

INNOVATION IN MOUTH LESIONS AND MOUTH ULCERS



Summary

The problem and the market

Zoralan Oral: activity and formulation

Zoralan Oral vs. competition

Our offer

THE PROBLEM AND THE MARKET

The problem (1)

A. MOUTH ULCERS

open sores in the mouth



- About 20% of population suffers from mouth ulcers *
 - Mainly women: 56%, especially category 20-40 year
- **Causes:** physical abrasion, acidic fruit, infection, other medical condition, stress, medication, hormonal fluctuations,...

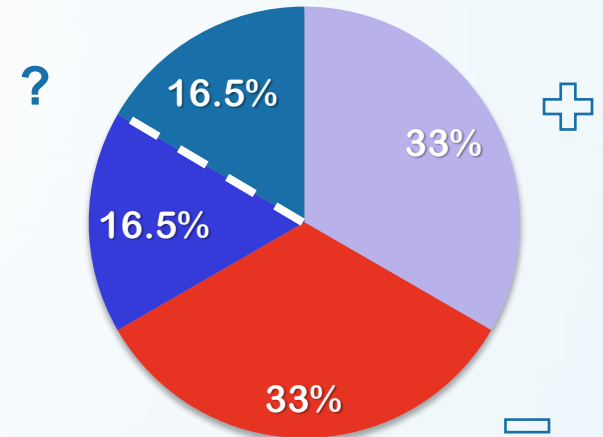
The problem (2)

B. DENTAL BRACES

- Irritate and abrade the cheeks and tongue
- Make cleaning of the teeth more difficult, resulting in elevated levels of bacteria in the mouth.



Higher level of infection



50% of adolescents

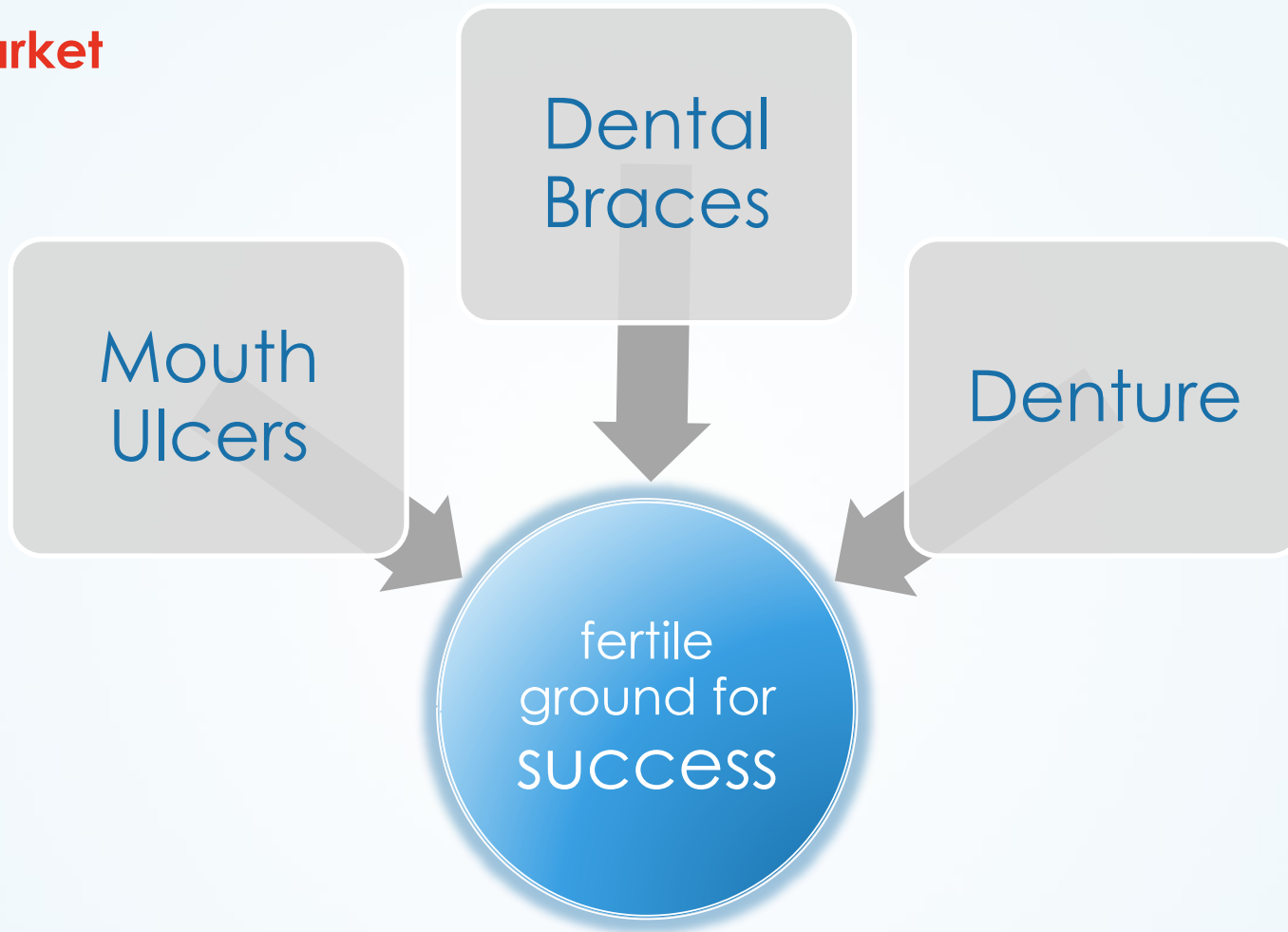
The problem (3)

