Topical formulations
Author: Dr Amanda Oakley, Dermatologist, Hamilton, New Zealand, 2010. Updated in February 2016.

General principals

Topical formulations are applied directly to the skin. Advantages of this include:

- Increased dose of medication where it is needed
- Reduced side effects and toxicity to other organs

Disadvantages include:

- Time consuming
- At times, complicated e.g. if several different formulations have been prescribed
- May be messy or uncomfortable

Topical formulations are made up in a vehicle, or base, which may be optimised for a particular site of the body or type of skin condition. The product may be designed to be moisturising or to maximise the penetration of an active ingredient, a medicine, into or through the skin.

The amount of the active ingredient that is absorbed through the skin depends on the following factors:

- Thin skin absorbs more than thick skin – skin thickness varies with body site, age and skin disorder.
- Skin barrier function disrupted by dermatitis, ichthyosis and keratolytic agents (such as salicylic acid) absorbs more than intact, normal skin.
- Occlusion increases absorption in skin folds, under dressings and greasy ointments.
- Small molecules are more easily absorbed through the skin than large molecules.
- Lipophilic compounds are better absorbed than hydrophilic compounds.
- Higher concentrations may penetrate more than lower concentrations.
- Other ingredients in the formulation may interact to increase or reduce potency or absorption rates.

Minor differences in formulation may make surprising differences to the effectiveness of a topical medication.

Quantity

How much topical medication to prescribe can challenge the most experienced dermatologist. It depends on:

- Vehicle
- Thickness of application
- Total area to be treated
- Frequency of application
• Duration of treatment

Expect 1 gram of cream to spread out over a 10-cm² area of skin; an ointment spreads a little further. The fingertip unit (0.5 g) is a guide to the amount of a cream or ointment needed to treat an area for a certain time. One fingertip unit covers one side of 2 flat hands and one gram covers both sides of the patient's two hands.

It takes 20 to 30 g of cream or ointment to cover an adult once.

Vehicles

Topical formulations contain an active ingredient, often a medication or drug or botanical, and a vehicle. The vehicle contains water, oil, alcohol or propylene glycol mixed with preservatives, emulsifiers, absorption promoters and fragrances.

The table below describes different formulations. Manufacturers interpret the definitions in various ways so a similar preparation might be called lotion, gel or cream.

<table>
<thead>
<tr>
<th>Classification of topical formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Solution</strong></td>
</tr>
<tr>
<td>Water or alcoholic lotion containing a dissolved powder</td>
</tr>
</tbody>
</table>

| **Lotion**                            |
| Usually considered thicker than a solution and more likely to contain oil as well as water or alcohol. A shake lotion separates into parts with time so needs to be shaken into suspension before use. |

| **Cream**                             |
| Thicker than a lotion, maintaining its shape, e.g., 50/50 emulsion of oil and water. Requires preservative to extend shelf life. Often moisturising. |

| **Ointment**                          |
| Semi-solid, water-free or nearly water-free (80% oil). Greasy, sticky, emollient, protective, occlusive. No need for preservative so contact allergy is rare. May include hydrocarbon (paraffin), wool fat, beeswax, macrogols, emulsifying wax, cetrimide or vegetable oil (olive oil, arachis oil, coconut oil). |

| **Gel**                               |
| Aqueous or alcoholic monophasic semisolid emulsion, often based on cellulose and liquefies upon contact with skin. Often includes preservatives and fragrances. |

| **Paste**                             |
| Concentrated suspension of oil, water and powder |

| **Aerosol foam or spray**             |
| Solution with pressurised propellant |

| **Powder**                           |
| Solid e.g. talc (a mineral) or corn starch (vegetable) |

| **Solid**                             |
| EG antiperspirant stick. May melt on reaching body temperature e.g. suppositories. |
Transdermal patch | Drug delivery system allows precise dosing: includes an adhesive.

