Kolodium forte: Results of the PMCF Study

In 2024, ENEO Pharmaceuticals s.r.o. conducted a clinical study to further improve the treatment of warts using the medical device Kolodium forte.

Objectives

The aim of this PMCF study was to collect data on the course of treatment directly from patients for further analysis and evaluation using statistical methods. The feedback should help to improve the effectiveness of treatment methods.

Kolodium forte

Kolodium forte is a solution containing medicinal substances used for gentle removal of warts, corns, hardened and calloused skin.

The product contains kolodium (a nitrated solution of cellulose mixed with alcohol), salicylic acid, and lactic acid. Salicylic acid softens the outer layer of the skin and has the ability to dissolve intercellular substance through a keratolytic effect (separation of the upper, fully keratinized layer of the skin). This effect is supported by lactic acid which also has an etching effect and reduces hyperkeratosis.

The medicinal substance, celandine extract, contains not only the most effective alkaloid chelidonin but also a range of other alkaloids that exhibit antiviral and antifungal effects when used externally.

Another medicinal substance is purified turpentine essential oil from pine resin (Terebinthinae etheroleum rectificatum), which contains terpene compounds pinene, camphene and limonene. They act antiseptically, promote tissue blood circulation, increase the resorption of pathologically altered tissue, and contribute to the formation of granulation tissue.

The product also contains an extract from the non-woody parts of the Western Zerava (Thuja Occidentalis), which contains a number of monoterpenes. These substances reduce the production of sebum (they have an antiseboric effect) and have a toning and smoothing effect.

Data collection

The PMCF study on the treatment of warts using the medical device Kollodium forte took place from June to September 2024.

Data collection was carried out using CAWI (Computer Assisted Web Interviewing), where respondents completed online questionnaires programmed using the Survey Monkey platform.

Respondents are individuals who completed the questionnaire and underwent wart treatment/removal, either on themselves or on another person.

The conditions for the respondent to participate in the questionnaire survey were:
• used the product Kolodium forte for the treatment/removal of warts, either on themselves or on another person
• agreed to share clinical treatment data for scientific evaluation purposes
• data sharing was carried out by logging into the PMCF study questionnaire
• by registering, the respondent agreed to be included in the group of voluntary patients and began treatment
• after completing the treatment, the respondent registered again and answered questions about the course of treatment
• the questionnaire had a total of 20 questions and in order to be included in the evaluation, it was necessary to fully complete both parts of the questionnaire

Summary and Conclusions

1.) Respondents and Their Experience with Kolodium forte

Selection Based on Recommendation:

- The majority of respondents (51%) chose Kolodium forte based on recommendations from acquaintances (72 respondents).
- A pharmacist's recommendation influenced 25% (35 respondents).
- Other reasons were less frequent: online information (6%), recommendation by a dermatologist (4%), personal experience (13%), and recommendation by a paediatrician (1%).

Greatest Benefit of Kolodium forte:

- 51% of respondents (73 individuals) consider the product’s effectiveness to be its greatest benefit.
- 27% of respondents (38 individuals) appreciate the gentle, painless application.
- The presence of herbal ingredients and the fact that the product is made by a Czech manufacturer were important to smaller groups (9% each).
- 4% of respondents valued the product’s composition, and only one respondent mentioned the price as the main benefit.

Conclusions:

- **Gender vs. Recommendation, perceived benefit of the product:** The analysis did not show a statistically significant relationship between the gender of

respondents and their choice of the product based on recommendations, nor with the perceived benefit of the product.

- **Age and perceived benefit of the product:** Similarly, no statistically significant relationship was found between respondents' age and their perception of the product's greatest benefit, or their selection of the product based on recommendations.
- **Correlation:** The correlations between respondents' age and gender and both their perception of the product's main benefit and their decision to use the product based on recommendation were very weak and also statistically insignificant.

Final Summary:

The conducted tests show that neither gender nor age have a significant impact on the selection of Kolodium forte based on recommendations or on the perception of its main benefits. The most important factor for choosing the product is its effectiveness, which is appreciated by more than half of the respondents.

2.) Wart Morphology

Summary of results:

- Most patients had only one wart at the beginning of treatment. Age has no influence on the frequency of occurrence in this case.
- The majority of patients had a wart located on the sole of the foot. However, wart location was significantly influenced by age. Warts on the sole were most common in children under 18. In older patients, the proportion of warts on the sole was significantly lower, while warts on the hands or other areas were more frequent.
- The observed warts were mostly small (up to 3 mm) or medium-sized (3–5 mm). Age did not play a role in wart size.
- Most warts had a flat or raised shape; filiform (thread-like) warts were rare. No statistically significant correlation was found between wart appearance and patient age.
- **Patient age had no statistically significant effect on the frequency, size, or appearance of warts**. No notable differences were observed between age groups in these aspects.
- **Wart location was affected by age**: children most commonly had warts on the soles of their feet, while older patients more frequently had warts on their hands or other parts of the body.

Overall, while the location of warts is related to age, other characteristics such as frequency, size, and appearance are not significantly affected by age.

