

Transdermal Ibuprofen Patch

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Introduction

- ▶ NSAID for pain and inflammation reduction
 - Non-steroidal anti-inflammatory drugs
- ▶ Localized Pain Patch
 - Alternative to oral dosage and injections
 - Reservoir Type
- ▶ Ibuprofen

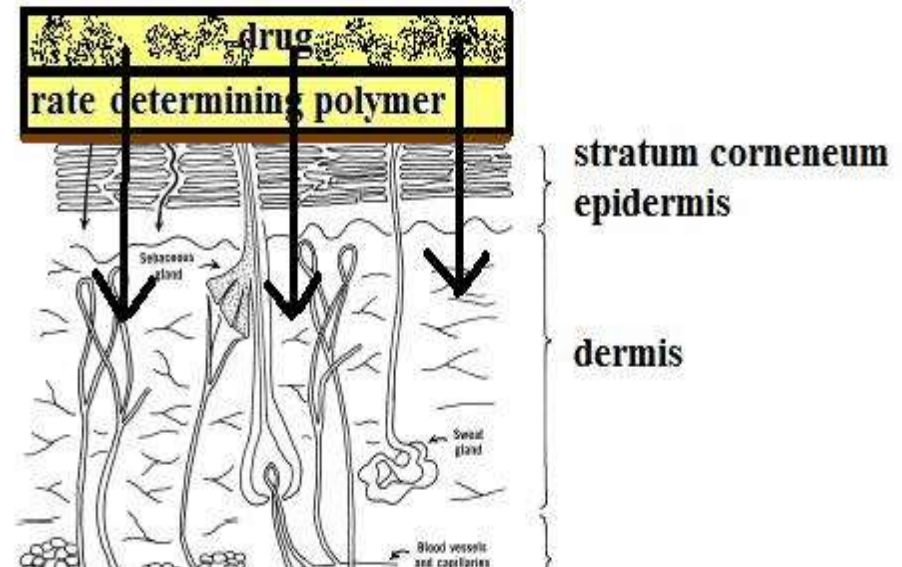


Business Opportunity

- ▶ Topical pain and anti-inflammatory patch
 - Marketable to arthritis sufferers and people with injuries
 - Those who would otherwise take an oral dose
- ▶ Drug Delivery
 - Drugs will reach area faster
 - Drug will not have to circulate through body

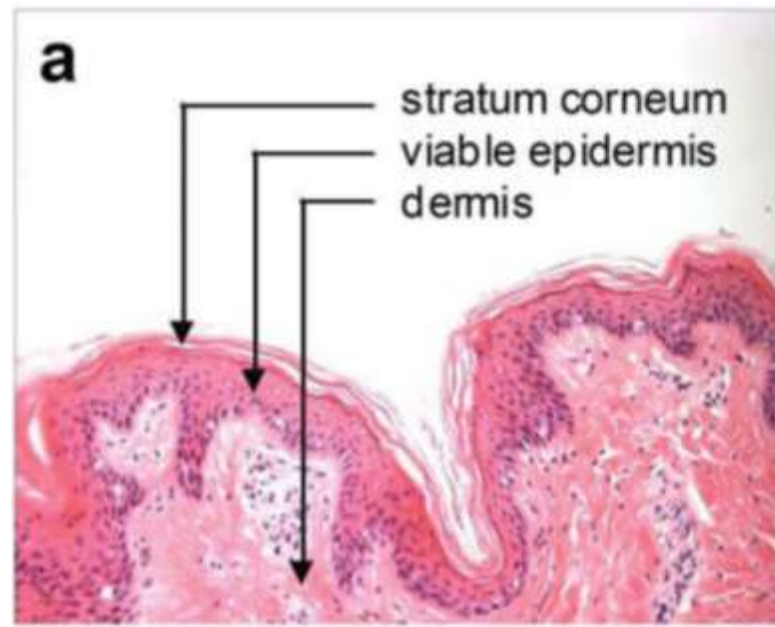
Transdermal Drug Delivery

- ▶ Transdermal Patch
 - Combination device
 - Directly on the skin for drug to diffuse
- ▶ Alternative to other drug therapies.
- ▶ Several types of patches




How It Works

- ▶ Overcomes the natural barriers in the skin
 - Use of an enhancer to disrupt the epidermis
 - Variations in the skin make this difficult
 - Drug formulation must be conducive to transport i.e. low molecular weight




Pros and Cons

▶ Advantages

- Application is easy and painless
 - Medication release is rapid and highly controlled
 - Do not pass through the whole body
 - Do not use needles
 - Easy administration lends to high compliance
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Pros and Cons

