALTH-ETHIOPIA

የዜጎች ጤና ለሃገር ብልጽግና!  
HEALTHIER CITIZENS FOR PROSPEROUS NATION!

# **Handbook for Extemporaneous Preparations**

**1<sup>st</sup> edition**

**July 2020**

**Addis Ababa, Ethiopia**



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## Preface

Compounding of non-sterile preparations at the health facility level has tremendous importance. It improves the healthcare services by ensuring the accessibility of these preparations including essential dermatological preparations. Quick assessment conducted by the ministry of health in few hospitals indicates that the availability of essential compounded dermatological preparations is too low with various causing factors. Among the causes, absence of standard operating procedures, guidelines, and other supporting materials, which can be used by both compounders and prescribers, is the major one. Nonetheless, neither national guideline for compounding of non-sterile preparations nor reference material is available in Ethiopia.

As a result, the development and implementation of national guideline for compounding of non-sterile preparations is crucial to improve the access to basic dermatological services which is currently associated with poor availability of pharmaceutical grade and inadequate compounding practice within hospitals. Besides, it used to revitalize the compounding service within health facilities; ensure good compounding practice of non-sterile preparations; and promote evidence-based management of problems and preparation of dermatological products in hospitals.

This handbook is a publication of the Federal Democratic Republic of Ethiopia, Ministry of Health which is emanated from mother document of the national guideline for compounding of Non-Sterile Preparations prepared for pharmacy professionals and physicians working in healthcare facilities. Especially, it is believed that the handbook is helpful for clinical practitioners as quick reference material. This guideline contains two chapters. General introduction present in the first chapter. The second chapter describes extemporaneous preparations used for management of common dermatological problems.

The formulation and other relevant information included in this document were extracted from standard references and in some cases, experts' opinion were also included.

This guideline can serve as a reference in healthcare facilities for the prescribing and compounding of non-sterile preparations of dermatological products.

Finally, I would like to take this opportunity to acknowledge all participants for their huge contributions in the preparation of the guideline and this handbook.



Dr. Lia Tadesse, Minister  
Ministry of Health

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## **How to use the guideline**

National Guideline for Compounding of Non-sterile Preparations brings practical and background information for compounding, dispensing, and use of dermatological preparation, antiseptics, disinfectants and other chemicals in healthcare facilities of the country.

This handbook intended to provide evidence on dermatological preparation needed for their management. It can be used as quick reference by mainly, dermatovenereologist, pharmacy professionals, and other healthcare providers in prescribing, compounding, dispensing and appropriate use of dermatological preparations.

For purpose of specific preparation procedure, compounders and other healthcare providers can use the guideline.

Chapter one comprises background information on the compounding and dosage forms of commonly compounded preparations.

Chapter two describes the major dermatological preparations. It contains a total of 42 preparations, 9 of these are base formulations used as vehicle and/or emollients and the remaining 33 are the main treatment formulations.

## Acronyms

AAU	Addis Ababa University
ALERT	All Africa leprosy Rehabilitation and Training Center
CNS	Central Nervous System
EDVS	Ethiopian Dermatology and Venereology society
EFDA	Ethiopian Food and Drug Authority
EPA	Ethiopian pharmaceutical Association
HU	Haramaya University
KOH	Potassium Hydroxide
MOH	Ministry of Health
MU	Mekelle University
NSP	Non-sterile Preparation
PMED	Pharmaceutical and Medical Equipment Directorate
PRP	Pityriasis Rubra Pilaris
QS	Quantity Sufficient
UOG	University of Gondar
USP	United States Pharmacopeia

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# Chapter One

## Introduction

### 1.1 Background

Compounding is an integral part of pharmacy practice and is essential for provision of healthcare services. It is an art and science of preparing, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner–patient–pharmacist/compounder relationship in the course of professional practice. It is the timely preparation of a drug product according to a physician's prescription, a drug formula, or a recipe in which calculated amounts of ingredients are made into a homogenous (uniform) mixture.

Compounding practice can be as simple as the addition of a liquid to a manufactured drug powder or as complex as the preparation of a multi component parenteral nutrition solution. In general, compounding differs from manufacturing, that compounding involves a specific practitioner–patient–pharmacist relationship (i.e., specific prescription orders) and the preparation of a relatively small quantity of medications.

Compounding may include the following:

- Preparation of drug in different dosage forms for human use
- Preparation of drugs in anticipation of prescription drug orders, on the basis of routine and regularly observed prescribing patterns,
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients, and
- Preparation of drugs or devices for the purposes of research (clinical or academic), teaching, or chemical analysis

Compounded non-sterile preparations (NSPs) include, but are not limited to the following types of dosage forms:

- **A Solution** is a homogeneous liquid preparation that contains one or more dissolved medicaments.

- **Tincture** is alcoholic or hydroalcoholic solution prepared from vegetable materials or from chemical substances. Depending on the preparation, tinctures contain alcohol in amounts ranging from approximately 15% to 80%.
  - **Elixir** is a clear, sweetened hydroalcoholic solution intended for oral use and is usually flavored to enhance palatability.
  - **Spirits** are alcoholic or hydroalcoholic solutions of volatile substances. Generally, the alcoholic concentration of spirits is rather high, usually over 60%.
  - **Collodion** is a clear or slightly opalescent viscous liquid prepared by dissolving pyroxylin (4% w/v) in a 3:1 mixture of ether and alcohol.
  - **Liniments** are alcoholic or oleaginous solutions or emulsions of various medicinal substances intended to be rubbed on the skin.
  - **Sprays** may be defined as aqueous or oleaginous solutions in the form of coarse droplets or as finely divided solids to be applied topically, most usually to the nasopharyngeal tract or to the skin.
- 
- **Suspension** is a heterogeneous preparation in which insoluble active ingredient (s) is suspended throughout the vehicle.
  - **Emulsion** is a mixture of two or more liquids that are normally immiscible.
  - **Lotions** are solutions, but may also be suspensions or emulsions, that are intended to be applied to the skin without friction on a carrier fabric such as lint and covered with a waterproof dressing.
  - **Ointments** are semisolid preparations that are applied externally to the skin or mucous membranes, in which solids or liquids are dispersed.
  - **Creams** are viscous semi-solids emulsion for external application.
  - **Pastes** are semi-solid preparations that contain a high proportion of powdered ingredients.
  - **Gels** are semi-solid systems consisting of dispersions of small or large molecules in aqueous liquid vehicle rendered jelly-like by the addition of jelling agent.
  - **Bulk powders** are dry, free-flowing preparations consisting of one or a mixture of finely powdered substances and intended for external application.