The Impact of Wart Morphological Characteristics on Treatment Effectiveness

- **The incidence of warts at the beginning of treatment** shows a very weak relationship with most observed factors, including the effectiveness of treatment. Its correlation with the length of treatment is insignificant, suggesting that the initial number of warts at the start of treatment does not affect the length of treatment or the number of applications.
- **Wart location** shows a weak correlation with treatment duration, where warts in certain areas may require a longer treatment period; however, this relationship is very weak. The number of applications has a similar effect.
- **Wart size** shows a stronger correlation with treatment duration and the number of applications — larger warts typically require more applications and a longer treatment period.
- **The appearance of the wart** has no significant impact on treatment effectiveness or the number of applications, suggesting that the aesthetic characteristics of the wart are not decisive for the length or complexity of treatment.

Overall, the results suggest that the most significant factor influencing treatment effectiveness is the size of the wart, while its location plays only a minor role. Other factors, such as the number of warts at the beginning of treatment and their appearance, are less relevant in terms of treatment outcomes.

3.) Frequency and Application Method of the treatment

Summary of Results:

- Treatment effectiveness is high — in 91% of cases, the wart was successfully removed within 40 days. Only 9% of respondents reported that they were unable to remove the wart even after 40 days of treatment.
- Some patients required a significantly higher number of applications. The most common number of applications was between 10 and 14, indicating that most patients performed more than just a few applications during the treatment.
- Most patients did not experience any adverse effects. There is no statistically significant correlation between adverse effects and age (except in a small subgroup of preschool children, where redness occurred in 2 out of 5 children, representing a higher proportion than in other age groups).
- Most patients did not experience any pain after application; only one in five reported mild pain. This corresponds with the responses regarding adverse effects

— in the small subgroup of preschool children, mild pain was reported in 4 out of 5 cases, which is a higher proportion compared to other age groups.

- In more than half of the cases, the product was applied two or more times per day. This pattern was similar across all age groups, with the exception of a small subgroup of school-age children, where once-daily application was more common compared to others.
- The most common application was in the morning and evening, the least common application was once a day in the morning. It was the same for all patients regardless of age (except for schoolchildren, where the application once a day, especially in the evening, is predominant).
- Only a quarter of them had the site of application of the product covered with a plaster. In most cases, the site was left without further intervention. This procedure was similar in most patients regardless of age (except for more frequent re-sticking in preschoolers).
- Nearly half of the patients removed the dead tissue by peeling it off using tweezers, scissors, or similar tools.

Conclusion:

The treatment proved to be very effective, as 91% of the patients were able to remove the wart within 40 days. The most common number of applications ranged from 10-14. Adverse effects were minimal, and most patients did not experience pain, with the exception of a small subset of preschool children who had a higher frequency of redness and mild pain.

Recommendation:

To ensure optimal treatment efficacy, it is recommended to apply the product at least twice daily, as this frequency was most common among patients. In preschool-aged children, it is advisable to monitor for potential adverse effects such as redness or mild pain and adjust the application accordingly.

Summary of Study Results

1.) Treatment efficacy: The wart treatment proved to be highly effective, with 91% of patients achieving wart removal within 40 days. Only 9% of respondents reported treatment failure even after this period.

2.) Impact of initial number of warts: The analyses did not reveal any statistically significant relationship between the initial number of warts and the length of treatment. This result suggests that the number of warts at the beginning of treatment does not influence the length of treatment or its effectiveness.

3.) Impact of Wart Location: The tests did not show a statistically significant relationship between wart location and length of treatment; however, the correlations suggest that warts located on the hands may require a longer treatment period. Warts on the soles of the feet tend to heal faster, while warts

located elsewhere (neither on the hands nor feet) also tend to be removed relatively quickly.

4.) Impact of wart size: Correlation results suggest that larger warts may require a longer length of treatment, although the relationship is weak.

5.) Considering the appearance of the wart: Although statistical tests do not show a strong relationship between the appearance of the wart and the length of treatment, clinical observation suggests that warts with a raised and rough appearance may require a longer time to remove.

6.) **Number of applications:** A strong positive correlation between the number of applications and the duration of treatment suggests that more frequent application may be associated with a longer treatment period, but also with a higher likelihood of successful wart removal. A higher frequency of application may be more effective in achieving wart removal.

7.) Adverse effects: There is no significant relationship between adverse effects and the duration of treatment. Although certain side effects, such as redness, may occur more frequently during longer treatment periods, the majority of patients report minimal adverse effects.

8.) Post-application pain: The weak positive correlation suggests that longer treatment may be slightly associated with increased post-application pain. In practice, this means that most patients do not suffer from significant pain problems, especially with shorter treatment periods.

9.) Application frequency and treatment duration: A higher frequency of application is often associated with a shorter time needed to achieve effectiveness. More frequent applications may shorten the treatment duration, suggesting that regular and intensive application can be more effective.

10.) **Covering and removal of dead tissue:** The choice of whether to cover the treatment area with a bandage or to remove dead tissue does not have a significant impact on the duration of treatment. These factors are not critical for treatment effectiveness in terms of treatment length.