

14.03 DOCETAXEL

Solution concentrate for I.V. infusion 160 mg in 8 mL

Docetaxel Accord[®], Accord Healthcare Australia

1 Purpose of Application

1.1 The minor submission requested an unrestricted listing for a new form of docetaxel.

2 Requested Listing

2.1 The submission requested no changes to the existing listing.

Name, Restriction, Manner of administration and form	Max. Amt	No. of Rpts	Dispensed Price for Max. Amt	Proprietary Manufacturer	Name and
DOCETAXEL injection, 160 mg / 8 mL	250 mg	5	\$ [REDACTED]	Docetaxel Accord [®]	Accord Healthcare Australia

3 Suitability for pharmacist substitution

3.1 As per existing listings for forms with the same total drug content per vial, Administrative Advice should state, "Pharmaceutical benefits that have the forms docetaxel solution concentrate for I.V. infusion 160 mg in 8 mL and docetaxel solution concentrate for I.V. infusion 160 mg in 16 mL are equivalent for the purposes of substitution."

4 Background

4.1 Docetaxel was listed on the PBS in the mid-1990s for the treatment of androgen independent (castrate resistant) metastatic prostate cancer.

4.2 At its July 2014 meeting, the PBAC recommended changing the listings for docetaxel from Authority required (STREAMLINED) to unrestricted benefit listings for all

indications following the substantial price reductions that the drug had been subject to since the PBAC's original recommendation for listing. The PBAC considered it highly likely that the incremental cost effectiveness ratio at the current price would be acceptable for the use of docetaxel upfront with androgen deprivation therapy.

5 Pricing considerations

- 5.1 Existing PBS listed forms of docetaxel separately have either the same total drug content (160 mg) or the same concentration (20 mg/mL) as the requested form, meaning that neither the total drug content nor the concentration of the requested form is new to the PBS. As the requested Dispensed Price for Maximum Amount is the same as the existing PBS listings, the inclusion of this new form of docetaxel is expected to be cost neutral to the PBS.

6 Other relevant factors

- 6.1 The maximum quantity and number of repeats are consistent with the recommended dosage and existing PBS listings.
- 6.2 Docetaxel is currently exempt from the Early Supply Rule and has a resupply interval of 4 days.

7 PBAC Outcome

- 7.1 The PBAC noted the change to the listings processed by the secretariat.

Outcome:

Recommended

8 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

9 Sponsor's Comment

The sponsor had no comment.