# Chapter Two

## Extemporaneous Preparation Formulary

### 2.1 Base Formulations

#### Aqueous cream

##### Formulation

Emulsifying ointment	30 gm
Phenoxyethanol	1 gm
Purified water qs	100 ml

##### Indication

- As emollient (for relief of symptom of dry skin)
- As a base/vehicle

##### Dose and Administration

- Apply in a thin layer as required.

##### Side effect

- It may cause sensitivity or an allergic reaction such as red, itchy skin.

##### Precautions

- Use with cautions in Atopic Dermatitis as it may cause skin irritation.

##### Additional Information

- 1% phenoxyethanol can be substituted by various other preservatives, for example 10% propylene glycol or Methylparaben.
- Glycerol can be incorporated additionally as necessary (for instance, for formulation of salicylic acid)

## Basic cream

### Formulation

Emulsifying wax	15 gm
Liquid paraffin	12.5 gm
White Soft Paraffin	22.5 gm
Methylparaben	0.15 gm
Water qs	100 gm

### Indication

- Used as a base (vehicle).
- Used for slight drying effect on the skin.

### Dose and Administration

- Apply in a thin layer as required.
- If the cream is inhomogeneous, it should be mixed before use.

### Precaution

- Sensitization due to methylparaben, white soft paraffin, and emulsifying wax may occur, but it is rare.
- If sensitization or severe irritation reactions develop, stop using this preparation.

### Additional information

- Basic cream is appropriate for intermittent treatment with strong corticosteroid preparations.
- The cream is easily washed off with water, and is therefore suitable for hairy parts of the skin.
- Methylparaben can be substituted by various other preservatives, for example 10% propylene glycol or 1% phenoxyethanol.

## Cetomacrogol Emulsifying ointment

### Formulation

Cetomacrogol Emulsifying Wax	30 gm
Soft Paraffin	50 gm
Liquid Paraffin	20 gm

### Indication

- As emollient for the symptomatic management of eczema, psoriasis and other dry skin conditions.
- Used as emulsifying agent and base.

### Dose and Administration

- Apply the ointment as required, preferably at night time. It should be applied directly to areas of dry skin in the direction of hair growth to prevent blocking hair follicles.

### Precautions

- Avoid contact with eyes.
- Keep away from naked flames as there is a fire hazard.
- Do not use it if there is a known allergy or sensitivity to any of the ingredients.

## Cetomacrogol Emulsifying wax (Non-Ionic Emulsifying Wax)

### Formulation

Cetostearyl Alcohol	80 gm
Macrogol Cetostearyl Ether (22)	20 gm

### Indication

- Used as emulsifying agent.

### Precautions

- Phenolic compounds (like salicylic acid, dithranol, hydroquinone, and etc) are incompatible with cetomacrogol emulsifying wax.

## Collodion

### Formulation

Pyroxylin	4 gm
Ether	75 ml
Ethanol (90%)	25 ml

### Indication

- As vehicle

### Precaution

- Collodion is highly flammable

### Additional Information

- Collodion can be prepared using industrial methylated spirit instead of ethanol (90% v/v).



## Emulsifying ointment

### Formulation

Emulsifying wax	30 gm
Liquid Paraffin	20 gm
White Soft Paraffin	50 gm

### Indication

- As emollient to moisturize and soften dry skin in eczema, dry cases of psoriasis and other dry skin conditions.
- As a base/vehicle.

### Dose and administration

- Apply to the affected area as often as required.
- Smooth gently into the skin in the direction of the hair growth.

### Side effect

- It may cause sensitivity or an allergic reaction such as red, itchy skin.

### Precautions

- Contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).
- Avoid contact with the eyes.

## Emulsifying wax (Anionic Emulsifying Wax)

### Formulation

Cetostearyl Alcohol	90 gm
Sodium Lauryl sulphate	10 gm
Purified Water	4 ml

### Indication

- Emulsifying agent

## Flexible collodion

### Formulation

Camphor	2 gm
Castor oil	3 gm
Collodion qs	100 gm

### Indication/Use

- As vehicle

### Precaution

- Collodion is highly flammable.

## Liquid paraffin/White Soft Paraffin (50/50) ointment

### Formulation

Liquid Paraffin	50 gm
White Soft Paraffin	50 gm

### Indication

- As strong emollient and symptomatic relief of very dry skin conditions

### Dose and administration

- Apply to the skin 3 to 5 times daily or as required.
- Apply in the direction of hair growth to reduce the incidences of folliculitis.

### Precautions

- Keep away from naked flames as there is a fire hazard.

### Side effect

- Rarely hypersensitive reactions.
- Prolonged use of large quantities may cause folliculitis

## 2.2 Treatment Formulations

### Aluminium Chloride solution, 20% w/v

#### Formulation

Aluminium chloride hexahydrate	20 gm
Absolute alcohol qs	100 ml

#### Indication

- Used as a first-line therapy for Primary Hyperhidrosis.

