Labelling Topical Preparations for the Skin

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Global Burden of Skin Disease

<table>
<thead>
<tr>
<th>Skin Disease</th>
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<tbody>
<tr>
<td>Eczema</td>
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<td>Psoriasis</td>
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<td>Acne vulgaris</td>
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<td>Pruritus</td>
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<td>Alopecia areata</td>
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<td>Decubitus ulcer</td>
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<td>Urticaria</td>
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<tr>
<td>Scabies</td>
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<tr>
<td>Fungal skin diseases</td>
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<td>Impetigo</td>
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<td>Abscess</td>
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<tr>
<td>Other bacterial skin diseases</td>
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<tr>
<td>Cellulitis</td>
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<td>Viral warts</td>
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<tr>
<td>Molluscum contagiosum</td>
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<tr>
<td>Non-melanoma skin cancer</td>
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</tbody>
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For all these skin diseases, topical medications exist.


What is a Topical Preparation

• *Topical* derives from τοπικός >> topikos >> "of a place”
  • local, localized, confined to a specific place

• *Topical* preparations are applied to surfaces with typical and specific surfaces on or in the body
What is a Topical Preparation

Vehicle / Formulation / Dosage Form

Ingredients

**Functional ingredients:**
- e.g., petrolatum, liquid paraffin, isopropyl palmitate, stearyl alcohol, dimethicone, PEG-100, glyceryl stearate, alcohol, water, cellulose, tocopherol, paraben, butane, butanediol, stearic acid, phenoxyethanol, etc.

Formats

**Monophasic systems:**
- e.g., ointment, gel

**Diphasic systems:**
- e.g., cream, lotion, paste

**Multiphasic systems:**
- e.g., cream paste, dressing

API/CA

- e.g.,
  - retinoids
  - corticosteroids
  - vitamin D derivatives etc.
  - aloe vera
  - glycerin
  - urea etc.


API: active pharmaceutical ingredient
CA: cosmetic active
Vocabulary of Topical Preparations

• Regulatory bodies
  • local, regional, international bodies

• Industry and Academia
  • pharmaceutical and cosmetic industry, academia

• Healthcare professionals
  • physicians, pharmacists, nurses

• Consumer
Definitions and Designations

• Compendial definitions (pharmacopeia)
  • ointment, cream

• Scientific and technical definitions
  • solution, emulsion // ointment, cream

• Fanciful designations
  • serum, fluid, concentrate

• Effect designations
  • moisturizer, emollient, lubricant
## Definitions and Designations

<table>
<thead>
<tr>
<th>Formats</th>
<th>Uses</th>
<th>Effects</th>
<th>Analogies</th>
<th>“Magics”</th>
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<tbody>
<tr>
<td>Ointment</td>
<td>Spray</td>
<td>Soak</td>
<td>Milk</td>
<td>Serum</td>
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<td>Gel</td>
<td>Shampoo</td>
<td>Lubricant</td>
<td>Shake</td>
<td>Fluid</td>
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<td>Cream</td>
<td>Roll-on</td>
<td>Absorbent</td>
<td>Paint</td>
<td>Concentrate</td>
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<td>Paste</td>
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<td>Humectant</td>
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<td>Balm</td>
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<td>Emollient</td>
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<td>Moisturiser</td>
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<td>Demollient</td>
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* Note, that format combinations are often created for marketing purposes.
Consumer’s Perception

- Quality
  - translucent
- Effect
  - cooling
- Target/use
  - young skin

- Quality
  - sticky
- Effect
  - occlusive
- Target/use
  - diseased skin

Metamorphosis

Sum of ingredients after evaporation of all volatile vehicle ingredients

**SOLUTION**

**SPRAY**

primary formulation

**FOAM**

fresh foam  collapsed foam

**GEL**

**OINTMENT**

secondary formulation  tertiary formulation

first encounter  second encounter

application feel  skin feel

Metamorphosis

Relative composition of

primary formulation

- Active
- Stearic acid
- Non-ionic emulsifier 1
- Non-ionic emulsifier 2
- Liquid paraffin
- Propylene glycol
- Sodium citrate
- Citric acid
- Disodium edetate
- Benzyl alcohol
- Water

tertiary formulation

- Active
Metamorphosis

1 second

liposomal product

1 minute

3 minutes

courtesy of Stephan Dähnhardt-Pfeiffer, Microscopy Services
Well Absorbed!
Plain Language Summary

Dressings and topical agents (gels, ointments and creams) for treating venous leg ulcers

Dressing

Impregnated dressings may have a range of bases, such as foams or alginates.

Topical agents

The following types of topical agents are considered as interventions in this review.

Cadexomer-iodine paste consists of a water-soluble, modified starch polymer containing iodine. It releases free iodine when ex-

Collagenase-containing ointment is an enzymatic debriding ointment. Collagenase is thought to digest collagen in necrotic

Hydrogels consist of a starch polymer and up to 96% water. They

Topical phenytoin is thought to promote wound healing by a

Silver sulfadiazine cream is a topical antimicrobial cream that

Authors’ Conclusions

There is a lack of high-quality research evidence relating to whether particular wound dressings or topical treatments have a beneficial impact on healing of venous leg ulcers. This is despite the existence

An update on the topical and oral therapy options for treating pediatric atopic dermatitis

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and caregivers are willing to apply. For example, some patients are not willing to use an ointment due to its greasy feel, but these same patients may be willing to apply a cream or a spray. Reassurance of the safety of topical corticosteroids,

to prevent transepidermal water loss [6]. Ointments are most effective, followed by creams. Due to their high water content, lotions are least effective in the treatment of AD [11]. Benefits

and ointments. Ointments are best for dry skin and are associated with less burning than creams and lotions [17]. Use of
Is there a Way out of this Babylonian Confusion?
Is there a Way out of this Babylonian Confusion?

• Do we recognize the challenge?
• Do we see a need for action?

• Are the linguistic and terminological difficulties recognized?
• Is it recognized that insufficient attention has been paid to the importance of vehicle, vehicle format and active substances in terms of effect?

• Is there a willingness to resolve the confusion?
### Treatment Area
- Small
- Large

### Skin / Dermatosis
- Humid
- Dry

### Polarity
- Hydrophilic
- Lipophilic

### Viscosity
- High
- Low

### Clinical Qualities
- Pharmaceutical Features

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Who is willing to help to find a mutual language, vocabulary, terminology or nomenclature?

Without alternative we fall back into default options