C. DENTURES: aging population → dentures ↑

Denture stomatitis is a common oral mucosal lesion in the United States and Western Europe. Prevalence rates up to 18.3% in adults aged 65-74*



The market

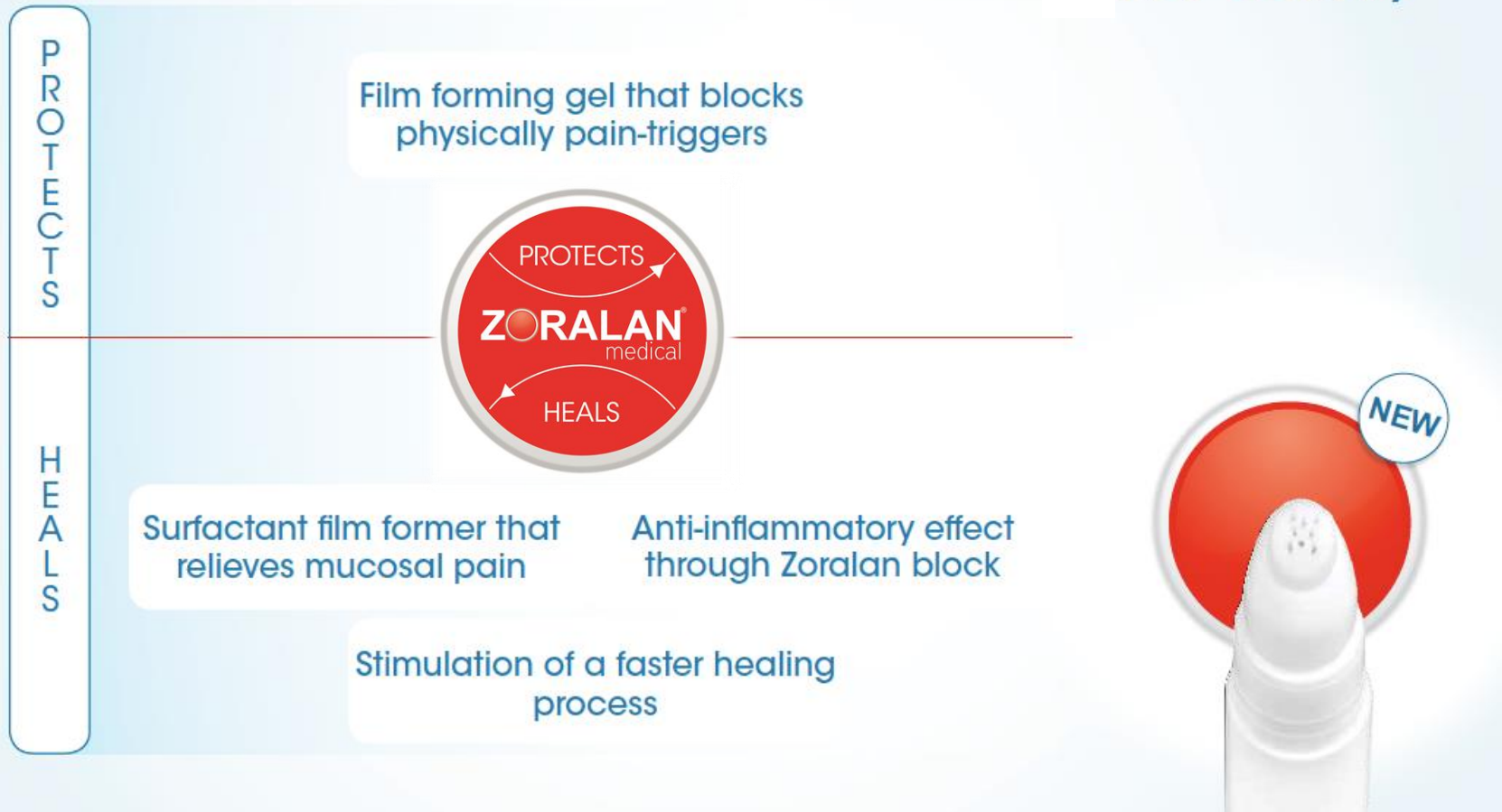


ZORALAN ORAL: ACTIVITY AND FORMULATION

Gives mouth lesions & ulcers no chance



4 in-1 activity



Unique formulation

Good adhesive film

Good film former:

contains a combination of PVP and a methylvinyl/ maleic acid copolymer.

Improved adhesive properties:

inclusion of polysaccharides of Larix decidua tree (Larch) for stickiness to mucosa

Improved water barrier

Unique combination of cellulose with larch polysaccharides

Soothing and pleasant

Painless use.