#### Dose and Administration

- Apply daily at night to affected area for three to five days, then every few days as needed.
- Wash off the following morning.

#### Precautions

- Avoid contact with the eyes, face, mucous membrane and healthy skin.
- Do not bath immediately before use.

#### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the solution.

#### Side effects

- It may cause skin irritation

#### Additional information

- Industrial Methylated Spirits may be used to prepare Aluminium Chloride Solution.
- Application to dry skin may reduce local irritation from aluminum chloride.
- It can be prepared from 10 to 35% w/v as required.

## Benzyl Benzoate lotion, 25% w/v

### Formulation

Benzyl benzoate	25 gm
Emulsifying wax	2 gm
Purified Water qs	100 ml

### Indication

- For treatment of scabies and lice (Pediculosis)

### Dose and Administration

- Scabies: Application 3 times (either 0, 12, 24 hours or once daily for 3 consecutive days).
  - During each application, take a hot scrubbing soap water bath initially. Apply the lotion from the neck down to the whole body and rub it into the skin. Make sure the lotion gets into contact with the whole body including skin folds. At the same time, treatment for the entire families or contact person is recommended.
- Decontaminate any household contacts like linens, towels, clothing, bed sheets, and pillowcases used in previous 4 days by hot water washing. Alternatively, seal and store in a plastic bag for 3 days.
- Lice: apply the lotion 2 to 3 times at weekly intervals.
  - Rub the lotion into all infected hairy areas and allow remaining for 24 hours. Wash off thoroughly and comb the hair with a fine comb to remove dead lice. Wash all bed sheets, pillowcases, and clothes, preferably in hot or boiling water and shake out blankets and outer wear. Repeat treatment two or three times at weekly intervals.
  - Infested patient and their sexual contact should be avoided until infestation cleared.
- Itch may persist for weeks after all the mites have been killed.
- Shake well before use.

### Precautions

- Avoid contact with the eyes.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the solution.

**Side effects**

- It may cause contact dermatitis.
- Sensitization reactions are rare, irritation reactions with a burning or stinging sensation may occur.

**Additional information**

- It also possible to prepare the lotion in different concentration (like 6.25% and 12.25%).
- Emulsifying wax may be substituted by cetomacrogol wax.

## Calamine lotion, 15% w/v

### Formulation

Calamine	15 gm
Zinc oxide	5 gm
Bentonite	3 gm
Sodium citrate	0.5 gm
Glycerin	5 ml
Liquefied phenol	0.5 ml
Purified Water qs	100 ml

### Indication

- For treatment of itch, stinging or burning pain from insect bites, allergic reactions, or mild sunburn
- Used as Antiseptic

### Dose and Administration

- Apply 2 to 3 times per day. It may be used, in acute disease, up to a maximum of ten times a day.
- Shake the lotion before use. It should be painted onto the skin using brush.
- Allow to dry and do not cover with wrappings or bandages.

### Precautions

- It should only be used on wounds with caution because of the risk of absorption of phenol.
- Avoid contact with the eyes.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the solution.

### Side effects

- It may cause sensitivity or an allergic reaction such as red, itchy skin.
- It should not be used on large parts of the body or for periods longer than 1 week due to systemic side effects of phenol.

### Additional information

- Calcium hydroxide solution 3% w/v (lime water) can be substituted in place of purified water as per USP.

- The lotion without a preservative should not be stored, but can be freshly prepared for immediate use. In addition to its preservative effects, phenol also exerts medicinal activity; calamine lotion without phenol is less effective.

## Dithranol cream, 1% w/w

### Formulation

Dithranol	1 gm
Ascorbic acid	0.1 gm
Salicylic acid	1 gm
Basic cream	98 gm

### Indication

- For treatment of Alopecia areata, Psoriasis, and Plantar Wart

### Dose and administration

- Alopecia Areata – Apply as thin layer once daily at night to the affected area and wash off after 30 minutes for the first 2 weeks, and then for the second 2 weeks apply once daily to the affected area and wash off after 45 minutes. For the last 2 weeks, apply once daily and wash off after 1 hour.
- Psoriasis – apply as thin layer once daily at night until the lesion resolves.
- Plantar wart – apply once daily until the lesion resolves.
- Rub the cream gently onto the skin.
- Avoid applying the cream to surrounding healthy skin. Adjacent healthy skin can be protected with white soft paraffin. Wash the hands after application.
- In the morning, remove the cream by washing with water only. Only after all the cream has been removed with water, wash the skin with water and soap.
- Mix the cream before use.

### Precautions

- Avoid contact with healthy skin and eyes.

### Pregnancy/breast feeding

- It should be used during pregnancy only if the benefit outweighs the potential risk.

### Side effects

- It may produce a burning feeling. Only when intense pain develops, treatment should be stopped.
- It may cause sensitivity or an allergic reaction such as red, itchy skin, etc.

### Additional information

- Alopecia Areata – Dithranol cream can be used in different concentration (0.5 to 2%)



- Psoriasis – Dithranol cream can be used in different concentration (0.05 to 4%)
- Plantar wart – Dithranol cream 2%
- Keep the amounts of salicylic acid (1g/100g cream) and ascorbic acid (0.1g/100g cream) the same for different dithranol preparations with other concentrations.
- Dithranol can also be incorporated in either white soft paraffin or emulsifying ointment. Dithranol in petrolatum is occlusive and less well tolerated.
- It is contraindicated in Pustular and Erythrodermic Psoriasis.

