PATIENT INFORMATION SHEET / INFORMED CONSENT FORM

Project Title: A Multicenter, Randomized, Open Label, Parallel Group, Comparative Clinical Study to Evaluate the Efficacy and Safety of Diclofenac Diethylamine Topical Spray (10.0 %w/w) Compared with VOVERAN EMUGEL® (1.0 %w/w) For the Treatment of Low backache, Sprain, Osteoarthritis and Myalgia.

Study Sponsor: Inventia Healthcare Private Limited

Study No: ECTS/11/005

Patient Initials	**Patient Birth Date**
_____	_____ (DD/MMM/YYYY)
Name of Investigator	**Contact Number**
_____	_____

1. Introduction

Thanks for showing interest in this research project. Above mentioned research project and this information sheet is approved by Independent Ethics Committee.

Please go through this document thoroughly and get it explained in suitable language. In case of any doubt feel free to ask questions. This document provides only a summary of the most important information regarding the study procedures, risk and other information. Please take the time to read the following information carefully. If you wish you may take the time you need to discuss it with friends, relatives, or your family doctor, and defer participation to another visit. After your questions about the study have been answered and if you decide to participate, you will be asked to sign this informed consent form which will be also signed by the investigator. You will receive a copy for your records. One form will be retained by your doctor.

As per your request we are providing you this document in English / local language.

2. Why is this study being done?

The purpose of study is to compare the efficacy and safety of Diclofenac Diethylamine Topical Spray 10%w/w with VOVERAN EMUGEL® 1%w/w for the treatment of Low backache, Sprain, Osteoarthritis and Myalgia.

3. How many people will take part in the study?

A total of 200 patients will take part in this study across 4-6 sites.

4. What is involved in the study?

You have been asked to participate in this study because you are suffering from low backache, sprain, osteoarthritis and/or myalgia. If you choose to participate in this study, on the day of screening, your blood sample will be taken to measure safety markers including SGOT, SGPT, urea, and creatinine. During this visit, your pain intensity will be measured by Visual Analogue Scale (VAS) and Physician's Global Assessment Scale. You will be recruited into study after screening visit after the assessment of eligibility criteria.

After meeting the inclusion criteria and none of exclusion criteria, you will be instructed to apply test or reference product as per randomisation sheet.
Test Product: Diclofenac Diethylamine Topical Spray 10%w/w will be applied four spray three times in a day at regular interval for 14 days.
Reference Product: VOVERAN EMUGEL® 1%w/w will be applied topically 5.4 g three times in a day at regular interval for 14 days.

You will also be instructed in procedure for maintaining a study diary for daily application and given a schedule for return to the clinic for follow-up evaluations as following.
Visit Schedule: V1: Visit 1: Screening Visit (Day -5 to 0)
V2: Visit 2: Day 1
V3: Visit 3: Day 7 (±1 day)
V4: End of Study Visit 4: Day 14 (±2 day)

At each follow up visit, you will be evaluated for use of any concomitant medications and occurrence of adverse events. The investigator will assess the clinical signs and symptoms of low backache, sprain osteoarthritis or myalgia and overall clinical response will be recorded. The investigator will also assess for the VAS and Physician's Global Assessment Scale at

each of the follow up visit. At the end of study visit 4 (Day 14), your blood sample will be collected for laboratory investigations (SGOT, SGPT, urea and creatinine) for your safety.

5. What are the risks of the study?

This study involves minimal risk as safety of the drug is already established. Study medication can cause skin disorders such as application site reactions, rashes, pruritus, urticaria, drying, reddening, burning sensations and contact dermatitis. If you experience any side effects of symptoms after being treated with study product, you should contact your study investigator.

You should discuss the risks of participating in this study with your study investigator that have been treating you. There also may be side effects that cannot be predicted. If there are any side effects that have any negative impact on your well being you will be immediately discontinued from the trial on safety grounds. Despite all these precautions, if you are physically injured due to trial related medications or procedures all the expenses of treatment will be paid by the trial sponsors and you will be compensated as per the legal status.

6. Are there benefits to taking part in the study?

Treatment with Diclofenac Diethylamine Topical Spray may improve signs & symptoms of low backache, sprain, osteoarthritis and/or myalgia. However, it is also possible that you may not experience any benefit from participation in this clinical study. Your participation may help your condition and in the future may be to other patients who need this treatment. By participating in study, you will contribute to gathering information regarding the use of diclofenac spray for the treatment of low backache, sprain or muscle pain in patients.