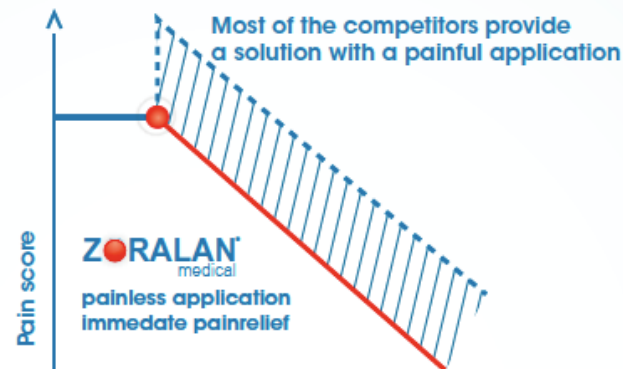
No stinging : No alcohol

Pleasant mouthfeel from licorice extracted glycyrrhethinic acid

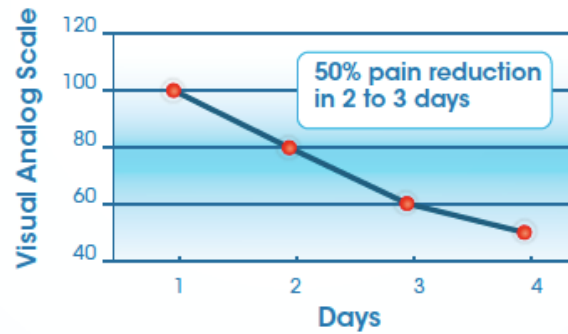


Convenient pen applicator

- Forms protective barrier without extra pain

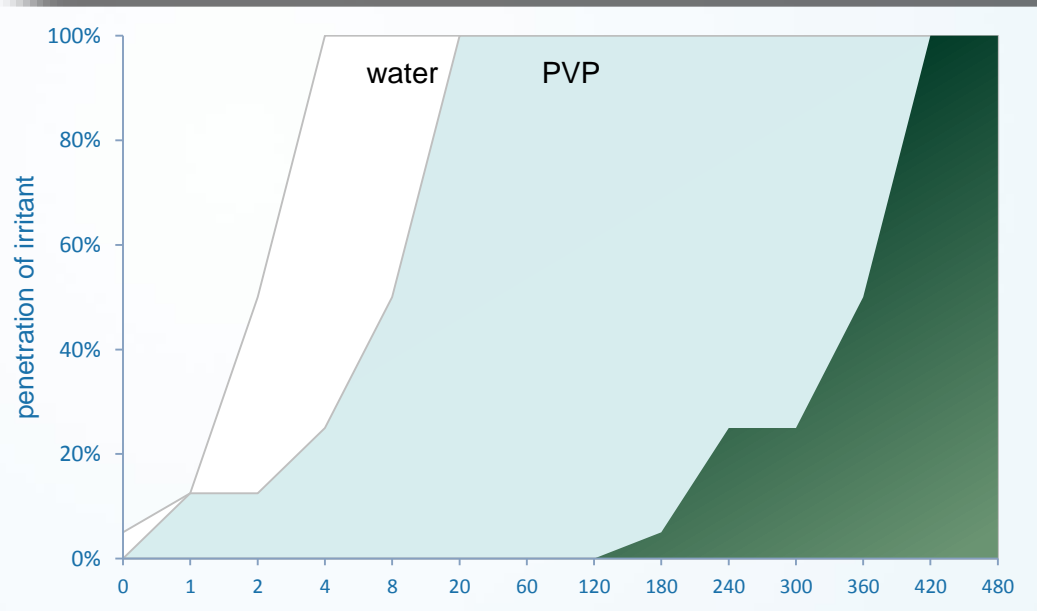
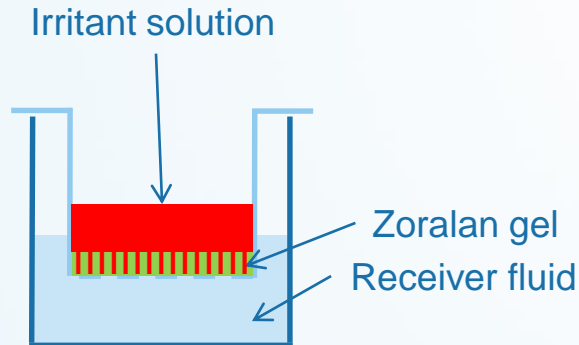


- Immediate pain relief



Barrier

- Application of irritants such as glucose or fruit juice (pH 3) on tested product
 - Apply Zoralan gel on semi-permeable wells with a receiver compartment
 - Put irritant on top of the gel barrier
 - Compare with controls such as water, PVP other gels
 - As a function of time, monitor the concentration of irritant in the receiver compartment