## Dithranol ointment, 1% w/v

### Formulation

Dithranol	1 gm
Salicylic acid	0.5 gm
Emulsifying ointment	98.5 gm

### Indication

- For treatment of Alopecia areata, Psoriasis, and Plantar Wart

### Dose and administration

- Alopecia Areata – Apply as thin layer once daily at night to the affected area and wash off after 30 minutes for the first 2 weeks, and then for the second 2 weeks apply once daily to the affected area and wash off after 45 minutes. For the last 2 weeks, apply once daily and wash off after 1 hour.
- Psoriasis – apply as thin layer once daily at night until the lesion resolves.
- Plantar wart – apply once daily until the lesion resolves.
- Rub the cream gently onto the skin.
- Avoid applying the cream to surrounding healthy skin. Adjacent healthy skin can be protected with white soft paraffin. Wash the hands after application.
- In the morning, remove the cream by washing with water only. Only after all the cream has been removed with water, wash the skin with water and soap.
- Mix the cream before use.

### Precautions

- Avoid contact with healthy skin and eyes.

### Pregnancy/breast feeding

- It should be used during pregnancy only if the benefit outweighs the potential risk.

### Side effects

- It may produce a burning feeling. Only when intense pain develops, treatment should be stopped.
- It may cause sensitivity or an allergic reaction such as red, itchy skin, etc.

### Additional information

- Alopecia Areata – Dithranol cream can be used in different concentration (0.5 to 2%)
- Psoriasis – Dithranol cream can be used in different concentration (0.05 to 4%)

- Plantar wart – Dithranol cream 2%
- Keep the amounts of salicylic acid (1g/100g cream) and ascorbic acid (0.1g/100g cream) the same for different dithranol preparations with other concentrations.
- Dithranol can also be incorporated in either white soft paraffin or emulsifying ointment. Dithranol in petrolatum is occlusive and less well tolerated.
- It is contraindicated in Pustular and Erythrodermic Psoriasis.

## Erythromycin gel, 2% w/v

### Formulation

Erythromycin	2 gm
Propylene glycol	24 ml
Hydroxypropyl cellulose 1500 cps	2 gm
Ethyl alcohol 70% v/v qs	100 ml

### Indication

- For treatment of Acne Vulgaris, Rosacea, and Periorificial dermatitis

### Dose and Administration

- Apply sparingly as a thin film once or twice a day after the skin is thoroughly cleansed and patted dry.
- Spread the medication lightly rather than rubbing it in.

### Precautions

- Avoid contact with eyes and all mucous membranes.

### Pregnancy/breast feeding

- It should be used in pregnancy only if clearly needed.

### Side effects

- Burning, desquamation, dryness, itching, and erythema.

## Lactic acid cream, 5% w/w

### Formulation

Lactic acid	5 gm
Propylene glycol	20 ml
Aqueous cream	75 gm

### Indication

- For the treatment of Xerosis Cutis, Ichthyosis Vulgaris, Darier's Disease.
- For the temporary relief of itching associated with the above conditions.

### Dose and administration

- Apply thoroughly twice daily.
- Adjacent healthy skin can be protected with petrolatum.

### Precautions

- Avoid contact with eyes, lips or mucous membranes.
- Sun exposure to area of skin treated with lactic acid cream should be minimized or avoided.
- Caution is advised when used on the face due to the potential for irritation.

### Pregnancy/breast feeding

- Lactic acid cream is safe and could be given to a pregnant woman and nursing mother as needed.

### Side effects

- Mild, stinging, burning or peeling may occur on sensitive, inflamed or irritated skin areas.

### Additional Information

- Lactic acid can also be prepared in higher concentration for crusted scabies, Darier's disease, Keratosis Pilaris, Lichen Spinulosus, Pityriasis Rotunda, Keratoderma and Chemical peeling.
- It is contraindicated in neonates and children with erythroderma.

## Hydroquinone cream, 4% w/w\*

### Formulation

Hydroquinone	4 gm
Ascorbic acid	1.5 gm
Basic cream	94.5 gm

### Indication

- For treatment of Hyper-pigmented skin conditions such as melasma, freckles, lentigines and Post inflammatory hyperpigmentation.

### Dose and administration

- Apply and rub well once or twice daily at night.
- Use sunscreen during the therapy.

### Precautions

- Avoid contact with eyes and mucous membranes.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the cream.

### Side effects

- Irritant dermatitis, contact dermatitis, post inflammatory pigmentation, cutaneous ochronosis.

### Additional Information

- Instead of basic cream, aqueous cream can be used as vehicle.

*\* The formulation is included based on Experts' opinion*

## Malathion lotion, 0.5% w/v

### Formulation

Malathion	0.5 gm
Isopropyl alcohol 70%	70 ml
Ethanol 95% qs	100 ml

### Indication

- For treatment of Pediculus (head lice and their ova) of the scalp hair.

### Dose and administration

- Apply sufficient amount on dry hair and scalp thoroughly.
- Allow hair to dry naturally and remain uncovered. After 8 to 12 hours, wash the hair.
- Rinse and use a fine-toothed (nit) comb to remove dead lice and eggs. Repeat after 7 - 9 days as required.
- Wash hands after applying to scalp.
- Wash combs, brushes, hairs clips, clothing, underwear, pajamas, hats, sheets, pillowcases, and towels, and other personnel items in hot water.

### Precautions

- Avoid contact with the eyes. Use only on scalp hair.
- Compound this preparation in a well-ventilated area.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the lotion.

### Side effects

- It may cause a mild, stinging, and burning or peeling.

### Additional Information

- Flavoring agent can be used in the preparation.
- Malathion lotion should not be used in children less than 2 years of age and should be used with caution in children 2-6 years of age.

## Menthol spirit, 1% w/v

### Formulation

Menthol	1 gm
Ethanol 70 % v/v qs	100 ml

### Indication

- Antipruritic effect and symptomatic treatment for Herpes Zoster and urticaria.

### Dose and administration

- Apply to affected area up to 3 to 4 times daily.

### Precaution

- It is highly flammable and volatile.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the spirit.

### Side Effects

- It may cause contact dermatitis.

