



Study of the tolerance of MUCOKEHL 3X ointment

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1. Introduction

In the first to third quarters of 1996 and the first quarter of 1998, a total of 124 patients in three medical practices were monitored whilst using the homeopathic medicine MUCOKEHL 3X ointment; 32 of these were children under the age of 12.

The aim of the study was to establish the actual use of the product and its local tolerance in everyday practice.

In accordance with the organisation of the study, only descriptive statistical procedures were used. It was not appropriate to use inductive methods. An 'intention to treat' assessment was made, in other words, all patients who had received at least one dose of the medicine were taken into account.

2. Patients involved

Altogether, 124 patients were monitored, 32 of whom were children under the age of 12, who were the subject of a separate statistical evaluation. Of the 32 children, 17 were boys (53.1%) and 15 girls (46.9%). The age of the young patients varied between 1 and 12 years, with an average of 7.6 years \pm 3.5. At 7.3 \pm 3.6 years, the boys were just slightly younger than the girls, at 7.8 \pm 3.3 years of age.

2.1 Diagnosis and concomitant diseases

The diagnosis and concomitant disease scatter was due to the wide range of applications for the homeopathic remedy. The most common diagnoses and concomitant diseases were neurodermatitis

and seborrhoeic dermatitis. No further evaluations or interpretations were made, since that was not the object of the study.

3. Dosage and duration of treatment

As a rule, the ointment was administered 2 to 3 times a day. The average daily dose was a 4.9 cm line of ointment with a standard deviation of \pm 3.7 cm. The average area of skin treated was 71 \pm 161 sq. cm. The duration of the treatment was 13.0 days + 5.5.

Of the total population of 124, 92 patients were aged between 13 and 79. The average daily dose in this group was a 10.1 \pm 4.7 cm line of ointment. The area of skin treated was an average of 177.6 \pm 173 sq.cm. The duration of the treatment was an average of 25.2 \pm 1.1 days.

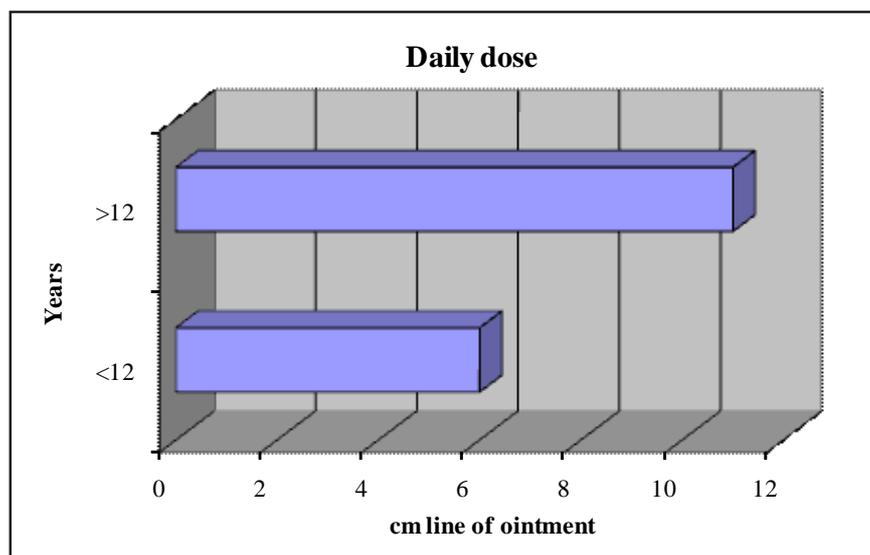
In the under 12 patient group, the average daily dose was about 50% of the adult dose. The size of the average area treated was also about 50% of that in the patient group aged over 12. The average