Measured glucose concentration (%) vs contact time (min)

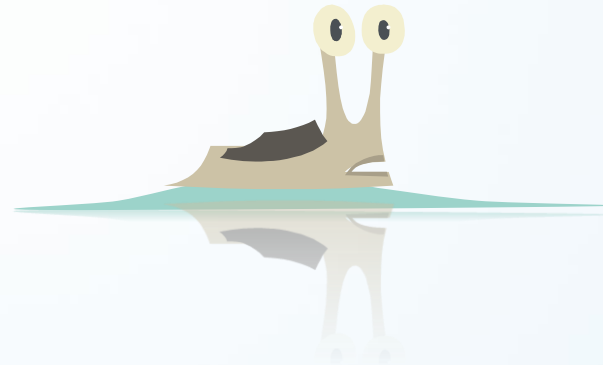
Painless – Physiological

• Slug (*Arion lusitanicus*) Mucosal Irritation Potency Test

- placing the slugs (n=5) on undiluted test item for contact periods of 30 minutes for five successive days
- measuring the amount of mucus produced
- phosphate buffered saline is added near the foot of the slug
- measure after each 30-min. contact period in PBS:
 - the protein and enzyme release (lactate dehydrogenase [LDH] and alkaline phosphatase [ALP]) from the body wall of the slugs
- with some irritants there is an obvious flight reaction :