### Additional Information

- Usually the concentration employed 0.25% to 2% w/v in alcoholic solution or paste.
- It should not be used in infants and children.



## Metronidazole cream, 0.75 % w/w\*

### Formulation

Metronidazole	0.75 gm
Aqueous cream qs	100 gm

### Indication

- For treatment of Rosacea and Periorificial Dermatitis.

### Dose and administration

- After washing, apply and rub in a thin layer once or twice daily.

### Precautions

- Avoid contact with the eyes.
- It should be used with care in patients with evidence of, or history of blood dyscrasia.

### Pregnancy/breast feeding

- It should be used in pregnancy only if clearly needed.

### Side effects

- Skin discomfort (dryness, burning and stinging) followed by erythema, skin irritation, pruritus and worsening of rosacea.

### Additional Information

- It can also be prepared in 1% w/w concentration.

*\* The formulation is included based on Experts' opinion*

## Potassium Hydroxide (KOH) solution, 5% w/v

### Formulation

Potassium hydroxide	5 gm
Purified water qs	100 ml

### Indication

- For treatment of molluscum contagiosum lesion and genital wart.

### Dose and administration

- Apply once to twice daily using cotton swab to all lesions until it undergoes inflammation and superficial ulceration.
- Protect the surrounding skin with white soft paraffin.

### Precautions

- Protect skin, clothing, and equipment.
- Avoid contact with eyes (highly corrosive).

### Pregnancy/breast feeding

- No studies are currently identified regarding the reproduction/developmental toxicity of potassium hydroxide.

### Side effects

- Stinging or burning sensations, temporary dyspigmentation.

### Additional Information

- Topical potassium hydroxide solution 10% w/v can be used for treatment of molluscum contagiosum lesion and genital wart.

## Salicylic acid ointment, 5% w/w

### Formulation

Salicylic acid	5 gm
White Soft Paraffin	95 gm

### Indication

- As adjuvant therapy for the treatment of Hyperkeratotic conditions (Psoriasis, Chronic Eczema, and Seborrheic Dermatitis) and Pityriasis Amiantacea.

### Dose and administration

- Apply the ointment as a thin layer once to twice daily after washing the skin.

### Precautions

- Prolonged use may lead to systemic toxicity.
- Over dose (> 2 gm in 24 hours) or frequent use of salicylates may cause salicylism.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using salicylic acid.

### Side effects

- Sensitization reactions, local irritation, acute inflammation, ulceration (with use of high concentration), and systemic toxicity

### Additional information

- Excessive or long-term use of salicylic acid containing preparations may cause systemic intoxication and characterized by:
  - Slight intoxication: sweating, abdominal pains, dehydration and loss of hearing.
  - More severe intoxication: excitation, confusion, fever and convulsions.
  - Severe intoxication: respiratory alkalosis followed by a metabolic acidosis and CNS depression, resulting in coma and death.

**Note: - Salicylic acid ointment can be used in different concentration (2-40%) based on severity, site of application, and disease type. The above master formula and procedures can be used in order to compound other strengths of salicylic acid preparations.**

- Salicylic acid ointment 2-6% - as adjuvant therapy for the treatment of Hyperkeratotic conditions (Psoriasis, Chronic Eczema, and Seborrheic Dermatitis) and Pityriasis Amiantacea.

- Salicylic acid ointment 12-40% - for chemical peeling and for the treatment of hyperkeratotic conditions such as Corn, Wart, Callus, Keratoderma and Hyperkeratotic nail.
- Acne is treated with a drying preparation with a lower concentration. Salicylic acid strong ointment should not be used for acne or psoriasis.
- For higher doses (> 10%) protect the surrounding skin with white petrolatum or plaster.
- Liquid paraffin or aqueous cream can be used as vehicle for scalp purpose.

## Salicylic acid solution, 5% w/v

### Formulation

Salicylic acid	5 gm
Industrial methylated spirit 70% v/v	100 ml

### Indication

- For the treatment of acne

### Dose and Administration

- Apply once to twice daily after washing the skin and drying.
- Apply the solution with some cotton wool or a clean piece of cloth, allow to dry.

### Precautions

- Prolonged use may lead to systemic toxicity.
- Over dose or frequent use of salicylates may cause salicylism.
- Close the bottle well after each use.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using salicylic acid.

### Side effects

- Sensitization reactions, local irritation, acute inflammation, ulceration (with use of high concentration), and systemic toxicity

### Additional information

- Lower concentrations of salicylic acid (2% w/v) may be used.
- Excessive or long-term use of salicylic acid containing preparations may cause systemic intoxication and characterized by:
  - Slight intoxication: sweating, abdominal pains, dehydration and loss of hearing.
  - More severe intoxication: excitation, confusion, fever and convulsions.
  - Severe intoxication: respiratory alkalosis followed by a metabolic acidosis and CNS depression, resulting in coma and death.
- Aqueous cream can be used as vehicle.

## Salicylic acid, 3 % w/w + Coal tar, 5% w/w ointment

### Formulation

Salicylic acid	3 gm
Coal tar	5 gm
White Soft Paraffin	92 gm

### Indication

- For treatment of Psoriasis, chronic Eczema and Seborrheic Dermatitis

### Dose and administration

- Apply to the affected area once daily.
- Wash your hands before and after use.

### Precautions

- Exposure to sunlight should be avoided during tar therapy at least until 24 hours after the last application.
- Avoid application to large skin surfaces and healthy parts of the skin.
- Do not apply on broken skin.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using coal tar and salicylic acid.

### Side effects

- A Stinging sensation on the skin
- Dryness of skin and increased sensitivity of the skin to the sun
- Over dose or frequent use of salicylates in children may cause salicylism

### Additional information

- The ointment can be used in different concentration based on severity, site of application, and disease type.
- For scalp use, the vehicle should be liquid paraffin.