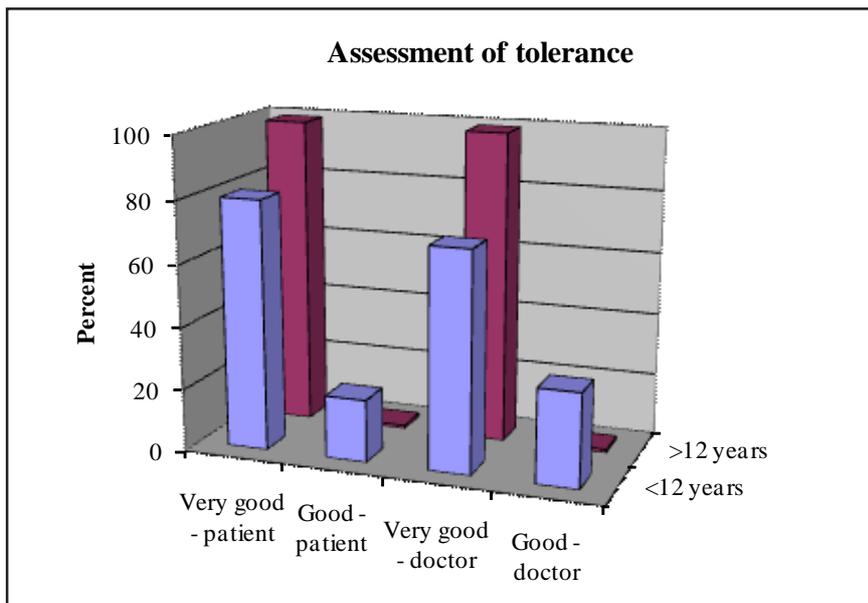
duration of the therapy in the children under 12 was 13.0 days, which was considerably lower than the 25.2 days in the over 12 patient group.

4. Tolerance

The doctor assessed local tolerance, using open-ended questions, drawing distinctions between symptoms, time of occurrence of a reaction and duration of a reaction. The doctor had to assess the intensity of the reaction and the possible connection with MUCOKEHL 3X ointment and give a description of the measures adopted. Finally, local tolerance was classified using the categories "very good", "good", "moderate" and "poor".

Local reactions or unwanted effects of the medicine were not observed in any of the 124 patients in the course of the treatment. Local tolerance was described as "very good" by 119 patients and "good" by 5. Within the under 12 group, 27 patients described it as "very good" and 5 as "good". In the doctors' assessment of tolerance





78.6% classified it as “very good” and 21.4% as “good”. In no case was tolerance classified as “moderate” or “poor”. In the over 12 age group the assessment of tolerance by doctors and patients was 100% “very good”. The application of MUCOKEHL 3X ointment was tolerated in all cases without local reactions.

5. Summary

In the period from first to the third quarter of 1996 and in the first quarter of 1998, a total of 124 patients aged from 1 to 79, including 32 children under 12, were incorporated in a monitoring study

of the homeopathic medicine MUCOKEHL 3X ointment.

The 32 children were subjected to a separate statistical evaluation. Of the 32 children, 17 were boys (53.1%) and 15 girls (46.9%). The age of the young patients varied between 1 and 12 years, with an average of 7.6 years \pm 3.5. As a rule, the average daily dose administered to the children was a 4.9 cm line of ointment. By comparison, the average daily dose in the patients over 12 was 10.1 cm.

The size of the average area of skin treated in the children was also

about 50% of that of the over 12 patient group. The average duration of the treatment of the children under 12 was 13.0 days, which was significantly lower than the 25.2 days for the over 12 patient group. No local reactions or unwanted effects were observed in any of the patients. The tolerance of MUCOKEHL 3X ointment was assessed both by the patient and by the doctor. No case was assessed as “moderate” or “poor”. In the under 12 group, 84.4% of the patients and 78.6% of the doctors assessed tolerance as “very good” and 25.6% of the patients and 21.4% of the doctors as “good”. In the over 12 patient group, the assessment of doctors and patients was 100% “very good”. In all cases, the application of MUCOKEHL 3X ointment was tolerated without local reactions.

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