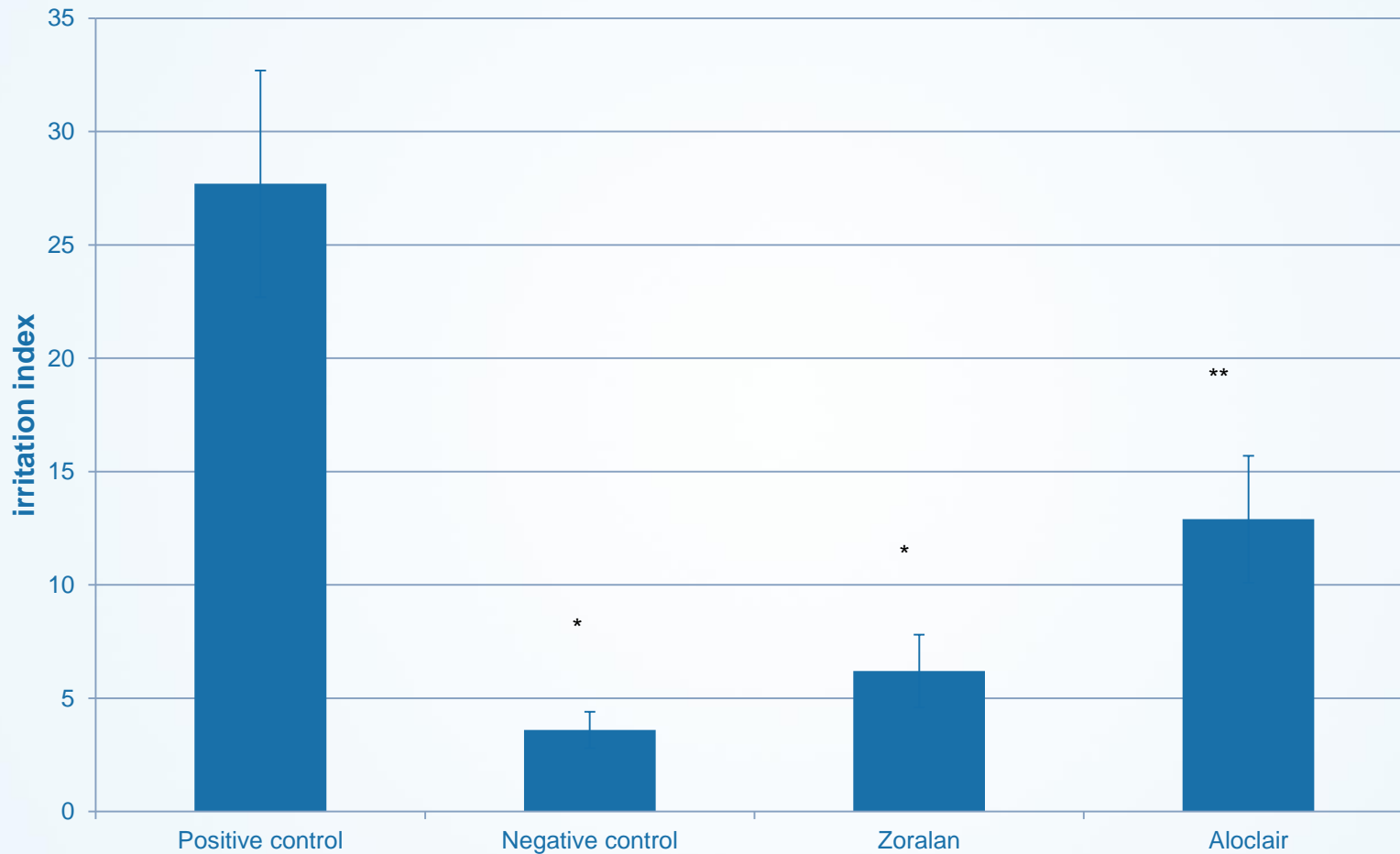


Zoralan



Competitor

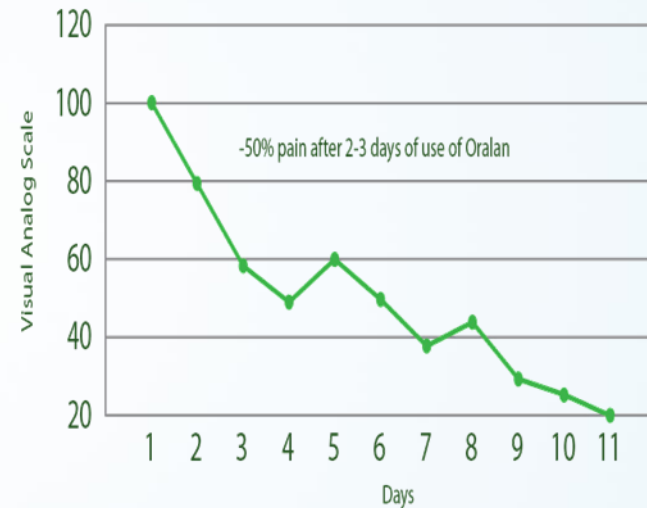
Results : Slug (*Arion lusitanicus*) Mucosal Irritation Potency Test