Other terms used by cosmetic and pharmaceutical manufacturers include emulsion, paint, suspension, milk, syrup, collodion, balm and mist. Formulae may have mixed ingredients with more than one type of vehicle.

Factors in the choice of vehicle or base for a topical medication include the nature of the dermatosis and its site.

When your pharmacist makes up a mixture, it is extemporaneously compounded. The crude ingredients (often natural in origin) are called galenicals. They may be added to a vehicle or to a brand-name product.

**Nature of the dermatosis**
- Wet or oozy skin conditions: creams, lotions, drying pastes
- Dry scaly skin conditions: ointments, oils
- Inflamed skin: wet compresses, soaks followed by creams or ointments
- Cracks and sores: bland applications – avoid alcohol and acidic preparations

**Site**
- Palms and soles: ointment or cream
- Skin folds: cream or lotion
- Hairy areas: lotion, solution, gel, foam
- Mucosal surfaces: non-irritating formulations

**Special circumstances**

**Newborn babies**
The skin barrier function of full term newborn babies is nearly the same as in older children and adults. However, the barrier function in premature babies is markedly impaired.

The surface area of a baby is proportionally much greater than that of an adult. Organs such as liver, kidneys, blood and central nervous system are not fully developed. This means topically applied medications can be more likely to result in side effects and toxicity.

**Pregnancy and lactation**
Like oral medicines, some topical medications may be unsafe during pregnancy. These include:

- Podophyllin
- Dithranol
- 5-Fluorouracil
- Salicylic acid

Medications are classified according to their risk. The FDA classification system is often used.

Pregnancy categories used in New Zealand
<table>
<thead>
<tr>
<th>Category</th>
<th>Drugs that have been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category B1</td>
<td>Drugs that have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals[1] have not shown evidence of an increased occurrence of fetal damage.</td>
</tr>
<tr>
<td>Category B2</td>
<td>Drugs that have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals[1] are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.</td>
</tr>
<tr>
<td>Category B3</td>
<td>Drugs that have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals[1] have shown evidence of an increased occurrence of fetal damage, the significance of which is considered uncertain in humans.</td>
</tr>
<tr>
<td>Category C</td>
<td>Drugs that, owing to their pharmacological effects, have caused or maybe suspected of causing harmful effects on the human fetus or neonate without causing malformations. These effects may be reversible.</td>
</tr>
<tr>
<td>Category D</td>
<td>Drugs that have caused, are suspected to have caused or may be expected to cause an increased incidence of human fetal malformations or irreversible damage. These drugs may also have adverse pharmacological effects.</td>
</tr>
<tr>
<td>Category X</td>
<td>Drugs that have such a high risk of causing permanent damage to the fetus that they should not be used in pregnancy or when there is a possibility of pregnancy.</td>
</tr>
</tbody>
</table>

**Tips for using topical agents**

- Topical steroids and emollients are more effective if the skin is slightly wet. So the most effective time to apply them is within 3 minutes after a bath or shower. Apply the steroid to active areas only. If you are also prescribed emollient, wait a few minutes for the topical steroid to penetrate, then apply emollient widely.
- Complaints that products sting on facial skin are common, especially if the skin is damp at the time of application. Wait 20 minutes and the stinging is often much less troublesome.
- Stinging is common with lotions and creams and sometimes also occurs with ointments. A change of formulation rather than medicament may solve the problem. Sometimes it is best to put up with stinging, which often only lasts a few minutes, because after a few applications of an effective treatment the skin heals and stinging lessens.
- If it is difficult to squeeze out a cream or ointment, cut off the end of tube. Note that this may invalidate the expiry date and increase the chance of contamination of the product.

**Related information**

**References:**
129 Other Topical Medications.

**On DermNet NZ:**
- Topical treatments

**Other websites:**
- Pformulate Pharmaceutical Formulation Databases and Resources

**Books about skin diseases:**
See the DermNet NZ bookstore

DermNet NZ does not provide an online consultation service. If you have any concerns with your skin or its treatment, see a dermatologist for advice.