



NegEnt Spray - Muscles and Joints: An Original CE Medical Device, Based on Liposomal Cannabidiol and Chamomile Hydrolate, for the Treatment of Muscles and Joints

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ABSTRACT

Musculoskeletal disorders are common in Europe, affecting millions and costing billions of euros in social security services. Traditional treatments using drugs like Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) can cause gastric damage, making prolonged use difficult. To address this issue, the author developed NegEnt Spray - Muscles and Joints, a topical medical device that uses liposomal cannabidiol and chamomile hydrolate to reduce inflammation and pain in musculoskeletal disorders. The liposomal technology used in NegEnt Spray - Muscles and Joints allows for better bioavailability and more targeted action, while chamomile hydrolate provides a natural anti-inflammatory and soothing effect. The spray is non-greasy, absorbs quickly, and can be used under any circumstances. Its pocket-sized design makes it easy to carry and use throughout the day. With NegEnt Spray - Muscles and Joints, patients can alleviate discomfort and pain associated with musculoskeletal disorders without worrying about the side effects of traditional treatments.

Keywords: Musculoskeletal disorders; Cannabidiol; Liposomal technology; Chamomile hydrolate; Topical treatment

INTRODUCTION

The incidence of musculoskeletal disorders in Europe is, unfortunately, very high, with millions of people affected and an estimated cost of billions of Euros to social security services, apart from that the personal and family distress of patients too [1].

Such disorders include a wide range of health problems, from mild discomfort and pain to more serious medical conditions that may require absence from work and specialized medical care. In particular, pathologies such as sprains, contusions, fasciitis, arthritis, and arthrosis are now prevalent, also about the increase in the average age of the population, and can be aggravated by physical, biomechanical, organizational, psychosocial, and individual risk factors [2].

The following data are recorded regarding the incidence of musculoskeletal disorders in Europe [1].

For adulthood

In Europe, 25% of workers suffer back pain, and 23% complain of muscle pain. 30% of European workers complain of back pain, 17% of muscle pain in their arms and legs, 45% report working in painful or tiring positions, and 33% have to carry heavy loads at work.

For old age

The prevalence of these conditions increases with advancing age and exhibits marked gender differences. Among the over 75's, 68.2% of women and 48.7% of men claim to suffer from arthrosis and arthritis.

These data highlight the importance of preventive and therapeutic interventions to manage the impact of musculoskeletal disorders in different age groups.

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Topical treatments for musculoskeletal disorders, implemented with the use of class I medical devices, constitute a significant therapeutic resource since the most commonly used drugs at the moment are the so - called NSAIDs, i.e., non-steroidal anti - inflammatory drugs. If taken orally, these drugs can be unwieldy due to the high potential for gastric disturbances and lesions, especially in prolonged treatments. For this reason, many medical devices proposed as NSAID-based creams and ointments have been developed and are currently on the market. However, although applied locally, the NSAIDs contained in these medical devices can be absorbed and poorly tolerated [3].

For this reason, remedies have been developed for application to the skin to treat muscular and osteoskeletal problems [4].

Cannabidiol, a substance derived from the inflorescences of the industrial variety *Cannabis sativa* light, appears to be an effective and well-tolerated remedy that can reduce inflammation and pain in musculoskeletal disorders [5].

At Herbal Neurocare, we set out to develop a medical device for topical use based on cannabidiol. After years of technological and clinical research, we developed NegEnt Spray - Muscles and Joints [6].

NegEnt Spray - Muscles and Joints comprise liposomal cannabidiol diluted in chamomile hydrolate.

Cannabidiol is a component extracted from the inflorescences of the industrial variety *Cannabis sativa*, known for its anti-inflammatory, analgesic, and muscle-relaxing properties. As a result of liposomal technology, cannabidiol has been encapsulated within microscopic lipid vesicles, promoting better bioavailability and a more targeted action at the application site.

Chamomile hydrolate is a natural extract obtained by distilling chamomile flowers. It is renowned for its anti-inflammatory, soothing, and calming properties.

NegEnt Spray - Muscles and Joints comes in a professional dispenser, made as an unbreakable 50 ml plastic bottle, designed and manufactured for pharmaceutical preparations, and equipped with a precise and ergonomic pressure spray pump that allows fine atomization of the preparation on the skin (Figure 1).

The absence of oily and creamy substances and the formulation in chamomile hydrolate, made possible by the liposomal preparation of cannabidiol, make the spray fresh and soothing on the skin. While facilitating the absorption of cannabidiol into the muscle tissue, muscle strips, and joint and bone tissue.

The skin is immediately cool, dry, and pleasantly scented with chamomile. Since NegEnt Spray - Muscles and Joints are non-greasy and absorb almost immediately. It can be used under any circumstances. It does not stain clothes and leaves the skin fresh and dry.