Clinically Tested

Excellent results:

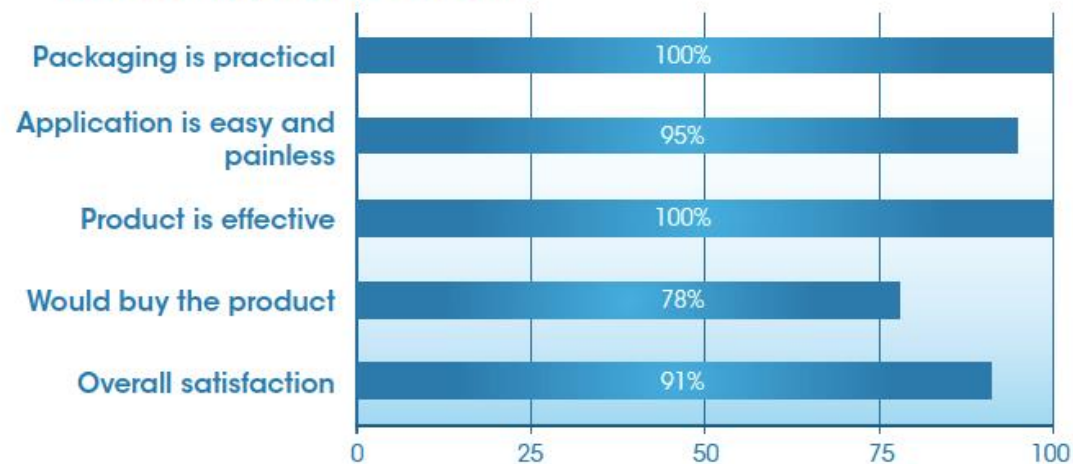
- Controlled cross-over study with aggressive orange juice stimulation
- **40% Less pain** in treated group Vs. Control group (regular water-based film former)
- After 2 days: pain reduction of **- 50%**



Clinically Tested

A NEW WINNER IN MOUTH LESIONS TREATMENT !

Excellent appreciation by users!



Source: Dermscan-Lyon, 25 participants



ZORALAN ORAL VS. COMPETITION

Solvent based



- Mouth ulcers only
- Stinging**
- Toxic solvent**
- Film/ no film
- Difficult application
- No instant relief**
- Cauterizing : adults only**



Water based



- Less/no sting
- Child proof
- Film forming
- Difficult dosing**
- No instant relief**
- Mild protection only**



ZORALAN



- Mouth lesions + ulcers
- No stinging
- Child proof
- Film forming
- Easy to dose/apply
- Instant relief
- Age 2 and older



Solvent based



(Brush)
Classical approach

Water based



(Gel in tube)
Second generation

ZORALAN

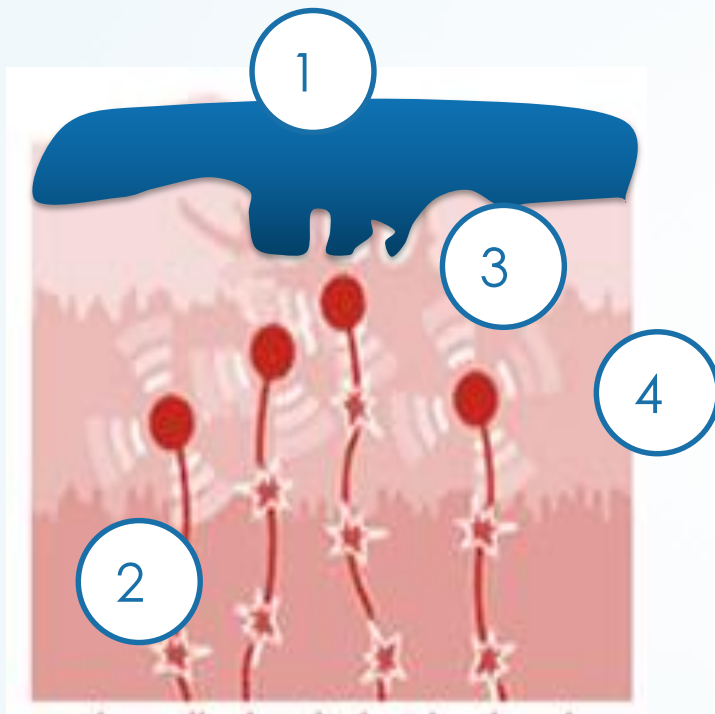


- Mouth lesions + ulcers
- No stinging
- Child proof
- Film forming
- Easy to dose/apply
- Instant relief
- Age 2 and older