## Salicylic acid, 17% w/v + Lactic acid, 17% w/v collodion\*

### Formulation

Salicylic acid	17 gm
Lactic acid	17 gm
Absolute alcohol	25 ml
Flexible Collodion qs	100 ml

### Indication

- For treatment of Wart (particularly palmoplantar wart, verruca vulgaris and mosaic wart), Corn and Callus

### Dose and Administration

- Wash the skin carefully and apply as a thin layer once daily.
- Protect the surrounding area with white soft paraffin or plaster.

### Precautions

- Avoid contact with the eyes, face mucous membrane, and healthy skin.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

### Side effects

- It may cause skin irritation and ulceration.

### Additional Information

- The collodion solution can also be prepared in different concentration salicylic and lactic acid (10-17% w/v).
- It should not be used in infants and children.

*\*The formulation is included based on Experts' opinion*

## Salicylic acid, 10% w/w + Lactic acid, 10% w/w ointment\*

### Formulation

Salicylic acid	10 gm
Lactic acid	10 gm
White soft Paraffin	80 gm

### Indication

- For treatment of Cutaneous Warts and Corn or Callus and Keratodermas.

### Dose and Administration

- Wash the skin carefully; hydrate the skin by keeping it wet for 10 to 15 minutes and then apply as a thin layer once to twice daily.
- Protect the surrounding area with white soft paraffin or plaster.

### Precautions

- Avoid contact with the eyes, face mucous membrane, and healthy skin.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

### Side effects

- It may cause mild skin burning, redness, and peeling of the treated area.

### Additional Information

- The ointment can be prepared in different concentration (10-17% w/w) based on severity, disease type, and prescriber's decision.

*\*The formulation is included based on Experts' opinion*



## Salicylic acid, 5% w/v + Steroid lotion

### Formulation

Salicylic acid	5 gm
Very and Moderate Potent Steroid ointment	10 gm
Liquid paraffin	85 gm

### Indication

- For treatment of Pityriasis Rubra Pilaris (PRP) on scalp and Seborrheic Dermatitis with extensive scale

### Dose and Administration

- Apply as a thin film once daily at bedtime using covered or gloved hand.

### Precautions

- Avoid contact with the eyes, face, mucous membrane, and healthy skin.
- Over dose or frequent use of salicylates may cause salicylism.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

### Side effects

- It may cause burning, itching, irritation, dryness, thinning and other skin problems.

### Additional Information

- The ointment can be prepared in different concentration (salicylic acid 5-6% w/w) for management of Psoriasis (on scalp).
- The ointment can be prepared using different amount of steroid ointment (10gm – 60gm) based on severity, disease type, site of application, coverage of body surface area, and age of patient.
- Selection of topical corticosteroids depends on disease conditions, site of application, and age of the patient (see table below).
- The use of corticosteroids is contraindicated in conditions such as viral skin infections (like vaccinia, varicella and herpes simplex), acne rosacea, fungal skin infections, perioral dermatitis, and ulcerative conditions.

*Table 1 Potency class of selected topical corticosteroid preparations*

Potency	Topical Corticosteroid Preparations
<b>Ultra-high potent</b>	Clobetasol propionate cream (0.05%)
<b>High potent</b>	Betamethasone dipropionate ointment (0.05%) Betamethasone dipropionate cream (0.05%) Betamethasone valerate ointment (0.1%) Mometasone furoate ointment (0.1%) Triamcinolone acetonide ointment (0.1%)
<b>Moderate potent</b>	Betamethasone dipropionate lotion (0.02%) Betamethasone valerate cream (0.1%) Hydrocortisone butyrate cream (0.1%) Mometasone furoate cream (0.1%) Triamcinolone acetonide cream (0.1%)
<b>Low potency</b>	Betamethasone valerate lotion (0.05%) Hydrocortisone acetate cream (1%)

## Salicylic acid, 10% w/w + Steroid ointment\*

### Formulation

Salicylic acid	10 gm
Potent and Moderate Potent Steroid ointment	15 gm
White Soft Paraffin	75 gm

### Indication

- For treatment of Pityriasis Rubra Piralis (PRP) on trunk and extremities; Psoriasis (trunk/extremity)

### Dose and Administration

- Apply as a thin film once daily at bedtime using covered or gloved hand.

### Precautions

- Avoid contact with the eyes, face, mucous membrane, and healthy skin.
- Over dose or frequent use of salicylates may cause salicylism.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

### Side effects

- It may cause burning, itching, irritation, dryness, and thinning.

### Additional Information

- The ointment can be prepared in different concentration for management of psoriasis (trunk/extremity).
- The ointment can be prepared using different amount of steroid ointment (10 – 60gm) based on severity, disease type, site of application, and age of patient.
- Selection of topical corticosteroids depends on disease conditions, site of application, and age of the patient.
- Steroid potency and amount varies depending on the severity of lesion, anatomic sites, and percentage body surface area involved (see for potency class of selected corticosteroids)
- The use of corticosteroids is contraindicated in conditions such as viral skin infections (like vaccinia, varicella and herpes simplex), acne rosacea, fungal skin infections, perioral dermatitis, and ulcerative conditions.

*\*The formulation is included based on Experts' opinion*

## Salicylic acid, 2% w/w + Sulfur, 2% w/w cream

### Formulation

Salicylic acid	2 gm
Sulfur	2 gm
Aqueous cream	96 gm

### Packaging

- Pack in a well-closed container.

### Storage

- Store at room temperature.

### Indication

- For treatment of seborrhoeic dermatitis of the scalp and acne.

### Dose and Administration

- Apply once or twice a day.

### Precautions

- Avoid contact with metals.
- Prolonged use may lead to systemic toxicity.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the cream.