The bottle's small size and safety closure make it pocket-sized for easy portability and repeated use, even multiple times during the day and in any scenario, including work or social.



Figure 1: NegEnt Spray - Muscles and Joints.

MATERIALS AND METHODS

The clinical research on NegEnt Spray - Muscles and Joints was conducted at the ALETEIA Clinical Centre, collaborating with patients who informed consent to the trial. The study design was observational, applying the experimental protocol with NegEnt Spray - Muscles and Joints when patients presented spontaneously at the center's outpatient facilities.

The clinical research was carried out following the single-case study series design, including ten systematic single-case studies of patients suffering from different diseases.

Importantly, NegEnt Spray - Muscles and Joints was offered free to patients for the treatment, thus ensuring product accessibility and equity in study participation.

To assess the efficacy and tolerability of the product, we used two validated instruments that allowed us to collect quantitative and qualitative data on patients' experience with the treatment. The two instruments used were:

Pain self-assessment questionnaire

For the research carried out by Herbal Neurocare, with NegEnt Spray - Muscles and Joints, the McGill Pain Questionnaire in the Italian version edited by Maiani et al. [7], was used.

The McGill Pain Questionnaire [8], is a widely used psychometric instrument with a good reputation in the field of algology, developed to assess the multidimensional experience of pain. The Italian version, translated and adapted by Maiani et al. [7], preserves the original structure of the questionnaire, offering a detailed measurement of the different qualities of pain through carefully selected verbal descriptors. This test is beneficial for clinicians and researchers in identifying the nature and intensity of pain, thus enabling a more targeted and personalized therapeutic approach. Its widespread application in

various clinical and research contexts makes it an effective and efficient tool in patient self - assessment of pain in clinical research [7].

Questionnaire for self-assessment of side effects of treatments

As part of the research on possible side effects of products, at Herbal Neurocare, we use the Italian version of the Patient-Reported Outcomes-Common Terminology Criteria for Adverse Events (PRO-CTCAE), in the Italian version carried out at the National Cancer Institute National Cancer Institute [9].

Fibromyalgia

A syndrome characterized by widespread muscle pain and fatigue.

The patient, a 47 - year - old woman, had been diagnosed with fibromyalgia after a long period of non - specific symptoms, including widespread muscle pain and fatigue, and had started on a multidisciplinary treatment pathway that included lifestyle modifications, physical therapies, psychological support, and targeted pharmacological treatment. To the treatment based on paroxetine and systemic NSAIDs was added NegEnt Spray - Muscles and Joints, applied three times a day on the painful parts. Due to the introduction of NegEnt Spray - Muscles and Joints into the treatment plan, the patient experienced a significant improvement in pain management and quality of life, resuming her daily activities with greater ease and less physical and psychological discomfort.

Traumatic contusion of a finger of the hand

Attributable to an injury caused by a direct impact of a sliding door leaf. The patient, a 36-year-old woman, had suffered a traumatic contusion to a finger of her hand when a sliding door leaf struck her. Despite initial pain and swelling, an X-ray excluded bone fractures. Initial treatment included immobilization with a brace and the application of ice to reduce the swelling. After a few days, NegEnt Spray - Muscles and Joints, applied three times daily to the bruised area, was introduced to manage pain and promote recovery. Regular use of NegEnt Spray - Muscles and Joints and targeted physical therapy allowed the patient to regain full finger function within a few weeks without long-term complications.

This case demonstrates the effectiveness of a combined therapeutic approach, including NegEnt Spray - Muscles and Joints, for treating traumatic finger contusions.

Traumatic toe contusion with lacerated injuries

Female, 28 years old, patient presents following direct trauma to her toe caused by impact with a blunt, sharp object. She reports acute pain and difficulty walking. Examination reveals minor lacerated and bruised wounds on the affected toe, with surrounding edema and redness. No bony deformations or changes in the normal anatomy of the finger are observed. The diagnosis of Traumatic toe contusion with minor lacerated-concused wounds is made.

After thorough wound disinfection, a sterile dressing is applied. Analgesics and non - steroidal anti - inflammatory drugs are prescribed to control pain and inflammation. In addition, treatment is started with NegEnt Spray - Muscles and Joints, which are applied directly on the bruised areas three times a day to promote pain relief and accelerate the healing process. It should be emphasized that in this case, in which the skin was lacerated, the use of class I medical device NegEnt Spray - Muscles and Joints proved particularly beneficial given the antibacterial and healing - promoting properties of the cannabidiol it contains. The patient was re - evaluated after seven days. The wounds showed signs of healing with no signs of infection. Pain has decreased, and the patient reports improved walking ability. It is recommended that the RICE protocol be continued and the wounds closely monitored until complete healing is achieved. NegEnt Spray - Muscles and Joints Spray was well tolerated and contributed to improving symptoms.

