Supplementary Online Content

Barry MJ, Meleth S, Lee JY, et al. Effect of increasing doses of saw palmetto extract on lower urinary tract symptoms: a randomized trial. *JAMA*. 2011;306(12):1344-1351.

eAppendix. Supplemental product information
eTable. Descriptions of all serious adverse events reported among participants by dose level

This supplementary material has been provided by the authors to give readers additional information about their work.

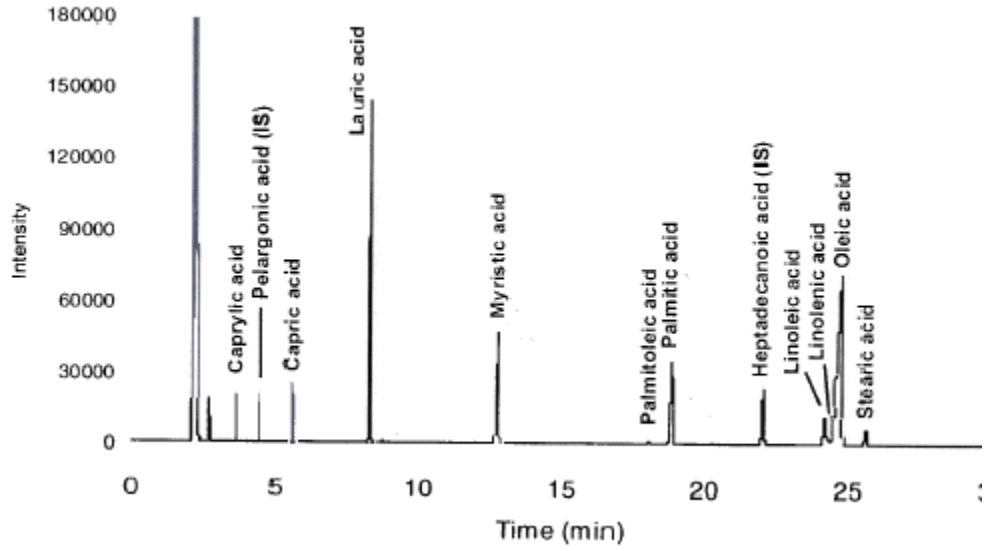
eAppendix. Supplemental Product Information

The Saw Palmetto berries for the study product were wild-collected by Euromed's Florida agricultural facility in Okeechobee, FL. Retained specimens from collections are stored at Euromed Barcelona, Spain. Visual inspections were conducted on all specimens, and testing was performed at all three stages of processing in accordance with USP monograph specifications. Two different lots were used for the trial, and all batches were tested against USP specification. Lot 1 was largely used for single and double dose therapy, and Lot 2 for triple dose therapy. Independent testing was not conducted for the trial, as the data regarding drug manufacturing and testing met the FDA IND requirements.

The batch Quality extract of Saw Palmetto berries is standardized to a content of 85%-95% of fatty acids.

The analytical specifications of the Saw Palmetto extract are:

Appearance:	Dark green-brown color, oily liquid with aromatic odor
Identification:	GC Fingerprint
Solubility:	Insoluble in water, soluble in organic solvents
Density at 20 C:	0.850 -0.950
Loss on drying:	Max. 5.0%
/n/20/D:	I .4 -1.5
Content of fatty acids	85 -95%
Saponification value	220 -240
Iodine value	30 -60



Standard-gas chromatogram of Saw Palmetto lipidic extract from EUROMED

eTable. Descriptions of all serious adverse events reported among participants by dose level

Dose level	Description of serious adverse event
Saw palmetto extract (n=18)	
Single (320 mg)	
1	Bladder cancer
2	Severe gastroenteritis
3	Syncope with transient high grade atrioventricular block
Double (640 mg)	
1	Elective knee replacement
2	Hospitalized for diverticulitis
3	Hospitalized for pneumonia
4	Gross hematuria
5	Elective plastic surgery
6	Automobile accident with multiple injuries
7	Pancreatic cancer
8	Elective repair of abdominal aortic aneurysm
Triple (960 mg)	
1	Cerebellar stroke*
2	Inferior wall myocardial infarction*
3	Metastatic recurrent follicular thyroid carcinoma**
4	Hospitalized for radioactive iodine treatment for thyroid cancer**
5	Hospitalized for chest pain due to coronary artery disease, underwent revascularization
6	Hospitalized for hypotension due to pneumonia and chronic kidney disease
7	Sepsis secondary to a pelvic fracture***
Placebo (n=18)	
Single	
1	Appendectomy for appendicitis
2	Back surgery for a lumbar spinal connective tissue cyst
3	Small bowel obstruction requiring laparoscopy lysis of adhesions
4	Hospitalized for knee pain secondary to torn vastus lateralis muscle
5	Hospitalized for abdominal pain, underwent laparascopic cholecystectomy
6	Lower gastrointestinal diverticular bleeding
7	Elective tonsillectomy and deviated nasal septum repair
Double	
1	Upper gastrointestinal bleeding requiring transfusion*
2	Appendectomy for ruptured appendix
3	Bacterial epididymitis requiring intravenous antibiotics
4	Hospitalized for chest pain that proved noncardiac after study
Triple	
1	Hospitalized after pacemaker insertion
2	Colon resection for a polyp
3	Elective knee replacement
4	Episode of atrial fibrillation
5	Hospitalized for cellulitis of the elbow, required intravenous antibiotics
6	Hospitalized for chest pain***

*Only these three SAEs were reported as possibly drug-related.
**These two SAEs were reported in the same CAMUS participant.
***These two SAEs were reported within 30 days after discontinuing the study drug.