

CLINICAL STUDY
PR. PHILIPS (CHU LIÈGE - BELGIUM)

ASSESSMENT OF THE EFFECT OF THE CREAM-GEL **LEGS & FEET** ON TYPE 1 AND TYPE 2 DIABETES
PATIENTS SUFFERING OF PAINFUL PERIPHERAL DIABETIC NEUROPATHY



October 16th, 2018

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STUDY PROTOCOL

- Period: April – August 2018
- 22 patients to be enrolled showing bilateral peripheral diabetic neuropathy assessed with the DN4 scale with a score ≥ 4 .
- Patients answer YES if symptom present or NO if no symptom
- V1 = initial visit
- V2 = visit after 2 weeks
- V3 = final visit after 1 month

DN4 – QUESTIONNAIRE

To estimate the probability of neuropathic pain, please answer yes or no for each item of the following four questions.

INTERVIEW OF THE PATIENT		
QUESTION 1:		
Does the pain have one or more of the following characteristics?	YES	NO
Burning	<input type="checkbox"/>	<input type="checkbox"/>
Painful cold	<input type="checkbox"/>	<input type="checkbox"/>
Electric shocks	<input type="checkbox"/>	<input type="checkbox"/>
QUESTION 2:		
Is the pain associated with one or more of the following symptoms in the same area?	YES	NO
Tingling	<input type="checkbox"/>	<input type="checkbox"/>
Pins and needles	<input type="checkbox"/>	<input type="checkbox"/>
Numbness	<input type="checkbox"/>	<input type="checkbox"/>
Itching	<input type="checkbox"/>	<input type="checkbox"/>

EXAMINATION OF THE PATIENT		
QUESTION 3:		
Is the pain located in an area where the physical examination may reveal one or more of the following characteristics?	YES	NO
Hypoesthesia to touch	<input type="checkbox"/>	<input type="checkbox"/>
Hypoesthesia to pinprick	<input type="checkbox"/>	<input type="checkbox"/>
QUESTION 4:		
In the painful area, can the pain be caused or increased by:	YES	NO
Brushing?	<input type="checkbox"/>	<input type="checkbox"/>

YES = 1 point
NO = 0 points

Patient's Score: /10

STUDY PROTOCOL

- Peripheral diabetic neuropathy assessed with DN4 at V1 and V3
- Assessment of the pain at legs level with VAS at V1, V2 and V3
- Other assessments at V3:
 - Improvement of pain
 - Assessment of EVAUX® **LEGS & FEET** cream-gel
 - Willingness to continue to use EVAUX® **LEGS & FEET** after study end
- Current treatment for painful peripheral diabetic neuropathy (pregabalin, gabapentin or duloxetine) maintained during study.
- Application of EVAUX® **LEGS & FEET** twice a day up to the knee on the most painful leg (if difference of pain between legs) at start during 2 weeks and on both legs from V2 until the end of the study.

STUDY POPULATION

- 22 patients enrolled
- 12 women / 10 males
- Mean age 64,2 years (35-85)
- Diabetes :
 - Type 1 : 22,73%
 - Type 2 : 77,27%
- Current DNP treatment:
 - Pregabalin : 40,91% of patients
 - Gabapentin : 9,09% of patients
 - Duloxetine : 0% of patients
 - Pregabalin & duloxetine : 9,09% of patients
 - None : 40,91% of patients
- Duration of the study – application of EVAUX® **LEGS & FEET** twice a day = 1 month

