Advancing the Science of Wound Care™

Frequently Asked Questions About SockIt! ™ Oral Pain Gel

Drug-Free Pain Management

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FREQUENTLY ASKED QUESTIONS ABOUT SOCKIT!™ ORAL PAIN GEL

1. What ingredients are in SockIt! gel?

The gel is composed of water, food buffers (to adjust the pH to that of saliva), food flavoring agents and food thickeners.

2. Is SockIt! gel covered by insurance?

Companies that have reimbursed for treatment with SockIt! gel include Aetna, United Healthcare, Cigna, Delta Dental, Comp Dent and Met Life. Insurance code 9910 (desensitizing medicament) is used.

3. Has the FDA authorized the sale of this product?

Yes. FDA has reviewed our formula and claims and has authorized us to market SockIt! gel as a medical device using the claims listed on the label. FDA routinely audits our manufacturing facility to ensure that we are marketing under the quality systems regulations (QSR) of the FDA.

4. How does SockIt! gel work?

First, the gel adheres to injured oral tissues and helps protect the wound from further irritation and contamination. It is buffered to have a pH compatible with saliva so that it is soothing to oral tissues.

Second, the gel matrix prevents the initiation of a pain signal. It does so by working outside nerve cells where it binds sodium ions and prevents their entry into the nerve cells. It is not absorbed into tissues or the bloodstream and it does not numb tissues as do benzocaine, lidocaine and other topical anesthetics.

5. Since SockIt! gel is composed entirely of food ingredients, will it contribute to dental caries and other microbial infections in the mouth, such as periodontitis, endodontic infections, and infective endocarditis.

SockIt! Oral Pain Gel ***will not*** promote growth of harmful bacteria in the mouth. Beta-linked polysaccharides are used as the thickening agent in the formulation because they do not break down in the mouth and thus do not 'feed' the growth of bacteria. Essential oils are used for their very powerful antimicrobial properties, as well as their flavor. Together, the polysaccharides and essential oils in the formula mechanically trap bacteria and pull Ca from their cell membranes, thereby disrupting the membranes and killing the bacteria. This technology can often control bacteria ***better than*** commonly used synthetic preservatives, antibiotics or antiseptics (biocides), which are harmful to healthy cells as well as to pathogenic microbes.

Microbial testing of SockIt! gel against pathogens implicated in dental caries, periodontitis, endodontic infections, and infective endocarditis showed that **SockIt! gel** kills virtually all organisms in ***30 seconds*** (Figures 1-4).

In contrast, **sodium hypochlorite**, the most common disinfectant used in endodontics, required ***30 minutes*** at the recommended concentration (0.5%) to inhibit the growth of S. aureus, E. faecalis and C. albicans (Vianna 2004); but sodium hypochlorite is highly toxic to human periodontal ligament cells at this concentration (Sedgley 2006). **Chlorhexidine** is used widely as an antimicrobial agent in periodontal disease and caries prevention. At a concentration of 0.2%, chlorhexidine required ***10 minutes*** of continuous cotact to inhibit growth of S. aureus and C. albicans and ***2 hours*** to inhibit E. faecalis (Vianna 2004). However, at concentrations as low as 0.0001%, chlorhexidine is also highly cytotoxic to human periodontal ligament cells (Chang 2001; Hidalgo 2001).

With these data, you need have no concern that SockIt! gel will contribute to dental caries and other microbial infections in the mouth. Also, with SockIt! gel, there is no concern that damage will occur to the healthy cells that are required for the healing process to proceed optimally.

Figure 1: Kill Time (Log Reduction) of SockIt! Gel (G0416A) Against Organisms Implicated in <u>DENTAL CARIES</u>

Microorganism	30 sec	5 min	1 hr	6 hr	12 hr	24 hr
S. mutans (ATCC 33402) (Inoculation level = 1.04x106)						
Average (cfu/ml)	100	25	No Growth	No Growth	No Growth	No Growth
Log Reduction	3.75	4.62	6.02	6.02	6.02	6.02
S. sobrinus (ATCC 33478) (Inoculation level = 6.57x105)						
Average (cfu/ml)	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
Log Reduction	6.08	5.82	5.82	5.82	5.82	5.82
L. fermentum (ATCC 9338) (Inoculation level = 5.05x105)						
Average (cfu/ml)	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
Log Reduction	5.28	5.7	5.7	5.7	5.7	5.7
Actinomyces viscosus (ATCC 19246) (Inoculation level = 5.05x105)						
Average (cfu/ml)	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
Log Reduction	5.7	5.7	5.7	5.7	5.7	5.7

SockIt! gel was effective against all organisms tested within 30 seconds.

