



HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

**TRANSPARENCY COMMITTEE**

OPINION

19 January 2011

**ABUFENE 400 mg, tablets**  
**B/30 (CIP code: 335 289-2)**

**Applicant: BOUCHARA RECORDATI**

Beta-alanine  
ATC code: G03X

Date of Marketing Authorisation: 23 September 1991 (national procedure)

Reason for request: Renewal of inclusion on the list of medicines refundable by National Health Insurance.

## 1. CHARACTERISTICS OF THE MEDICINAL PRODUCT

### 1.1. Active ingredient

Beta-alanine

### 1.2. Indication

“For use in menopausal hot flushes.”

### 1.3. Dosage

“The dosage is 1 to 2 tablets a day. This dosage can safely be increased to 3 tablets a day if necessary.

The medicinal product is to be administered for periods of 5 to 10 days until the hot flushes abate.

When they reappear, a further cycle of drug treatment must be administered again for the same period.

As no habituation is observed, treatment can be prolonged throughout the entire duration of clinical vasomotor disorders, with no time limit.”

## 2. SIMILAR MEDICINAL PRODUCTS

### 2.1. ATC Classification (2010)

G : Genitourinary system and sex hormones  
G03 : Sex hormones and modulators of the genital system  
G03X : Other sex hormones and modulators of the genital system

### 2.2. Medicines in the same pharmaco-therapeutic category

2.2.1 Strictly comparator medicines  
Not applicable.

2.2.2 Not-strictly-comparator medicines  
Not applicable.

### 2.3. Medicines with a similar therapeutic aim

Hormone replacement treatments for the menopause

### 3. REMINDER OF THE COMMITTEE'S PREVIOUS OPINIONS

#### Opinion of 10 February 1993

Proposal for inclusion on the list of medicines refundable by National Health Insurance and on the list of medicines approved for hospital use and various public services in all the therapeutic indications indicated in the Marketing Authorisation.

#### Opinion of 4 December 1996 - Reassessment

Reassessment of actual benefit:

The treatments conventionally used in menopausal disorders are hormone replacement treatments for the menopause. The therapeutic use of ABUFENE is therefore limited.

#### Opinion of the Committee of 19 January 2000

The Committee is awaiting the reassessment of the actual benefit of proprietary medicinal products in this class.

Proposal for inclusion on the list of medicines refundable by National Health Insurance

#### Opinion of 2 April 2003 - Reassessment

The actual benefit of ABUFENE is low.

#### Opinion of 25 September 2005

##### Actual benefit

Hot flushes are common in menopausal women and can also arise as complications of hormone-dependent cancers (of the breast, uterus and ovaries).

This condition is not life-threatening, nor does it cause serious complications, or any disability, or a marked deterioration in quality of life.

This proprietary medicinal product is a symptomatic therapy.

The efficacy/adverse effects ratio for this proprietary medicinal product is low.

Alternative medicinal products exist.

The actual benefit of ABUFENE is low.

#### 4. UPDATING OF AVAILABLE DATA SINCE THE PREVIOUS OPINION

A placebo-controlled study published in 1991<sup>1</sup> was not taken into consideration because of methodological shortcomings (in particular: 44% of the female patients taking part were not menopausal, no description of the statistical tests used was provided).

The pharmaceutical company has not provided any new data showing the efficacy of ABUFENE compared to the effect of a placebo.

#### 5. DATA ON THE USE OF THE MEDICINE

According to IMS data (moving annual total November 2010), 377,000 prescriptions were issued for ABUFENE 400 mg. ABUFENE was prescribed mainly for menopausal and perimenopausal disorders (85.7%).

#### 6. TRANSPARENCY COMMITTEE CONCLUSIONS

##### 6.1. Actual benefit

The vasomotor symptoms of the menopause can impair quality of life.

This proprietary medicinal product is a symptomatic therapy.

The data available are insufficient to distinguish between ABUFENE and a placebo. The efficacy/adverse effects ratio for this proprietary medicinal product is low.

In the light of the data available, this proprietary medicinal product is not expected to have any impact on menopausal disorders and the quality of life of patients undergoing treatment compared to the alternatives available.

Consequently, ABUFENE is not expected to have an impact on public health.

ABUFENE has no role in the treatment strategy of menopausal hot flashes.

There are treatment alternatives (hormone replacement treatments for the menopause, in accordance with the precautions for use, contraindications and Afssaps guidelines).

In the light of this information, the Transparency Committee is of the opinion that the actual benefit of this proprietary medicinal product, which does not seem to be any more effective than a placebo, is insufficient to justify inclusion on the list of medicines refundable by National Health Insurance.

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1 Roueche J.C. *et al.* ABUFENE 400 mg et bouffées de chaleur. Etude en double aveugle versus placebo. [ABUFENE 400 mg and hot flashes. Double-blind placebo-controlled study.] La revue du praticien – médecine générale. 1991 ; 5 : 2385-88

## **6.2. Therapeutic use**

### **6.2.1 Therapeutic strategy**

HTM is still indicated for menopausal women suffering from functional disorders that are associated with the menopause and that affect their quality of life. It must be prescribed at the lowest effective dose, for the shortest possible period, in accordance with the precautions for use and contraindications, after giving the patient clear information as to the risks. Afssaps reminds physicians that all women undergoing HTM must have their treatment reviewed on a regular basis at least once a year<sup>2</sup>.

### **6.2.2 Therapeutic use of the proprietary medicinal product**

As the available data is insufficient to distinguish between the proprietary medicinal product and a placebo in terms of efficacy, ABUFENE has no role in the treatment strategy of menopausal hot flushes.

## **6.3. Transparency Committee recommendations**

The Transparency Committee does not recommend continued inclusion on the list of medicines refundable by National Health Insurance in the indication and at the dosage in the Marketing Authorisation.

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<sup>2</sup> Afssaps - Traitement hormonal de la ménopause(THM) - Point d'information [Hormonal treatment of the menopause (HTM) – update] – February 2008.