

Extract from:

Toxicology and Teratology Review of the Active Ingredients of Professional Therapy Muscle Care Products

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Abstract

This review examines the commercially available topical analgesic, Professional Therapy MuscleCare, to determine the general safety and potential developmental and reproductive effects of both the ointment and roll-on gel. Reported and theoretical adverse effects from systemic exposure are detailed.

Some of the active ingredients of the PTMC ointment and roll-on are powerful toxins when ingested orally (e.g. camphor and methyl salicylate). In addition to their general toxicity, some of the active ingredients have been shown to cause adverse developmental and reproductive effects in animal and human studies when used in high dosage. The doses represented in these studies however are hundreds to thousands fold greater than those available systemically after topical use of PTMC products at the recommended maximum dose of 10 grams per day.

Therefore,, this review provides evidence that, when used as indicated, PTMC is safe for pregnant women and their unborn babies as well as for lactating women.

1.0 Introduction: Professional Therapy MuscleCare Products

The line of Professional Therapy MuscleCare (PTMC) products includes an ointment and roll-on gel containing a combination of ingredients that is recommended for topical application to areas of body soreness for the relief of pain due to inflammation, muscle strains and spasms, and joint arthritis.

Pregnancy is associated with increased rates of muscle and joint aches, sprains and inflammation (Foti et al, 2000). Due to fears of fetal risk from systemically used medicinal drugs, many women do not optimally treat these symptoms, and for them the use of a topical preparation is attractive. A recent randomized control study has shown the effectiveness of PTMC products in non pregnant individuals (Avrahami et al, 2012). Yet, to allow safe use in pregnancy, one must carefully review the fetotoxic potential of PTMC ingredients.

The objective of this paper was to review the fetal safety of PTMC ingredients for both the ointment and roll-on gel in order to allow an evidence-based framework for its use during gestation.

1.1 Methods

We reviewed all existing toxicological evidence for the ingredients found within PTMC, including the concentration of each compound within the cream, by searching medical and toxicological databases, including Web of Science, EMBASE, Medline and Micromedix. Where available, an attempt has been made to focus on studies employing external (dermal) rather than internal (oral) exposure to the ingredients, and to highlight studies carried out on humans rather than lab animals or *in vitro* cell culture systems.

The review of general toxicology for each ingredient is followed by the available animal and human data on fetal toxicology, followed by synthesizing an overall fetal safety estimate.

PTMC as a formulation has not been studied *in vitro* or *in vivo*. Thus, safety and toxicology data are extrapolated from studies examining the ingredients contained in PTMC products alone or from studies using similar creams containing some of the ingredients found within PTMC. Invariably the compounds in similar creams are present at different ratios and other ingredients may be present (that are not found within PTMC) that could influence the properties of the cream. Additionally, when examining single ingredients, they will invariably be studied at different concentrations and many studies have been performed in animals alone. Thus, caution must be exercised in the extrapolation of data from other products to PTMC and from the wider literature.

1.4 Uses

PTMC is used as a topical analgesic.

The route of administration for PTMC products is strictly limited to external (dermal) application to areas of body soreness, and is recommended to be used at up to 10 grams per day.

PTMC is labeled for self-care relief of pain and inflammation associated with common ailments that include muscle aches and strains, spasms and osteoarthritis.

Its effectiveness has been validated by comparison to national OTC brands in a randomized double-blind clinical study where MuscleCare roll-on outperformed other national brands tested (Avrahami et al, 2012).

2.0 Human Exposure

The principal source of human exposure to PTMC occurs from dermal contact when using the ointment or roll-on gel for personal care. The components of PTMC remain on the skin for hours providing sufficient time for dermal absorption.

2.1 Doses Following Dermal Exposure

A 70 kg person applying 10 grams of MuscleCare Ointment or Roll-on Gel would topically receive:

| Active Ingredient | Amount received from ointment | | Amount received from roll-on gel | |
|-----------------------------|-------------------------------|-------|----------------------------------|-------|
| | Mg | Mg/kg | Mg | Mg/kg |
| MSM | 500 | 7.14 | 50 | 0.71 |
| Camphor | 300 | 4.28 | 300 | 4.28 |
| Menthol | 400 | 5.71 | 1000 | 14.28 |
| Methyl salicylate | 100 | 1.43 | -- | -- |
| Glucosamine sulfate | 300 | 4.28 | 20 | 0.28 |
| Sodium chondroitin sulfate | 10 | 0.14 | 10 | 0.14 |
| Eucalyptus Oil | 50 | 0.71 | 300 | 4.28 |
| Grape seed oil | 100 | 1.43 | -- | -- |
| Vitamin E | 100 | 1.43 | -- | -- |
| Thymol | 20 | 0.28 | -- | -- |
| Sea cucumber extract | 100 | 1.43 | -- | -- |
| Aloe barbadensis leaf juice | 10 | 0.14 | -- | -- |
| Peppermint oil | -- | -- | 300 | 4.28 |
| Boswellia | -- | -- | 70 | 1.0 |
| Ilex | -- | -- | 70 | 1.0 |
| Magnesium | 20 | 0.28 | 10 | 0.14 |

4.0 Synthesis of Findings

In general, women commonly hesitate to take systemic analgesics such as NSAIDs for pregnancy-related muscle and joint aches and pain, due to strong perception of teratogenic risk (Koren). As a result, women are commonly under treated for such conditions, with major impact on their quality of life. It is therefore important to assess the reproductive safety of topical preparations, which women are much more likely to accept during pregnancy.

Some of the active ingredients of PTMC products are potent toxins when used orally (e.g. camphor and methyl salicylate). Some of them have been shown to cause fetal damage in animal studies when used in high dosage. However, these doses are thousands of times larger than those available systemically after topical use at the recommended maximum dose of 10g/day of PTMC.

Hence, this review provides strong evidence that, when used as indicated, PTMC is safe for pregnant women and their unborn babies as well as lactating women and their infants.

5.0 References

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