▶ Disadvantages

- Adhesives can cause irritations
 - Irritation in the skin can interfere with drug diffusion
 - Large molecules cannot pass through the skin
 - Limits on dosing size
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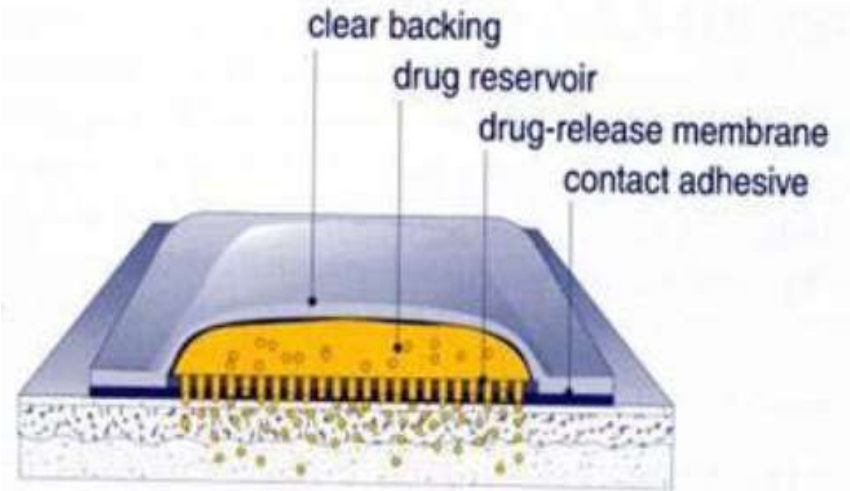
Patch Types

- ▶ Two categories
 - Passive Transport
 - Active Transport
- ▶ Types
 - Single layer drug-in-adhesive
 - Multi layer drug-in-adhesive
 - Monolithic patch
 - Vapor patch
 - Reservoir patch

Patch Overview

▶ Our Patch


- Type: Reservoir
 - Drug depot: Ibuprofen, enhancers, and gelling component
 - Adhesive/Membrane: Porous rate control
 - Backing: Occlusive dressing
- ▶ Benefit: Tight control of drug release
- ▶ Drawback: Higher doses of the residual drug




Patch Information

- ▶ **Liner**
 - Durable; no interference with mechanism of use
 - 3M - Scotch Pak
- ▶ **Backing Layer**
 - High oxygen transmission rate
 - Polyethylene
- ▶ **Membrane Layer**
 - Chemically inert
 - Ethylene vinyl acetate
- ▶ **Adhesive Layer**
 - Hypoallergenic
 - Polyisobutylene

Safety Concerns

- ▶ FDA
 - Drug approval
 - Develop in vitro (In lab) and in vivo (animal testing)
 - Clinical trials
 - ▶ Environmental Consideration
 - Contract chemical disposal company
 - ▶ Safety Issues
 - Clear instructions for use
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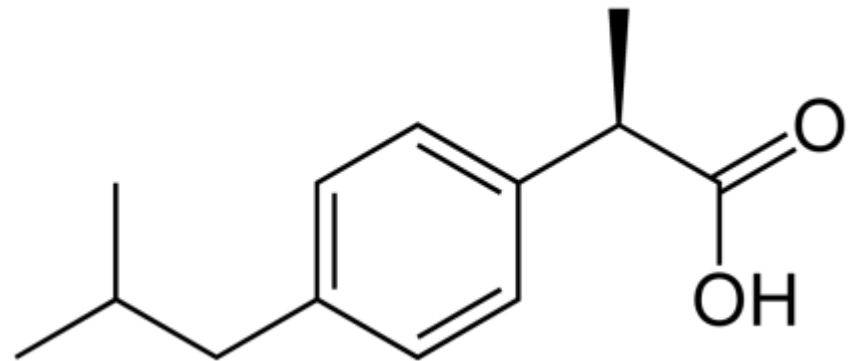
Patch Summary

- ▶ Many advantages to pills or injections
 - ▶ Reservoir patch allows better regulation of drug release
 - ▶ Chosen materials to optimize drug delivery and minimize risk for use
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Drug Information

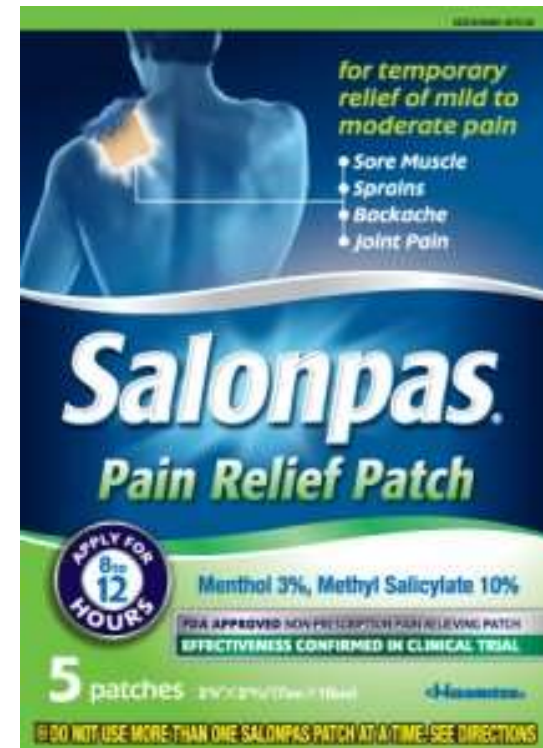
▶ Ibuprofen

- NSAID and well know
- Propionic acid derivative
- Treats the symptoms of rheumatoid and osteoarthritis
- 400 mg of ibuprofen recommended for mild to moderate pain every 4-6 hours



