

# Abraxane®

(nanoparticle albumin-bound paclitaxel)

## Request for Further Information

I would like to request the following Abraxane information :  
(Please tick relevant boxes and complete your details)

- ASCO 2010 Abstract Booklet  
(featuring 31 abstracts showing interim or final results for trials with Abraxane across various tumour types including breast, NSCLC, melanoma, ovarian, head and neck, pancreatic, and bladder cancer from ASCO)
- I would like a STA Representative to visit to discuss clinical trials or for further information
- I would like further information regarding Abraxane. Please specify:

Name:

Practice Address:

Postcode:

Email Address:

Telephone:

Please fax this form back to STA on:

# 1800 798 829

**Minimum Product Information:** ABRAXANE Nanoparticle albumin-bound paclitaxel 100 mg powder for injection (suspension). **INDICATIONS** Metastatic carcinoma of the breast after failure of anthracycline therapy. **CONTRAINDICATIONS** Baseline neutrophil count <  $1.5 \times 10^9/L$ , hypersensitivity to paclitaxel or albumin, pregnancy, lactation. **PRECAUTIONS** ABRAXANE should be administered under the supervision of a physician experienced in the use of chemotherapeutic agents. Appropriate management of complications is possible only when adequate diagnostic and treatment facilities are readily available. An albumin form of paclitaxel may substantially affect a drug's function properties relative to those of drug in solution. DO NOT SUBSTITUTE ABRAXANE WITH OTHER PACLITAXEL FORMULATIONS. Dose dependent and dose limiting bone marrow suppression (frequent peripheral blood cell counts are recommended for all patients), sensory neuropathy, hepatic impairment, fertility, pregnancy (category D), lactation, paediatric use, use in the elderly. For more details, refer to full PI. **INTERACTIONS** Paclitaxel is metabolised, in part, by CYP2C8 and CYP3A4. Caution should be exercised when administering ABRAXANE with known inhibitors (e.g. erythromycin, fluoxetine, imidazole antifungals, gemfibrozil, cimetidine, ritonavir, saquinavir, indinavir, and nelfinavir) or inducers (e.g. rifampicin, carbamazepine, phenytoin, efavirenz, nevirapine) of either CYP2C8 or CYP3A4. *In vitro* studies have shown that the metabolism of paclitaxel is inhibited by a large number of drugs, including CYP2C8 and CYP3A4 substrates, quinidine, PEG-35 castor oil, quercetin, clozapine, morin, and resveratrol. For more details, see full PI. **ADVERSE REACTIONS** Neutropenia, anaemia, leukopenia, thrombocytopenia, lymphopenia, infections, abnormal ECG, dyspnea, sensory neuropathy, myalgia/ arthralgia, asthenia, fluid retention/ oedema, nausea, vomiting, diarrhoea, anorexia, alopecia, alkaline phosphatase elevations, AST (SOG) elevations, bone marrow suppression and mucositis. This is not a full list – for more details, refer to full PI. **DOSE** Recommended regimen for ABRAXANE is 260 mg/m<sup>2</sup> administered intravenously over 30 minutes every 3 weeks. Dose Adjustment: Patients who experience severe neutropenia (neutrophil < 500 cells/mm<sup>3</sup> for a week or longer) or severe sensory neuropathy during ABRAXANE therapy should have dosage reduced to 220 mg/m<sup>2</sup> for subsequent courses. For recurrence of severe neutropenia or severe sensory neuropathy, additional dose reduction to 180 mg/m<sup>2</sup> should be made. For grade 3 sensory neuropathy hold treatment until resolution to grade 1 or 2, followed by a dose reduction for all subsequent courses. Hepatic Insufficiency: Patients with severe hepatic impairment should not be treated with albumin-bound paclitaxel. **ADMINISTRATION** No pre-medication to prevent hypersensitivity reactions is required prior to administration of ABRAXANE. DO NOT MIX ANY OTHER DRUGS WITH THE ABRAXANE INFUSION. **PREPARATION FOR INTRAVENOUS ADMINISTRATION** ABRAXANE is supplied as a sterile lyophilised powder for reconstitution before use. ABRAXANE should be reconstituted with 20 mL of diluent. The reconstituted suspension contains 5 mg/mL paclitaxel. Inject the appropriate amount of reconstituted ABRAXANE into an empty, sterile, polyvinyl chloride (PVC) or non-PVC type IV bag for IV infusion. For more details, refer to full PI.