Figure 2: Kill Time (Log Reduction) of SockIt! Gel (G0416A) Against Organisms Implicated in PERIODONTITIS

Microorganism	30 sec	5 min	1 hr	6 hr	12 hr	24 hr
A. actinomycetemcomitans (ATCC 43718) (Inoculation level = 1.41 x 106)						
Average (cfu/ml)	190	60	No Growth	No Growth	No Growth	No Growth
Log Reduction	2.42	4.37	6.15	6.15	6.15	6.15
T. forsythensis (ATCC 43037) (Inoculation level = 1.44 x 106)						
Average (cfu/ml)	555	110	No Growth	No Growth	No Growth	No Growth
Log Reduction	2.31	4.12	6.16	6.16	6.16	6.16
P. gingivalis (ATCC 49417) (Inoculation level = 5.05 x 105)						
Average (cfu/ml)	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
Log Reduction	4.7	5.75	5.75	5.75	5.75	5.75
F. nucleatum (ATCC 10953) (Inoculation level = 5.05 x 105)						
Average (cfu/ml)	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
Log Reduction	5.75	5.05	5.7	5.7	5.7	5.7

SockIt! gel was effective against all organisms tested within 30 seconds.

Figure 3: Kill Time (Log Reduction) of SockIt! Gel (G0416A) Against Organisms Implicated in ENDODONTIC INFECTIONS

Microorganism	30 sec	5 min	1 hr	6 hr	12 hr	24 hr
Enterococcus spp. (ATCC 19952) (Inoculation level = 6.06x105)						
Average (cfu/ml)	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
Log Reduction	6.51	5.78	5.78	5.78	5.78	5.78
E. faecalis (ATCC 51299) (Inoculation level = 9.85x105)						
Average (cfu/ml)	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
Log Reduction	5.99	5.99	5.99	5.99	5.99	5.99

SockIt! gel was effective against E. faecalis within 30 seconds.

Figure 4: Kill Time (Log Reduction) of SockIt! Gel (G0416A) Against Organisms Implicated in INFECTIVE ENDOCARDITIS

Microorganism	30 sec	5 min	1 hr	6 hr	12 hr	24 hr
S. mutans (ATCC 33402) (Inoculation level = 10x1.04x106)						
Average (cfu/ml)	100	25	No Growth	No Growth	No Growth	No Growth
Log Reduction	3.75	4.62	6.02	6.02	6.02	6.02
S. sobrinus(ATCC 33478) (Inoculation level = 6.57x105)						
Average (cfu/ml)	No Growth	No Growth	No Growth	No Growth	No Growth	No Growth
Log Reduction	6.08	5.82	5.82	5.82	5.82	5.82

6. Are there any known interactions between SockIt! gel and any medications, herbs, supplements or food?

No.

7. What side effects are known to be associated with the product?

None.

8. How often can the gel safely be reapplied?

As often as needed for unlimited applications.

9. Is the product safe for children?

Yes. SockIt! gel is composed of 100% food ingredients and is extremely safe. A box of 24 syringes (about 240 grams of SockIt! gel) can be swallowed without any concern for toxicity.

10. How should I store SockIt! gel?

It should be stored at room temperature or in a refrigerator. It should not be frozen.

11. Could any of SockIt! gel's ingredients cause allergies?

SockIt! gel does not contain ingredients that commonly cause allergies. FDA reviewed the gel's ingredients and required no warnings on the label as must be included for products that contain ingredients such as wheat, peanuts, tree nuts, soy, milk, gluten, etc. However, people can have allergies to other food ingredients. Patients who think they are having an allergic reaction should simply stop using the product.

12. Does SockIt! gel help control bleeding?

Certain of the ingredients in SockIt! gel are long-chain polysaccharides. These molecules are known to assist in blood clotting.

13. The product burns a little on ulcers when first applied. Is that a concern?

Just as some spices can feel "hot" to oral tissues, SockIt! gel may produce a mild, hot sensation in some individuals upon first application (usually limited to canker sores). This sensation quickly dissipates and lessens with additional applications. The gel does not harm the tissue.

14. Does the use of other oral products such as mouthwash and toothpaste affect the performance of SockIt! gel?

SockIt! gel will eventually wash out of the affected area. If your patients eat or drink, brush their teeth, or rinse their mouths out, they will probably need to reapply the gel.

15. Does the gel interfere with the taste of food?

SockIt! gel has a very mild flavor. Most people report that it doesn't interfere with their sense of taste.

16. Does the product have gluten in it?

No.

17. Is the product sterile?

SockIt! gel is not sterile. It contains food-grade preservatives, and passes the USP preservative challenge test. (PD07008)

References

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