Alternative Products

- ▶ Current Products
 - Nurofen
 - 5% w/w ibuprofen
 - Only In UK
 - Salonpas
 - Aspirin patch
 - Marketed in US



Drug Delivery

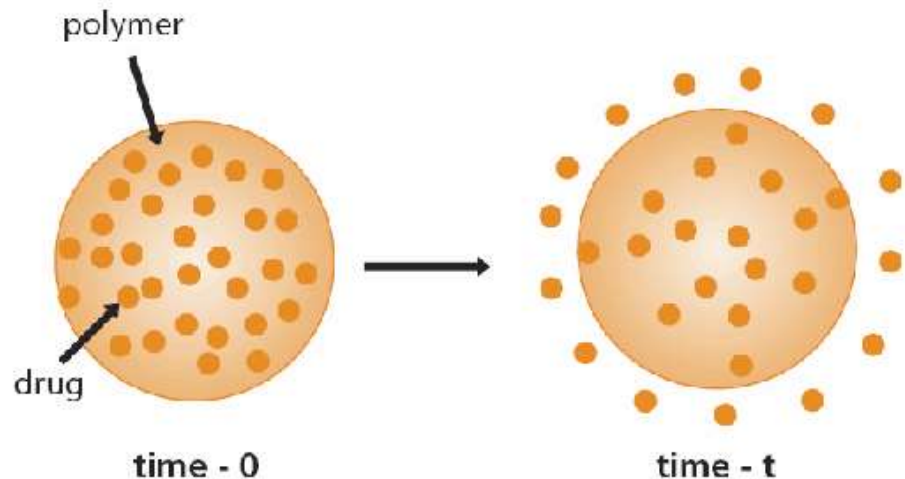
▶ Gel

- 5% w/w ibuprofen
- 10% w/w menthol (terepene)
 - Classified by the FDA as safe and effective adsorption promoter
- Palm olein esters
 - Hydrate the skin
 - Enhances transdermal delivery
- Triethanolamine, sodium benzoate and carbopol

▶ Better than Nurofen gel

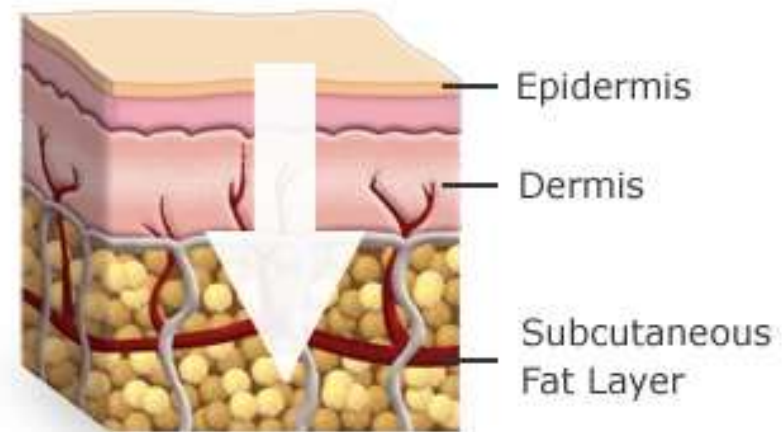
Drug Delivery

- ▶ Comparison with marketed product
 - Increase flux of drug
 - 1.1-1.6 times
 - Ibuprofen can transfer faster than in nurofen gel
- ▶ Increased Dose
 - Increase the amount of drug in the gel
 - Increase wt. % of ibuprofen



Drug Summary

- ▶ An Ibuprofen gel can achieve therapeutic dosing using a transdermal delivery system
 - Terpenes and palm olein esters
 - Increased solubility
 - Increased percentage permeated
 - Increased adsorption
 - Higher flux of drug



Production

▶ Doyen Medipharm

- Produces patch production systems
 - Backing, gel, membrane, adhesive and protective seal
- Packages patches individually as well as combines them into cartons for sale



Production


DOYEN
MEDIPHARM 



Economics

- ▶ \$1.5 - \$3 million per system
 - 250 patches per minute, 50 million patches per year
 - Estimated costs for tanks
 - \$1.2 million in clean room costs
- ▶ Net Present Value
 - \$269 million in 20 years
- ▶ Internal Rate of Return
 - 46.8%
- ▶ Estimated \$1.5 per patch
 - Comparable to Salonpas patch
 - Did not include the cost of the patch materials
 - Does not represent the R&D FDA medical trials costs

Conclusion

- ▶ Viable option for pain sufferers
 - ▶ The drug can be promoted through the skin
 - Increased flux, adsorption, and solubility over marketed product
 - ▶ Acceptable return on investment
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Questions?