7. What are the costs?

Inventia Healthcare Private Limited will provide the study medication free of charge during this study. You will not be required to pay for any investigations or study medication during the study. In case of study related injury or death, Inventia Healthcare Pvt. Ltd., Thane (West) 400 604 will provide complete medical care along with compensation for injury or death. However, CRO has purchased an insurance policy to pay you for illness or injuries that are a direct result of your participation in this study. All adverse events will be closely monitored till their resolution.

8. What are the other alternative treatments?

If you decide not to enter this study, there is other care available to you, such as other medications or treatments for low backache, sprain, osteoarthritis and/or myalgia. The study investigator will discuss this with you. You do not have to participate in this study to receive treatment for low backache, sprain, osteoarthritis and/or myalgia. There are numerous drugs of different types available as established treatment for low backache, sprain, osteoarthritis and/or myalgia. For details on the benefits and risks of other treatments, please consult your study investigator.

9. What about confidentiality?

Documents identifying your name will be kept confidential but your medical records (medical history, laboratory test results, physical examination details, etc) will be made available to the trial related authorities/personnel (Sponsor of the study, study monitors or auditors, the Ethics Committee and the regulatory authorities). The data and information collected during this study may be published, but will not include your personal identity. The access to medical records will be granted without violating the confidentiality of the patients, to the extent permitted by the applicable laws and regulations.

10.What are my rights as a participant?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You can withdraw from this study or can refuse to participate in the study at any point without giving any reason. Refusal to participate or discontinuation from the study will not affect your treatment.

You may be discontinued from the study for following reasons:

- If treatment doesn't seem to be effective
- If your doctor thinks that your continuation in the study may affect your health status significantly.
- If study is terminated by the sponsor
- You did not follow the study schedule and/or procedure as defined by the protocol

As the study progresses, you will be informed about any new information, which might affect your health, welfare and willingness to continue your participation in the trial.

11.What are my responsibilities during the study?

If you are eligible and decide to take part in the study, you will need to do the following:

- Report to the study clinic for all scheduled visits, and other visits as requested by the study staff
- Follow instructions on receiving study treatment
- Report any side effects
- Report taking any side effects (adverse events)
- Report taking any additional medications (including herbal or any other remedies)

12. Who do I call if I have question or problems?

For questions about the study or a research-related injury, contact your study investigator at:

Name of Investigator: _____

Address of Institution: _____

_____

_____

Contact No.: _____

For questions about your rights as a study participant, please contact respective IEC chairperson at:

Name of Chairperson: _____

Address of Ethics Committee: _____

_____

_____

Contact No.: _____

In case you have any doubts regarding study drugs, trial procedures or trial related injuries you can contact to Ethicare Clinical Trial Services at +91 9825585119.

13. INFORMED CONSENT FORM

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Study Sponsor: Inventia Healthcare Private Limited.

Study No. ECTS/11/005

Name of Investigator:_____

Study Site No.: _____ Patient Screening No.:_____

Name of Patient:_____ Patient Initial: _____

Date of Birth: ☐☐ ☐☐☐ ☐☐☐☐ OR Age: _____ Years

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Please Initial Box (Patient)

- I have read and understood the preceding information describing this research study dated 18/JAN/2012 (Version No. 00) and my questions have been answered to my satisfaction. [ ]
- I have received / will receive a copy of the signed Patient Information Sheet / Informed Consent Form. [ ]
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

- I understand that the authorized representatives from Sponsor and others working on behalf, the Ethics Committee and regulatory authorities will not need my permission to look at my health records in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

- I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]

- I agree to take part in the above study. [ ]

Signature (or Thumb Impression*) of the Patient:_____

Signatory's Name: _____

Date: | | | | | | | | | |
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*If patient is illiterate,

Signature of the witness: _____

Signatory's Name :_____

His/ Her relation with Patient: _____

Address: _____

Contact Number: _____

Date: | | | | | | | | | |
D D M M M Y Y Y Y

Signature of the Investigator:_____

Signatory's Name _____

Date: | | | | | | | | | |

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