



HAUTE AUTORITÉ DE SANTÉ

The legally binding text is the original French version

TRANSPARENCY COMMITTEE

OPINION

5 January 2011

THELIN 100 mg, film-coated tablets
B/28 (CIP code: 379 171-7)

Applicant: PFIZER

sitaxentan
ATC code: C02KX03

List I

Medicine for hospital prescription only, restricted to specialists and/or departments specialising in cardiology, pneumology, or internal medicine.
Medicine requiring special monitoring during treatment.

Date of Marketing Authorisation (centralised procedure): 10 August 2006
Orphan drug (designation granted on 21 October 2004)

Reason for examination: Reassessment of actual benefit and improvement in actual benefit (IAB) under article R-163-21 of the Social Security Code.

Indications:

“Treatment of patients with pulmonary arterial hypertension classified as WHO functional class III, to improve exercise capacity. Efficacy of treatment has been shown in primary pulmonary arterial hypertension and pulmonary arterial hypertension associated with connective tissue disease”.

Dosage: see SPC

The Transparency Committee has reassessed all treatments for PAH. The actual benefit of each drug has been assessed (see complete report attached).
As far as THELIN is concerned, the Transparency Committee's conclusions have been amended from those given in the opinion dated 20 June 2007, and are as follows:

Actual benefit (AB)

The European and French health authorities were notified by PFIZER on 10 December 2010 that it was withdrawing the proprietary drug THELIN from the international market and terminating ongoing clinical trials. The pharmaceutical company took this decision in the light of reports of three cases of liver damage with fatal outcome in England, India and the Ukraine.

THELIN has been known to be potentially hepatotoxic since the drug was granted marketing authorisation, and is subject to close monitoring.

In the light of this information, the Transparency Committee takes the view that there is no longer any need for it to draw up an opinion as to the product's actual benefit.

Improvement in actual benefit (IAB)

Not applicable.

Medical, Economic and Public Health Assessment Division