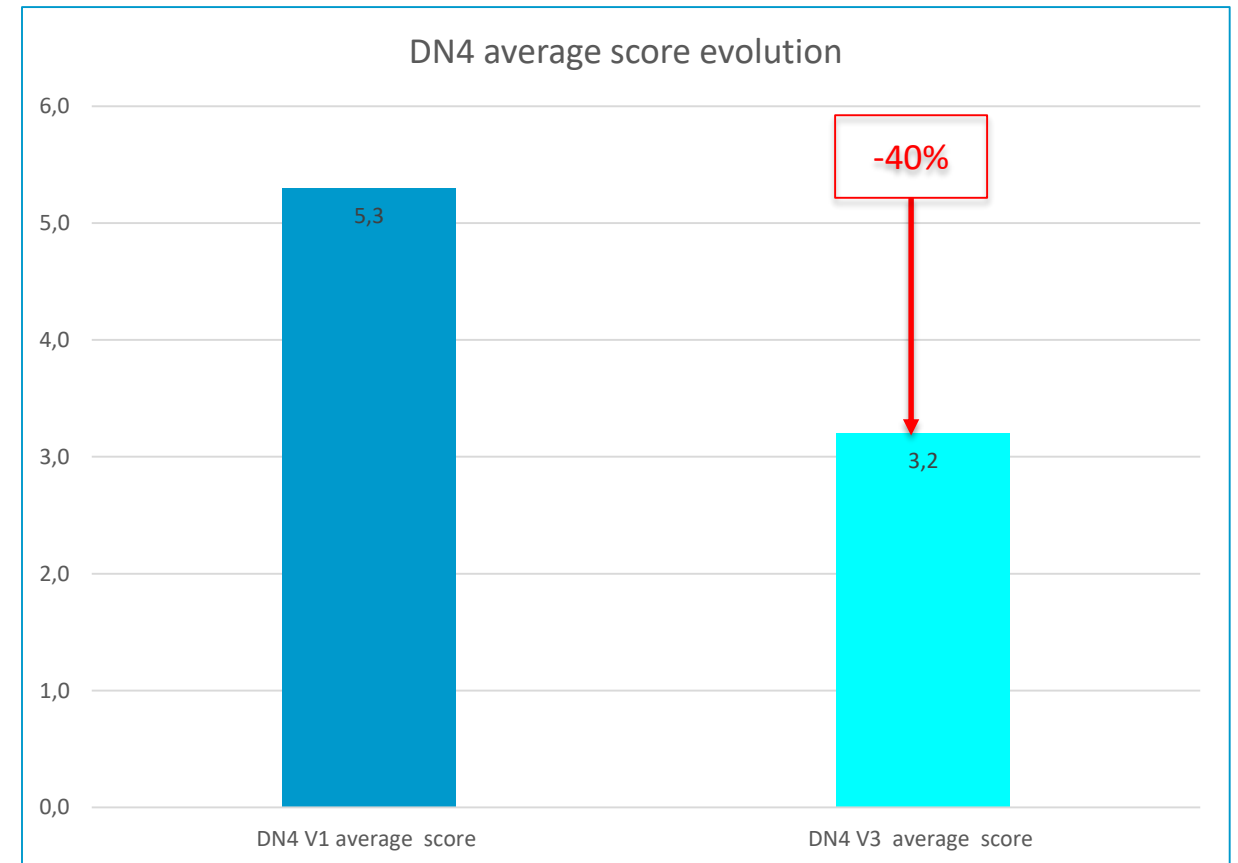


CLINICAL STUDY : RESULTS

40% decrease of the DN4 average score

- DN4 average score at V1 = 5,3
- DN4 average score at V3 (1 month) = 3,2

↓ ↓ of 40%

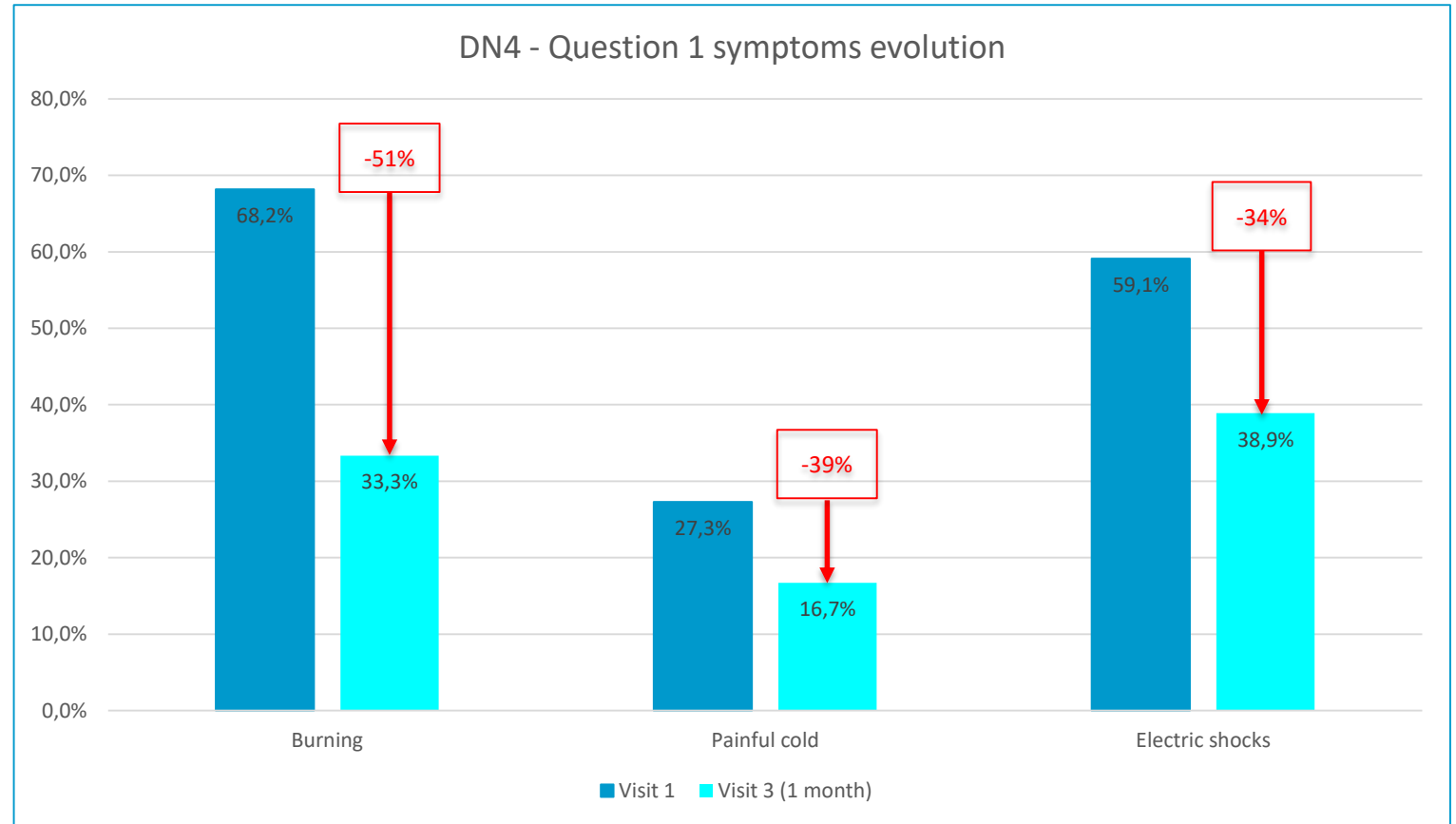


* After 1 month of EVAUX® LEGS & FEET use

CLINICAL STUDY : RESULTS

All patients have an important reduction of burning, painful cold and electric shocks symptoms*

- Does the pain have one or more of the following characteristics?
 - Burning
 - Painful cold
 - Electric shocks
- YES or NO