### Side effect

- Local irritation
- Mild cold or burning sensation at the site of application
- Severe allergic reaction

### Additional Information

- Keratolytics based on salicylic acid (2–6 %) with or without sulfur (2–5 %) help the removal of adherent scales.
- The cream can be prepared in different concentration for management of acne.

## Salicylic acid, 10% w/w + Urea, 10% w/w + Lactic acid, 6% w/w ointment\*

### Formulation

Salicylic acid	10 gm
Urea	10 gm
Lactic acid	6 gm
White Soft Paraffin	74 gm

### Indication

- For treatment of Keratoderma, Cutaneous Wart, Corn and Callus

### Dose and Administration

- Wash the skin carefully; hydrate the skin by keeping it wet for 10 to 15 minutes and then apply as a thin layer once to twice daily.
- Protect the surrounding area with white soft paraffin or plaster.

### Precautions

- Avoid contact with the eyes, face mucous membrane, and healthy skin.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the ointment.

### Side effects

- It may cause mild skin burning, redness, and peeling of the treated area.

### Additional Information

- The ointment can be prepared in different concentration based on severity, disease type, and prescriber's decision.

*\* The formulation is included based on Experts' opinion*

## Salicylic acid, 2% w/w + Zinc oxide paste

### Formulation

Salicylic Acid	2 gm
Zinc oxide paste 25% w/w	98 gm

### Indication

- For the treatment of juvenile Plantar Dermatoses

### Dose and administration

- Apply twice daily.

### Precautions

- Avoid contact with eyes, lips or mucous membranes.
- Prolonged use may lead to systemic toxicity.
- Over dose or frequent use of salicylates in children may cause salicylism.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using the paste.

### Side effects

- It may cause mild stinging, burning or peeling, sensitization.

## Silver nitrate solution, 0.5% w/v

### Formulation

Silver nitrate	0.5 gm
Purified Water qs	100 ml

### Indication

- For infection prevention in large deep burns
- For treatment of leg ulcers, Pyogenic Granuloma, Molluscum Contagiosum, and Wart
- As a wet dressing in the treatment of infected eczema, gravitational ulcers, and other weeping and/or infected skin lesions caused by Gram-positive or Gram-negative bacteria.

### Dose and administration

- Apply the solution on the affected area 2 to 3 times per week using cotton applicator.
- Burns: silver nitrate treatment should be started immediately after burning, or at least within a few hours. The dressings have to be saturated with silver nitrate solution every two hours. Dressings should be changed once daily.
- Ulcers: leg ulcers infected with *Pseudomonas* species are treated with silver nitrate compresses. The dressings should be changed every hour.
- Protect the surrounding skin with white soft paraffin.

### Precautions

- Avoid prolonged contact with skin.
- The use of silver nitrate solution on large burns may cause hypochloremia.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using silver nitrate solution.

### Side effects

- It causes burning, skin irritation, and staining of wounds and skin (argyria).

### Additional information

- When the water to prepare silver nitrate solution is rich in chlorides, a silver chloride precipitate will be formed. To avoid this reaction, use distilled water for the solution.

## Sulphur cream, 10% w/w

### Formulation

Sulphur	10 gm
Basic cream	90 gm

### Indication

- For treatment of scabies

### Dose and administration

- Apply the cream on 3 consecutive evenings after washing the skin.
- Mix the cream before use and make sure the cream contacts the whole body, including skin folds. Wash away in the morning. Repeat this every evening for 3 consecutive days.
- Wash all clothes, bed sheets and pillowcases that have been in close contact with the skin, preferably in hot or boiling water, to prevent re-infestation.
- Itch may persist for weeks after all the mites have been killed.

### Precautions

- It may cause skin irritation that may predispose the skin to infections.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using sulphur.

### Side effects

- Sensitization and may also cause skin irritation.

### Additional information

- Sulphur can be used in lower concentrations (2-3% w/w) in the same cream for acne vulgaris.
- Sulphur can be used in lower concentrations for scabies in infants and other indications.
- When basic cream is unavailable, sulphur ointment can be used instead.



## Sulphur lotion, 3% w/v

### Formulation

Sulphur	3 gm
Zinc oxide	20 gm
Bentonite	3 gm
Sodium citrate	0.5 gm
Glycerin	5 ml
Liquefied phenol	0.5 ml
Purified Water qs	100 ml

### Indication

- For treatment of Acne and Rosacea
- Used as antiseptic and antipruritic agent

### Dose and administration

- Apply the lotion once to twice daily using cotton or clean cloth after washing the skin. Allow to dry and leave exposed to the air.
- Shake the lotion before use.

### Precautions

- Avoid contact with the eyes.
- It should cautiously be used on wounds because of the risk of phenol absorption.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using sulphur.

### Side effects

- Sensitization reactions with a burning feeling may occur.

### Additional information

- Other concentrations of sulphur (up to 6% w/v) can be used.

## Sulphur ointment, 10% w/w

### Formulation

Sulphur	10 gm
Emulsifying ointment qs	100 gm

### Indication

- For treatment of scabies

### Dose and Administration

- Apply the cream on 3 consecutive evenings after washing the skin and make sure the ointment contacts the whole body, including skin folds.
- Wash away in the morning. Repeat this every evening for 3 consecutive days.
- Wash all clothes, bed sheets and pillowcases that have been in close contact with the skin, preferably in hot or boiling water, to prevent re-infestation.
- Itch may persist for weeks after all the mites have been killed.

### Precautions

- It may cause skin irritation that may predispose the skin to infections.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using sulphur.

### Side effects

- Sensitization and may also cause skin irritation.

### Additional information

- Sulphur can be used in lower concentrations in this ointment for scabies in infants and other indications.
- Sulphur ointment can be prepared using white soft paraffin as a base.
- Sulphur can also be prepared for children using liquid paraffin with polysorbate 60 as suspension.