The management of traumatic toe contusion with lacerated wounds requires a careful approach to prevent complications such as infection. Timely treatment, conservative measures such as the RICE protocol, and the addition of NegEnt Spray - Muscles and Joints contributed to a favorable outcome in this case. Further follow-ups are necessary to ensure complete resolution of the clinical picture.

This clinical case illustrates the importance of immediate intervention and appropriate follow-up in the treatment of traumatic contusions complicated by laceration injuries. The prognosis is generally favorable if appropriate management is implemented, and the addition of topical treatments such as NegEnt Spray - Muscles and Joints can be beneficial in the healing process due to its antibacterial effect, favoring skin wound healing, as well as anti - inflammatory and analgesic.

Arthrosis of the hands

Female, 76 years old, the patient presents a history of arthrosis with progressive degeneration of cartilage in the joints of the hands. She reports chronic pain and stiffness, limiting daily activities. On physical examination, swelling and reduced joint mobility are observed without apparent signs of active inflammation, as in the case of rheumatoid arthritis. A course of treatment with NegEnt Spray - Muscles and Joints, a topical spray indicated to relieve joint pain, was prescribed. The patient was instructed to apply the spray three times a day to the affected areas and to supplement the treatment with mobility and strength exercises for the hands.

After two weeks of treatment, the patient reported improved pain and greater ease in daily activities. No side effects were reported. Encouraged by the improvement achieved with NegEnt Spray - Muscles and Joints, the patient subsequently started a program of specific hand exercises, which further contributed to the improvement in function. Treatment with NegEnt Spray - Muscles and Joints proved to be effective in reducing the symptoms of arthrosis in this clinical case. The combination of topical therapy and specific exercises improved the patient's quality of life.

Arthrosis of the knee

Pain due to degeneration and inflammation of the cartilage of the knee joint.

The patient, a 51 - year - old man, suffered from osteoarthritis of the knee, a degenerative condition that caused pain, stiffness, and restricted movement. Despite following standard treatments, including analgesics and physiotherapy, he continued to experience significant symptoms that affected his quality of life. It was therefore decided to supplement his treatment regime with NegEnt Spray - Muscles and Joints, applied directly to the affected area four times a day. After introducing this topical treatment, the patient reported a noticeable improvement in pain management and increased joint mobility. This change allowed him to participate more actively in daily and work activities, positively impacting his personal and professional life.

This case highlights the importance of a customized therapeutic approach and the effectiveness of NegEnt Spray - Muscles and Joints as a complement and supplement to conventional treatments for knee arthrosis.

Fasciitis

Inflammation of the plantar fascia, the tissue that connects the heel to the toes.

The patient, a 28 - year - old woman, presented with symptoms of plantar fasciitis, characterized by acute pain in the heel and sole, especially in the morning. Despite standard conservative treatments, the symptoms persisted, limiting her daily activities. He, therefore, introduced NegEnt Spray - Muscles and Joints into his treatment plan and applied it three times a day to the affected area. After adding this topical treatment, the patient reported significant pain relief and improved function, which allowed her to resume her activities with intense relief from the previous discomfort.

This case highlights the effectiveness of NegEnt Spray - Muscles and Joints as a complement to traditional treatments for plantar fasciitis.

Cervical pain

Treatment of pain localized in the cervical region of the patient's spinal column, including the C4 to C6 vertebrae. The symptoms complained of by the patient included pain ranging from mild to severe, radiating pain to the shoulders, arms, or hands, and tingling or numbness due to nerve root compression or irritation.

Lumbar pain

Lumbar pain occurring in the lower spine of a 25-year-old young woman. It was attributable to muscle contracture and ligament sprains rather than disc herniations, vertebral injuries, or other degenerative conditions of the spine. Symptoms consisted of dull, constant burning pain, often radiating to the buttocks or legs, as in the case of sciatica.

Muscular and joint pain in the shoulder

The patient, a 46-year-old man with an active and athletic lifestyle, presents complaining of persistent muscle and joint pain in the left shoulder region. He reports no recent traumatic events but reports increased physical activity in recent weeks. On physical examination, the left shoulder shows signs of muscle tension and pain on palpation of the joints. Shoulder mobility is slightly limited due to pain, but there are no structural deformities or signs of acute trauma. A diagnosis of suspected rotator cuff tendonitis or muscle overload due to physical activity is made.

The patient is then advised to temporarily reduce the intensity of physical activity and apply the RICE (Rest, Ice, Compression, Elevation) protocol. For pain control and reduction of inflammation, treatment is started with NegEnt Spray - Muscles and Joints, which are to be applied directly on the affected area three times a day. After one week of treatment, the patient reports a significant improvement in pain and greater freedom of movement in the shoulder. The treatment with NegEnt Spray - Muscles and Joints was well tolerated and contributed to the functional recovery of the shoulder.

