

The Pain Killers

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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

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
- 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

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; resistant to cracking or reacting in any way with the 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

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

Drug Information

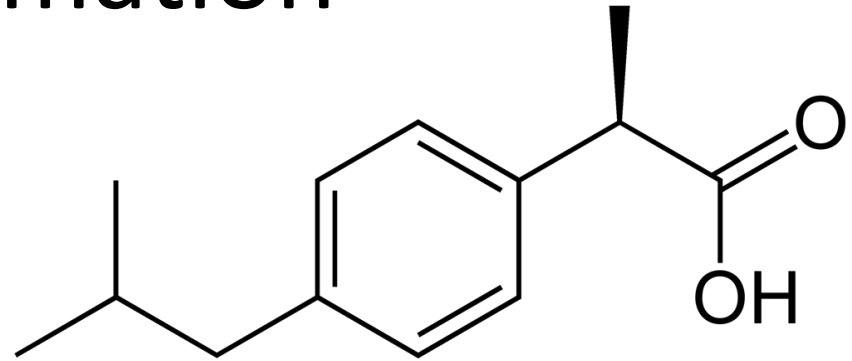
- Ibuprofen

- NSAID and well know

- Propionic acid derivative

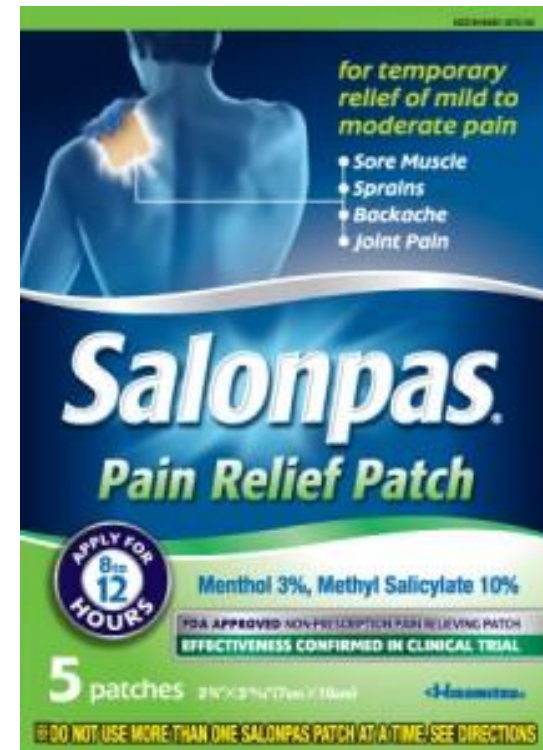
- Treats the symptoms of rheumatoid and osteoarthritis

- 400 mg of ibuprofen recommended for mild to moderate pain every 4-6 hours



Drug Delivery

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

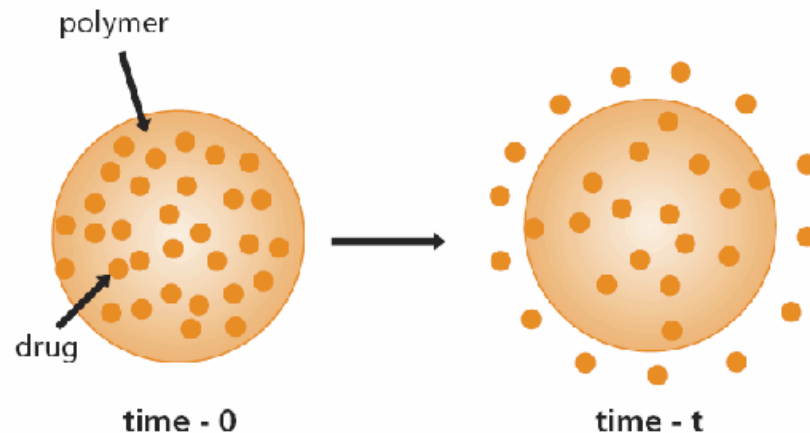


Drug Delivery

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

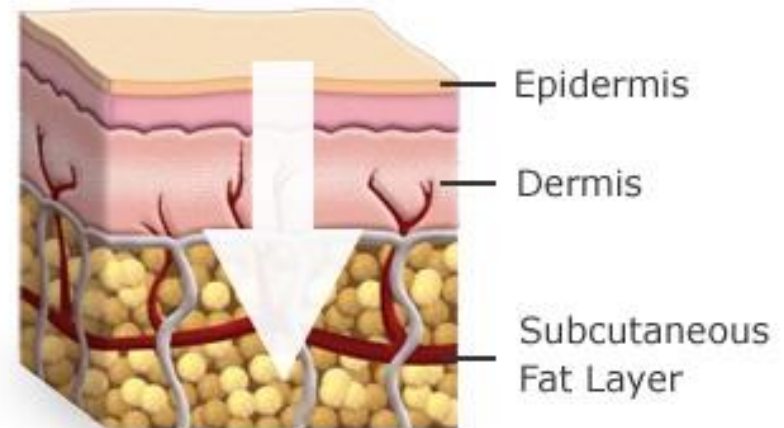
Drug Delivery

- 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 sorption
 - Higher flux of drug



Production

DOYEN
MEDIPHARM 



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



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, percentage permeated, sorption, and solubility than marketed product
- Acceptable return on investment

Questions?