Third generation
(Convenient and accurate pen)



The superiority of Zoralan

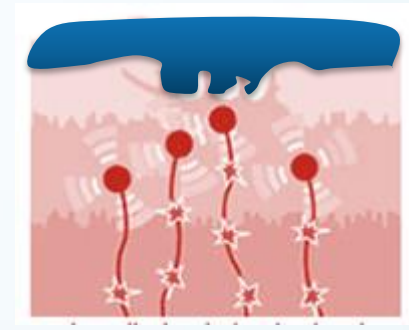
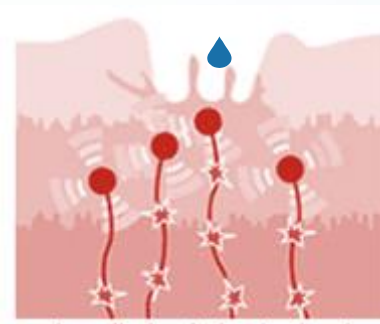
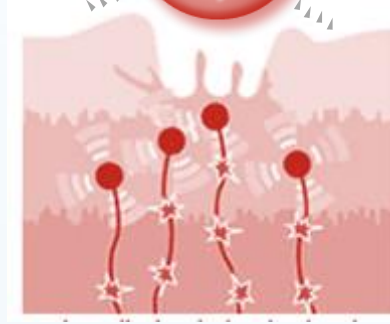
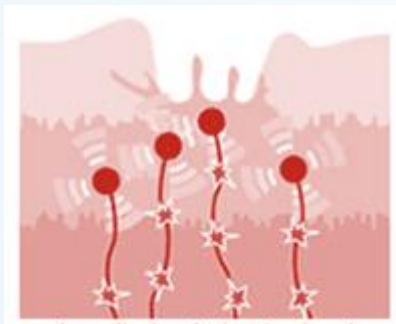
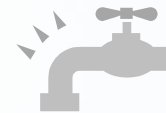


Zoralan: 4-in-1 treatment

- 1 Blocks external pain triggers
- 2 Soothing effect on irritated nerve endings
- 3 The gel creates an ideal woundhealing environment
- 4 Anti-inflammatory effect

The superiority of Zoralan (2)

Schematic representation of main activities



OUR OFFER

Our offer

- Gel pen more hygienic and easier
- Applies an even and flexible film on the ulcer
- A thin layer remains after disappearance of apparent mouthfeel
- Easy to apply, even in difficult corners
- 60 applications per pen
- MEDEV Class 1



Indications and claims

Unique painless treatment of mouth lesions and mouth ulcers

- Immediate pain relief
- Faster healing
- Forms protective barrier
- Clinically tested

Can be used from 2 years old

Zoralan[®] contains a sticky polymer that deposits a thin and unnoticeable film over the ulcer or lesion. This forms a barrier against food, saliva and acidic drinks.

Injuries resulting from bad fitting prostheses or braces can also be treated this way.

Application

- Adults (>12 years):

3-10 applications per day until the symptoms have disappeared.

- Children (2-12 years):

a maximum of 3 applications per day until the symptoms have disappeared.

Shelf life

24 months

12 months in use stability

Standard packaging

A pen with 4C label, 1C leaflet, 4C box

A succes story !!!

Launch : september 2012

Numeric distribution : 1200 shops

After 2 months (end of October) :

sales of +/- 900 pcs /week



Conclusions

- MOUTH LESIONS AND PAIN constitute a growing segment, due to the wider use of dental braces (adolescents) and dentures (seniors) -> **big potential**
- A lot of customers are DISSAPOINTED with current products in these indications
- Zoralan medical offers a 4 IN 1 APPROACH in the treatment of mouth lesions + mouth ulcers → high consumer satisfaction
- Oystershell offers an excellent product innovation for IMMEDIATE LAUNCH