The clinical case highlighted the importance of a conservative approach in treating muscle and joint pain in the shoulder. NegEnt Spray - Muscles and Joints has proven to be an effective treatment option for alleviating symptoms and aiding the athlete's recovery. Further evaluation and a gradual return to physical activity will be necessary to prevent recurrence.

This single case study illustrates a multimodal therapeutic approach for treating muscle and joint pain in the shoulder, emphasizing the effectiveness of topical treatments such as NegEnt Spray - Muscles and Joints in combination with conservative measures.

Dysodontiasis of the third molar included

NegEnt Spray - Muscles and Joints are non - toxic, if ingested, and even edible [10]; it was also tested in a bone and connective tissue affection related to the mouth, with application on a tooth and gums. The patient presented with dysodontiasis of the third molar, which manifested pain and discomfort in the left mandibular region. On clinical examination, swelling and redness were observed in the area of the impacted third molar, with difficulty fully opening the mouth and pain on palpation. A provisional diagnosis was then made, pending specialist and radiographic examination, of dysodontiasis of the impacted third molar with symptoms of pericoronitis. In addition to standard oral hygiene measures, it was decided to supplement the treatment with the application of NegEnt Spray - Muscles and Joints directly on the affected buccal mucosa and the gingiva surrounding the tooth. The product is applied three times daily, after main meals and before bed. In this case, reliance was also placed on the antiseptic and antibacterial potential of the product. After three days of treatment, the patient reported a significant improvement in symptoms. Pain was significantly reduced, and jaw mobility improved, allowing more comfortable chewing and a wider oral opening. The use of NegEnt Spray - Muscles and Joints showed a beneficial effect in controlling the

pain and inflammation associated with dysodontiasis of the third molar included.

RESULTS

A synopsis of the research's results is included in Table 1. Participants in the experimental group treated with NegEnt Spray - Muscles and Joints reported a marked clinical improvement, subjectively perceived as a significant increase in psychophysical well-being. None of the subjects reported any side effects. The Fisher's test (1922) application to the collected data showed a high statistical significance, with a *p* value of less than 0.001% [11].

Table 1: A synopsis of the research results.

Clinical problems	Significant pain reduction (Yes or No)	Side effects presence (Yes or No)
Fibromyalgia	Yes	No
Traumatic contusion of a finger of the hand	Yes	No
Traumatic toe contusion with lacerated injuries	Yes	No
Arthrosis of the hands	Yes	No
Arthrosis of the knee	Yes	No
Fascitis	Yes	No
Cervical pain	Yes	No
Lumbar pain	Yes	No
Muscular joint pain in the shoulder	Yes	No
Dysodontiasis of the third molar included	Yes	No

DISCUSSION

It seems important to emphasize that these potential results are only a preliminary indication. The limited sample size imposes caution when interpreting the data and emphasizes the need for more extensive and methodologically rigorous clinical trials. Such studies should include adequate participants and control groups treated with placebo and other medical devices to confirm the efficacy and safety of NegEnt Spray - Muscles and Joints and the absence of side effects. Precisely in order to extend the collection of clinical data on the efficacy and tolerability of NegEnt Spray - Muscles and Joints, we have decided to include in the package leaflet of the medical device an invitation to download free of charge from the Herbal Neurocare website (www.herbalneurocare.it) a copy of two tests for self-administration, one for the self-assessment of pain and the other for the detection and quantification of side effects, such as the PRO-CTCAE carried out in Italy at the National Cancer Institute [9], and the McGill Pain Questionnaire [7]. NegEnt Spray - Muscles and Joints users are invited to contribute to clinical research on the product by completing questionnaires at the beginning of product use and seven and

fifteen-day intervals. Including a clinical efficacy protocol in the packaging of a class I medical device, which involves the patient in monitoring the efficacy and absence of side effects of product use, is a promising development in the sales strategies of medical device companies.

CONCLUSION

The article presents the results of the first systematic, single-case study series demonstrating the effectiveness and lack of any side effects of a liposomal cannabidiol preparation diluted in chamomile hydrolate. The product has been registered with the Italian Ministry of Health as a Medical Device CE. It can be safely used throughout Europe to treat muscular and osteoskeletal diseases, contributing to public health. The NegEnt Spray - Muscles and Joints is easy to use and pocket-friendly. Its quick absorption, without any greasy residue, makes it a potential prospect for improving human health. Some good results have also been reached with pets. However, data about this aspect will be presented and discussed in another article focused on using NegEnt Spray - Muscles and Articulations with dogs.

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DATA ACCESS STATEMENT

All relevant data is included in the paper, and it is supporting information files.

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