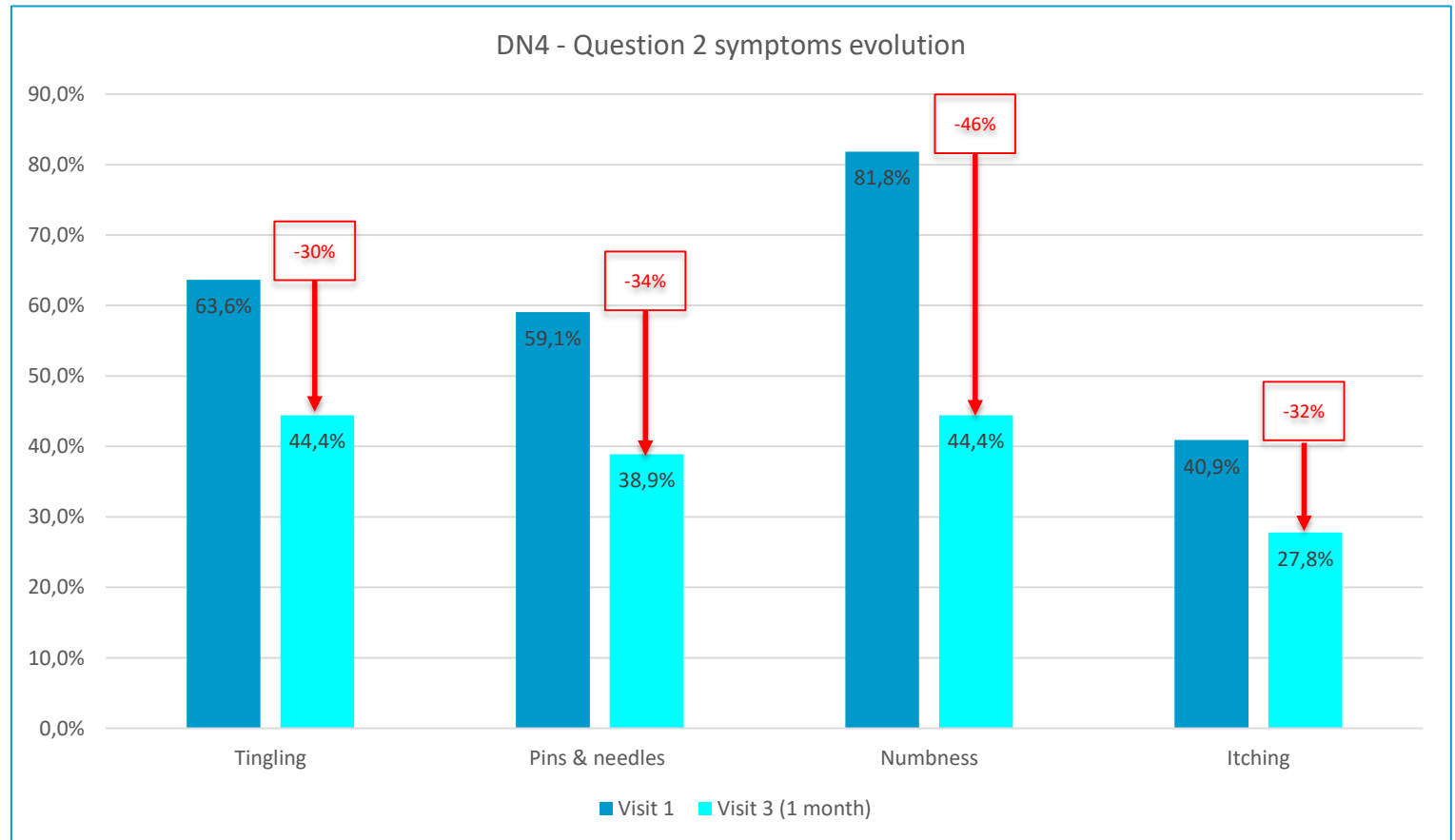


* After 1 month of EVAUX® LEGS & FEET use

CLINICAL STUDY : RESULTS

Significantly less patients having tingling, pins & needles, numbness and itching symptoms*

- Is the pain associated with one or more of the following symptoms in the same area?
 - Tingling
 - Pins and needles
 - Numbness
 - Itching
- YES or NO

