

## Hot flashes and suspected anticipation of menarche in young girls treated with food supplements containing *Serenoa repens*

M.Miroddi<sup>1</sup>, P.Morabito<sup>1</sup>, S.Giovinazzo<sup>2</sup>, C.Mannucci<sup>1</sup>, A.Carni<sup>1</sup>, M.Navarra<sup>3</sup>, E.Spina<sup>1</sup>, G.Calapai<sup>1</sup>

<sup>1</sup>Dept. of Clinical and Experimental Medicine, University of Messina, Italy

<sup>2</sup>Unit of Endocrinology, Department of Clinical and Experimental Medicine, University of Messina, Italy

<sup>3</sup>Dept. of Drug Sciences and Products for Health, University of Messina, Messina, Italy

*Serenoa repens* (Bartr.), commonly known as *assaw palmetto*, is a low shrubby palm native of West Indies growing also in North America and European Mediterranean countries. The fruits of the saw palmetto are highly enriched with fatty acids and phytosterols. Extracts of the plant *Serenoa repens* are widely used in male adults for the treatment of benign prostatic hyperplasia (BPH). In the recent years it has been proposed to treat androgenic alopecia and other hair disorders. We reported two cases of hot flashes in young (11 years old) girls using a food supplement containing extract of *Serenoa repens* for the treatment of alopecia (*telogen effluvium*) and hirsutism, respectively. The first case of an 11-year-old girl presented hot flashes after treatment of *telogen effluvium* with a food supplement containing *Serenoa repens* that lasted about 2 months. When use of the product was discontinued, the hot flashes no longer occurred. Four months after the start of *S. repens* intake and 45 days from the cessation of therapy, the girl experienced menarche at the age of 11 years. The second case was about a 11-year-old girl who experienced hot flashes several times during a day during the third month of treatment with *Serenoa repens*. When she stopped the treatment, hot flashes disappeared in a couple of weeks. After rechallenge with *Serenoa repens*, symptoms reappeared in 4 days. Therefore the treatment was definitely suspended. About 4 months (113 days) after the start of therapy and 25 days from the cessation of the intake of the phytotherapeutic agent, the girl experienced menarche with polymenorrhea (cycle of 17 days) and hypermenorrhea. The Naranjo adverse drug reaction probability scale indicated a probable relationship (score of 6) between the appearance of hot flashes and the intake of *Serenoa repens* in both the cases. A correlation between exposure to *Serenoa repens* and changes in the onset of menarche is not certain. However, it cannot be excluded that in one or both the cases reported food supplement intake could have anticipated the age of menarche. On the light of this evidence we believe that medicinal products or food supplements containing *Serenoa repens* are generally well tolerated in male adults, and we think that their use in pediatric patients should be better evaluated.