## Tar cream, 3% w/w

### Formulation

Coal tar	3 gm
Basic cream	97 gm

### Indication

- For treatment of Psoriasis, Parapsoriasis, Eczema, and Pityriasis Lichenoides Chronica

### Dose and administration

- Apply as thin layer once daily at night time to the affected parts of the skin after washing the skin.
- Apply using covered or gloved hands.

### Precautions

- Avoid exposure to sunlight.
- Avoid application to large skin surfaces and healthy parts of the skin.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using tar.

### Side effects

- It may cause skin irritation and folliculitis.

## Tar paste, 5% w/w

### Formulation

Coal tar	5 gm
Zinc paste	95 gm

### Indication

- For treatment of Psoriasis, Parapsoriasis, Eczema, and Pityriasis Lichenoides Chronica

### Dose and Administration

- Apply the paste as layer just thick enough once daily at night time after washing the skin.
- Apply using covered or gloved hands.

### Precautions

- Avoid exposure to sunlight.
- Avoid application to large skin surfaces and healthy parts of the skin.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using tar.

### Side effects

- It may cause skin irritation and folliculitis.

### Additional information

- Lower concentrations of tar are prepared by further diluting the paste.
- Not suitable for hairy areas.
- Tar paste has a protective effect.

## Tar solution, 20% w/v

### Formulation

Coal tar	20 gm
Polysorbate 80	5 gm
Industrial methylated spirit 95% v/v qs	100 ml

### Indication

- For the treatment of Psoriasis and Eczema.

### Dose and administration

- Apply the solution once daily at night time after washing the skin.
- Apply using covered or gloved hands.
- Close the bottle well after use.

### Precautions

- Avoid exposure to sunlight.
- Avoid application to large skin surfaces and healthy parts of the skin.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using tar.

### Side effects

- It may cause skin irritation and folliculitis.

### Additional information

- Lower concentrations of tar may be used.

## Trichloroacetic acid solution, 30% w/v

### Formulation

Trichloroacetic acid	30 gm
Purified water qs	100 ml

### Packaging

- Pack in a well-closed container.

### Storage

- Store at room temperature (15-25 °C) and away from fire.

### Indication

- For treatment of flat warts (facial peels (10% to 35%)), cutaneous warts, and anogenital warts (80-90%).
- For treatment of Grover Disease (20–30 %), Actinic Keratosis (30%) and Molluscum Contagiosum (25- 50%).

### Dose and Administration

- It is applied sparingly on the affected area either by a cotton tip or an applicator, on a weekly basis.
- The solution should be applied to individual papular lesions for a few seconds until they turn white.
- Protect the surrounding area with white soft paraffin or plaster.
- Higher concentration of TCA has to be applied by physician and cannot be applied by patient.

### Precautions

- Avoid contact eyes and healthy skin.

### Pregnancy/breast feeding

- It is safe during pregnancy.

### Side effect

- It causes a burning sensation, inflammation or tenderness.

## Urea cream, 10% w/w

### Formulation

Urea	10 gm
Basic cream	90 gm

### Indication

- For treatment of Ichthyosis, Atopic Dermatitis, and hyperkeratotic skin conditions
- Used for softening nail before surgical removal

### Dose and administration

- Apply as a thin layer twice daily after hydrating the skin by keeping it wet for 10 to 15 minutes.
- For nail softening: Apply on the nail under occlusion and leave for 24-72 hours.
- Protect the surrounding area with white soft paraffin or plaster (Urea above 20% w/w).

### Precautions

- Avoid contact with the eyes.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using urea.

### Side effects

- It may cause burning feeling, particularly when used in the face or on broken skin.

### Additional Information

**Note:** - Urea cream can be used in different concentration (5-40% w/w) based on severity, site of application, and disease type.

- Urea cream 5-10% w/w - As moisturizer
- Urea cream 10-40% w/w - As keratolytic agent for the treatment of Hyperkeratotic conditions (such as dry, rough skin, Dermatitis, Psoriasis, Xerosis, Ichthyosis, Eczema, Keratosis Pilaris, Keratosis Palmaris, Keratoderma, Corns and Calluses, as well as damaged, ingrown and devitalized nails onychomycosis) and Pityriasis Rotunda.

## Urea ointment, 10% w/w

### Formulation

Urea	10 gm
Water	20 gm
Emulsifying ointment	70 gm

### Indication

- For treatment of Ichthyosis, Atopic Dermatitis, and hyperkeratotic skin conditions
- Used for softening nail removal before surgical removal

### Dose and administration

- Apply as a thin layer twice daily after hydrating the skin by keeping it wet for 10 to 15 minutes.
- For nail softening: Apply on the nail under occlusion and leave for 24-72 hours.
- Protect the surrounding area with white soft paraffin or plaster (Urea above 20% w/w).
- Mix the ointment before use.

### Precautions

- Avoid contact with the eyes.

### Pregnancy/breast feeding

- Evaluate the benefit/risk ratio before using urea.

### Side effects

- It may cause burning feeling, particularly when used in the face or on broken skin.

### Additional information

- The water is used for easier processing of urea and to ensure homogeneous distribution in the ointment.



## **Zinc paste, 25% w/w**

### **Formulation**

Zinc oxide	25 gm
Starch	25 gm
White Soft Paraffin	50 gm

### **Indication**

- As photo protective and vehicle agent
- Diaper Dermatitis

### **Dose and administration**

- Apply the paste as required
- The paste layer may be covered with a loose bandage.

### **Pregnancy/breast feeding**

- Evaluate the benefit/risk ratio before using the paste.

### **Additional information**

- Talc can be used instead of starch.
- Zinc paste can be prepared in different concentration (50% w/w zinc oxide and 50% w/w white soft paraffin).
- Starch is inappropriate for hot and humid climates because it is usually highly contaminated with micro-organisms.

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