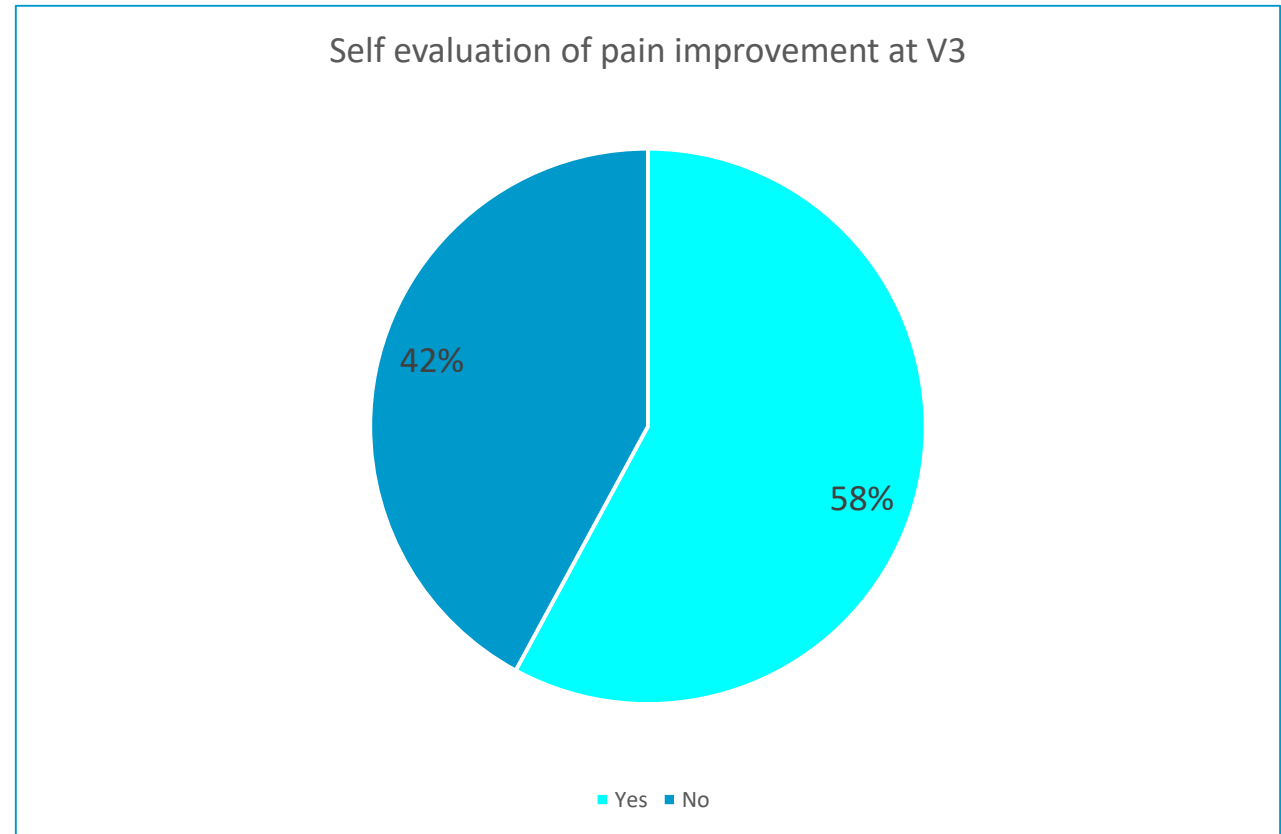


* After 1 month of EVAUX® LEGS & FEET use

CLINICAL STUDY : RESULTS

58% of the patients experienced a reduction of the pain

- Self evaluation of the pain reduction at V3
- YES or NO

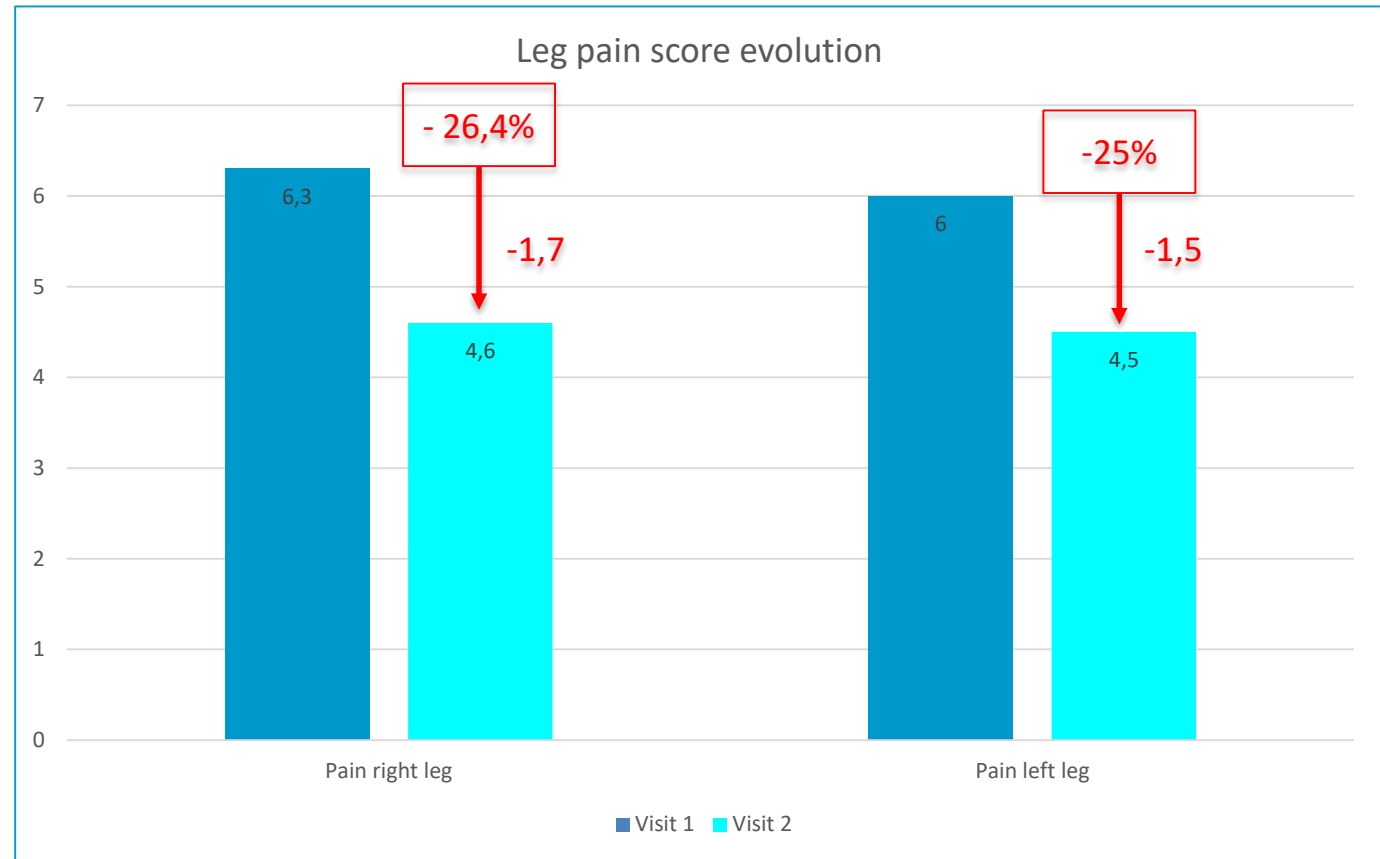


* After 1 month of EVAUX® LEGS & FEET use

CLINICAL STUDY : RESULTS

Patients have 1,7 & 1,5 points reduction of pain on the most painful leg*

- Self evaluation of the pain evolution using VAS on the most painful leg at V2

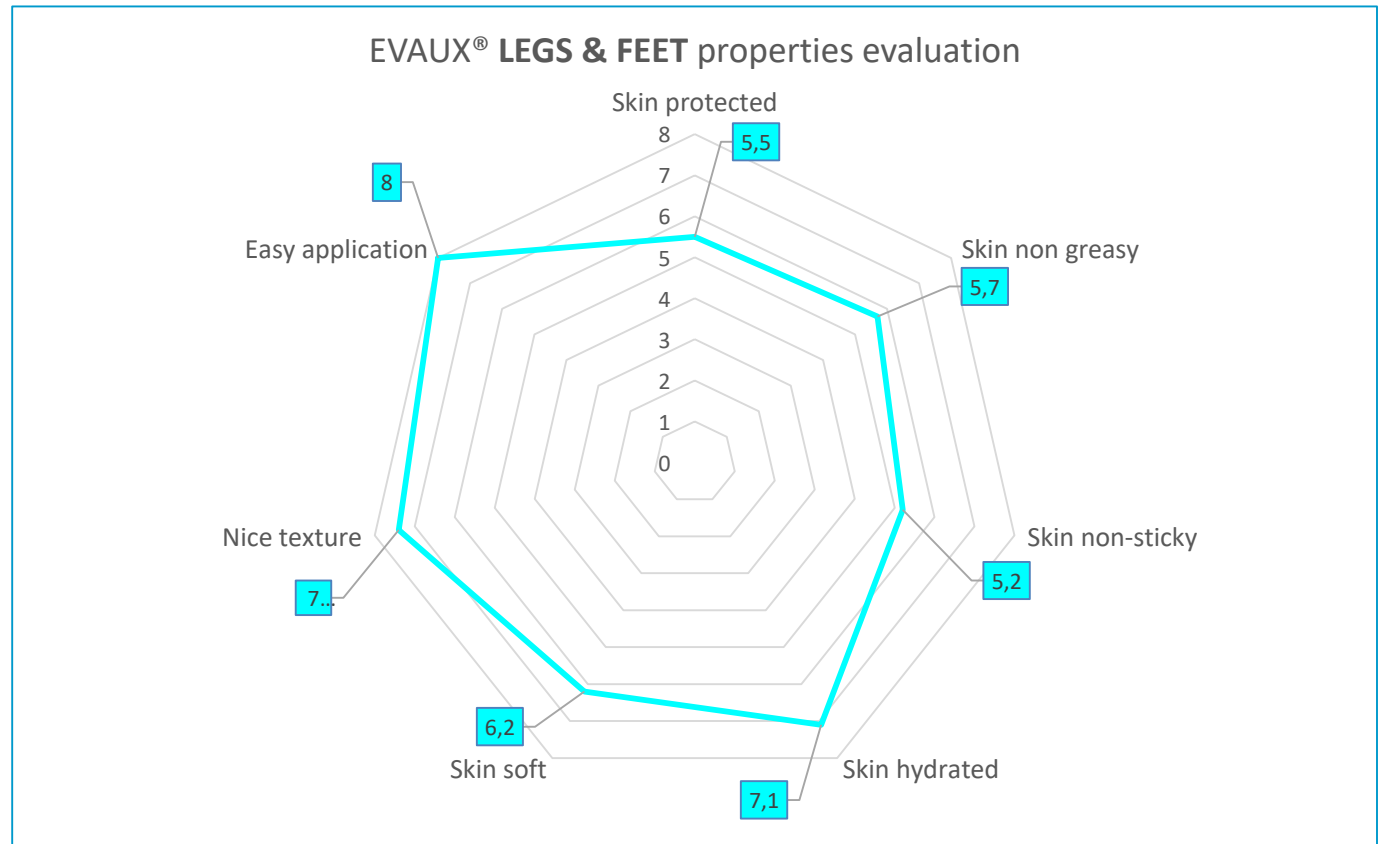


* After 2 weeks of EVAUX® LEGS & FEET use

CLINICAL STUDY : RESULTS

47% of the patients want to continue using cream-gel **LEGS & FEET**

- Rating by patients on VAS scales on product **LEGS & FEET** properties



CLINICAL STUDY : RESULTS

PR. PHILIPS' COMMENTARIES

- A reduction of pain is observed from the first 2 weeks of cream application. The average **DN4** questionnaire was 5.3 / 10 at initiation, reductions of the order of 30 to 65% were recorded detailing the complaints (burns, painful cold, tingling, itching ...) included in the **DN4**.
- The reduction of pain is 1.6 on average on the **VAS** pain scale (0 to 10).
- More than half of the patients reported a significant improvement in general and wished to continue the application of the cream, it being particularly simple and pleasant to apply according to them.

CLINICAL STUDY : RESULTS PR. PHILIPS' CONCLUSION

- Management of diabetic neuropathy is difficult, particularly because of the imperfect effectiveness and frequent side effects caused by oral treatments. The search for a local treatment is of great interest. The application of the cream used here (EVAUX® **LEGS & FEET**) demonstrates an early improvement of pain and complaints for half of the patients, who have greatly appreciated the comfort and ease of application thereof.



LEGS & FEET 250ML & 15ML SAMPLE

