CLINICAL TRIALS

LAY SUMMARY

SHORT STUDY TITLE

Study evaluating if one sachet of Daflon® 1000 mg works as well or almost as well as 2 tablets of Daflon® 500 mg for people with vein disease, after 8 weeks of treatment

IN THIS LAY SUMMARY:

CLINICAL TRIALS LAY SUMMARY

Study evaluating if one sachet of Daflon® 1000 mg works as well or almost as well as 2 tablets of Daflon® 500 mg for people with vein disease, after 8 weeks of treatment

Welcome

This summary explains how the study was done. It also explains what the results are. Researchers need many studies to decide which medicines work best and are safest. It takes lot of people in many studies all around the world to advance medical science. This summary only shows the results from this one study. However, other studies may find different results.

1 WHAT WAS THE OBJECTIVE OF THE STUDY?

The name of the study drug is Daflon. It is used for venous circulation disorders.
Numerous studies showed a benefit for vein conditions. It is a medicine marketed for many years.
This study compared the same medicine (Daflon) in 2 different forms:

- Sachet is a new form.
- Tablet is already on the market.

1 sachet contains the same dose as 2 tablets.
Sachet may be easier to take for patient.

The aim of this study was to show that 1 sachet works as well or almost as well on the disease symptom as 2 tablets.

2 WHEN AND WHERE THIS STUDY TOOK PLACE?

When was it performed?

- This trial started in July 2013.
- It ended in December 2014.

Where the clinical trial took place?

The study included 1 139 patients in the following countries:

Country	Number of patients
Argentina	146
Brazil	65
Czech Republic	94
Malaysia	3
Mexico	48
Romania	194
Russia	255
Slovakia	94
Slovenia	53
Spain	67
Thailand	47
Turkey	51
Vietnam	22

3 WHO PARTICIPATED IN THE STUDY?

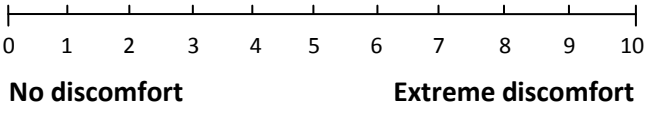
What patients were included in the study?

Patients in the clinical trial should meet the following criteria:

- male or female
- aged between 20 to 75
- with long-term vein disease
- with leg discomfort and leg pain

To be included, patients should feel on the following scale:

- leg discomfort ≥ 4
- and leg pain ≥ 3



How many men and women were in the clinical trial?

FEMALE	MALE
86 %	**14 %**

How old the patients were?

20 to 64 years	65 to 75 years
92 %	**8 %**

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4 WHAT TREATMENTS DID PATIENTS RECEIVE?

Patients were put by chance into 2 groups:

- Daflon® 1000 mg group included 571 patients.
- Daflon® 500 mg group included 568 patients.

This is called "randomized" study:

- Half took 2 tablets of active substance and 1 sachet of placebo.
- Half took one sachet of active substance and 2 tablets of placebo.

Placebo does not contain active medicine. To not influence the results in any way, neither patients nor doctors knew if the active substance was in the tablet or in the sachet form. This is called "double-blinded" study.

5 WHAT WERE THE SIDE EFFECTS?

What about side effects?

Side effects may happen during any study. They are reported because they are thought to be related to the treatments in the study by the trial doctor. Like all medicines, this medicine can cause side effects although not everybody gets them.

The table below shows the number of patients who experienced side effects.

	Patients taking 1 sachet of Daflon® 1000 mg	Patients taking 2 tablets of Daflon® 500 mg
Patients who had side effects	24 patients (4.2%)	20 patients (3.5%)
Patients who had serious side effects	-	2 patients (0.4%)
Patients who had withdrew because of a side effect	4 patients (0.7%)	6 patients (1.1%)

How many serious side effects occurred?

In this study, 2 patients experienced serious side effects. Both took tablets of Daflon®.
The serious side effects reported were allergic reactions: swelling face, hives, difficulty in swallowing and rash.
These side effects led to withdrawal of the 2 patients.

Side effect is serious when:

- The patient needs to be hospitalized.
- The patient life is in danger.
- It causes permanent damage or death.
- Or a medical intervention is needed to prevent situations listed above.

What were the other side effects?

The table below shows the other side effects found in each group. Only the most common (reported by at least 2 patients) are presented.

	Patients taking 1 sachet of Daflon® 1000 mg	Patients taking 2 tablets of Daflon® 500 mg
Feeling sick (nausea)	7 patients (1.2%)	4 patients (0.7%)
Bowel pain	3 patients (0.5%)	2 patients (0.4%)
Bowel discomfort	3 patients (0.5%)	-
Diarrhoea	2 patients (0.4%)	4 patients (0.7%)
Indigestion	2 patients (0.4%)	2 patients (0.4%)
Involuntary contraction of a muscle	2 patients (0.4%)	-
Headache	1 patient (0.2%)	2 patients (0.4%)
Inflammation of the stomach	-	2 patients (0.4%)
Pins and needles	-	2 patients (0.4%)

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6 WHAT WERE THE STUDY RESULTS?

The study was completed as planned.

What are the results of the clinical trial?

- At the beginning of the study, all patients had similar leg discomfort. They indicated an average of 6.7 on the scale.
- With either sachet or tablet of Daflon®, leg discomfort decreased similarly. The decrease of leg discomfort represented around 50% of improvement. The change was on average of 3.3 on the scale.

What does it mean?

1 sachet of Daflon® 1000 mg works as well or almost as well as 2 tablets of Daflon® 500 mg in lowering leg discomfort.

7 HOW HAS THIS STUDY HELPED PATIENTS AND RESEARCHERS?

The study found that:

- People with sachet or tablet of Daflon had similar lowering of leg discomfort.
- Side effects with the sachet were similar to those already known with the tablet.

These results will be used to obtain an approval of sachet of Daflon® 1000 mg from the Health Authorities.

The new sachet form which allows 1 intake per day without water should ease patients' intake.

8 ARE THERE PLANS FOR FURTHER STUDIES?

No other trials with Daflon® 1000 mg sachet are foreseen to date.

9 FURTHER INFORMATION

What is the full title name of the clinical trial?

The full title of this study is "Clinical non-inferiority study between Daflon® 1000 mg, 1 oral suspension in a sachet per day and Daflon® 500 mg, 2 tablets daily after eight weeks of treatment in patients suffering from symptomatic Chronic Venous Disease (CVD). International, multicenter, double-blind, randomized, parallel group study."

What is the identification number of the clinical trial?

- Protocol Number: CL3-05682-105
- EudraCT Number: 2012-003559-13
- Universal trial Number: U1111-1135-8530

What is the name of the Sponsor?

The company organizing and funding the research, called sponsor, is the Institut de Recherches Internationales Servier based in Suresnes, France.

How contact the sponsor?

Contact us on Servier website (www.servier.com).

Where can you learn more about this study?

- To learn more about this trial, please visit the European Clinical Trials Register (www.clinicaltrialsregister.eu).
- In this document, we translated medical terms into lay terms. You can find the corresponding medical terms in the Servier glossary on Servier Clinical Trial Data website (www.clinicaltrials.servier.com).
- The scientific summary is also available on Servier Clinical Trial Data website. (www.clinicaltrials.servier.com)