HAUTE AUTORITÉ DE SANTÉ

ONCOLOGY
New indication
February 2015

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

TAXOTERE (docetaxel), antineoplastic agent

In combination with doxorubicin and cyclophosphamide, the actual benefit of TAXOTERE is insufficient in the treatment of operable node-negative breast cancer, according to the TAC protocol (TAXOTERE, Adriamycin, cyclophosphamide)

Main points

- TAXOTERE now has Marketing Authorisation in the adjuvant treatment of operable, node-negative breast cancer, in combination with doxorubicin and cyclophosphamide.
- The benefit of TAXOTERE on use of the TAC protocol (TAXOTERE, Adriamycin, cyclophosphamide) is analysed as regards the reduction in the risk of recurrence versus haematological toxicity (febrile neutropenia).
- Given the availability of alternatives with fewer haematological adverse effects, TAXOTERE administered concomitantly with cyclophosphamide and Adriamycin (TAC) has no role in the adjuvant treatment of node-negative breast cancer.
- Outside the TAC protocol, TAXOTERE retains its role in the adjuvant treatment of breast cancer (sequential regimen of FEC 100 followed by TAXOTERE).

Pre-existing indications

TAXOTERE already has Marketing Authorisation in the management of cancers in various locations (breast, lung, prostate, stomach, upper aerodigestive tract).
This summary does not cover these indications.

Therapeutic use

- If there are no contraindications, the adjuvant chemotherapy of breast cancers consists of anthracyclines and taxanes. The FEC 100 protocol (5-fluorouracil, epirubicin, cyclophosphamide) habitually used in Europe is preferred to FAC 50 (5-fluorouracil, Adriamycin, cyclophosphamide) because it has less cardiotoxicity.
- According to the latest ESMO guidelines (2012), sequential administration of these substances is more effective than concomitant administration. In addition, the results of a study have shown the superiority of the regimen consisting of three cycles of FEC 100 followed by three cycles of TAXOTERE over the administration of six cycles of FEC in terms of progression-free survival and overall survival at 5 years. TAXOTERE is therefore prescribed according to this sequential regimen in operable node-positive breast cancer. According to expert opinion, the sequential regimen of 3 FEC 100 followed by 3 TAXOTERE 100 is also recommended in node-negative patients who are eligible for adjuvant chemotherapy.
- **Role of the medicinal product in the therapeutic strategy**

Given the therapeutic alternatives, TAXOTERE in combination with doxorubicin and cyclophosphamide according to the TAC protocol, has no role in adjuvant treatment in patients with operable breast cancer whose risk of recurrence is smaller because they are node-negative.

Clinical data

- The efficacy and safety of TAXOTERE have been evaluated in an open, randomised, two-parallel-group study the aim of which was to compare the efficacy of six cycles of the TAC protocol (docetaxel-doxorubicin-cyclophosphamide) with that of six cycles of the FAC protocol (5-fluorouracil-doxorubicin-cyclophosphamide). The primary endpoint was disease-free survival. This study included 1051 women with operable node-negative breast cancer of histological grade II or III.
- Over a total median follow-up period of 77 months, one of the events defined in the primary efficacy endpoint (local or regional recurrence, appearance of metastasis or of a second cancer, or death from all causes) occurred in 12.2% of the patients in the TAC group versus 18.2% in the FAC group. Nevertheless, the results of this study cannot be transferred to current practice, since the TAC regimen is not recommended in this indication.
- Serious adverse events were reported in 22.4% of the patients in the TAC group (of which 20.3% linked to treatment), and in 4.2% of the patients in the FAC group (of which 3.3% linked to treatment), mainly febrile neutropenia and gastrointestinal disorders.

Special prescribing conditions

- Medicine for hospital prescription
- Prescription reserved for certain specialists
- Medicine requiring special monitoring.

Benefit of the medicinal product

- The actual benefit* of TAXOTERE, when used in the TAC protocol in combination with doxorubicin and cyclophosphamide, is insufficient in the indication of operable, node-negative breast cancer. However, the Committee underlines the benefit of the role of TAXOTERE in France in the sequential regimen consisting of 3 FEC 100 followed by 3 TAXOTERE.
- Does not recommend inclusion on the list of reimbursable products for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 18 February 2015 (CT-13382) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.