OTHER NAMES	**CLASSIFICATION**	
TAXOTERE	Antineoplastic (Irritant)	

INDICATIONS FOR IV USE

HEALTH CANADA APPROVED[1]

- Alone or in combination with other antineoplastic agents in various conditions including breast, head and neck, ovarian or non-small cell lung cancer.

NON HEALTH CANADA APPROVED INDICATIONS BUT SUBSTANTIATED IN THE LITERATURE[2]

- Alone or in combination with other antineoplastic agents in various conditions including small cell lung, prostate, urothelial transitional cell cancer and mesothelioma.

CONTRAINDICATIONS

- *Hypersensitivity to docetaxel or other taxoid compounds, e.g. paclitaxel. Exception: patients with objective tumour responses, and in whom the benefit outweighs the risk, may be rechallenged with aggressive premedication.*[2]
- *Hypersensitivity to polysorbate 80 or polysorbate 80-containing preparations, e.g. etoposide.*[2]
- Severe hepatic impairment.[1]

CAUTIONS[2]

- Hepatic impairment: dose reduction required. Alcoholics; increased risk of severe neurotoxic reactions.
- Pre-existing effusions; possible exacerbation of condition, monitor closely.

DRUG INTERACTIONS:

- Drugs that induce, inhibit or are metabolised by cytochrome P450 3A4, such as cyclosporine, ketoconazole and erythromycin: metabolism of docetaxel may be modified.

PREGNANCY/BREAST FEEDING: Contact Drug Information for most recent information.

ADMINISTRATION[2]

BCCA administration guideline in ***bold, italics***

MODE	**DIRECT INTO IV TUBING**	**INTERMITTENT INFUSION**	**CONTINUOUS INFUSION**
	NO	YES	NO
WHO MAY GIVE		Registered nurses with specialized skills - non-vesicant chemotherapy administration training.	
ADULT		Pharmacy to prepare dose and dilute ***in 250 mL NS*** or D5W to a final concentration of 0.1 to 0.9 mg/mL. If slow initiation is needed: 30 mL/h for 5 min, 60 mL/h for 5 min, 120 mL/h for 5 min then complete infusion at 250 mL/h	
PAEDIATRIC		Limited information	
REQUIREMENTS	Polyethylene-lined administration set without a filter (e.g. docetaxel tubing) Non-PVC container (e.g. polyolefin bag)		

MONITORING

REQUIRED

- Baseline BP, HR, RR and temperature, then 10 minutes after start of infusion and 15 to 30 minutes after completion of infusion.
- Observe continuously for signs of anaphylactoid reaction (i.e., dyspnoea, hypotension, bronchospasm, wheezing) for 10 minutes after the start of each dose.

RECOMMENDED

- Baseline CBC with differential, then weekly during therapy or as per protocol.
- Baseline AST, alkaline phosphatase, and bilirubin, and then weekly during therapy, or as per protocol.

RECONSTITUTION

- Available as docetaxel 20 mg and 80 mg vials, plus required diluent.

COMPATIBILITY/STABILITY

- Do not filter.[2]
- Compatible with D5W and NS.
- All products are individually labelled with an expiry date and storage instructions.
- For drug-drug compatibility, contact Drug Information.

ADVERSE EFFECTS[1,2]

HAEMATOLOGICAL

- Neutropenia, dose limiting toxicity. Nadir 8 days, duration of severe neutropenia 7 days.
- Anaemia, leukocytopenia, thrombocytopenia.

HYPERSENSITIVITY REACTIONS

- Generally occur within the first few minutes of starting infusion. Signs and symptoms typically resolve within 15 minutes of stopping the infusion.
- Minor reactions - flushing, skin reactions, back pain, drug fever, chills.
- Severe reactions (rare) - requires immediate discontinuation of docetaxel and aggressive symptomatic therapy. Dyspnoea, hypotension, generalised rash/erythema.

FLUID RETENTION

- Oedema, usually beginning with the lower extremities. Onset generally occurs after 4 treatment cycles or at a cumulative dose of 400 mg/m^2 or greater. May be dose limiting. Premedication with oral corticosteroids delays onset, reduces incidence and/or severity.

DERMATOLOGICAL

- Rash, including localised eruptions mainly on hands and feet. Onset 1 week, usually resolves before next infusion.
- Reversible alopecia. Involves all body hair. Onset 2 to 4 weeks, may be sudden.[3]
- Pruritus, hypo- or hyperpigmentation of nails.

GASTROINTESTINAL

- Nausea, onset 12 to 24 hours, duration 3 to 4 days. Generally mild to moderate. Antiemetics are not routinely required.
- Diarrhoea, stomatitis, vomiting.

MISCELLANEOUS

- Fatigue and asthenia, particularly with the weekly schedule. May be severe and dose limiting.
- Tearing/watery eyes; particularly with weekly schedule after a median cumulative dose of 400 mg/m^2
- Neuropathy; both sensory and motor.
- Arthralgia, myalgia.
- Infusion site reactions: generally mild, including hyperpigmentation, inflammation, local erythema.

DOSE

Numerous dosing schedules exist and depend on disease, response and concomitant therapy. Guidelines for dosing include consideration of white blood cell count and/or dose limiting side effects; when dosages may be reduced or delayed. Refer to individual chemotherapy protocol whenever possible.

ADULT[2] BCCA usual dose noted in ***bold, italics***

- All patients should be premedicated with oral corticosteroids starting on the day before treatment and continuing for a total of 3 - 5 days. (see Adverse Effects) Slow initiation of infusion is not routinely needed as long as patient is premedicated appropriately.
- ***100 mg/m^2*** (range 40-100 mg/m^2) ***for one dose on day 1. Repeat every 3 weeks.***
- 20-40 mg/m^2 for one dose on days 1 and 8 (total dose per cycle 40-80 mg/m^2). Repeat every 3 weeks.
- 25-90 mg/m^2 for one dose on day 1. Repeat every 4 weeks.
- 36 mg/m^2 for one dose on days 1, 8, 15, 22, 29 and 36 (total dose per cycle 216 mg/m^2) NB, sometimes referred to as the "weekly schedule" Repeat every 8 weeks.

ELDERLY

- No age related dosage adjustment required. Monitor hepatic function carefully.

PAEDIATRIC

- Limited information available at this time. Adolescents involved in phase I and II trials have received doses similar to adults.[4-6]

RENAL IMPAIRMENT ADJUSTMENTS

- None required.[2]

HEPATIC IMPAIRMENT ADJUSTMENTS

- Dose modification depends on frequency of administration and concomitant therapy – refer to individual protocol.

HEMO/PERITONEAL DIALYSIS

- No information available at this time.

MISCELLANEOUS

- Extravasation - irritant – there is no consensus on the application of warm or cold compresses. Use patient's preference.
- Environmental concerns - use chemotherapy precautions.
- IM and subcutaneous use: no information available at this time.

docetaxel - REFERENCES

1. Repchinsky C, ed. Compendium of Pharmaceuticals and Specialties. 40th ed. Ottawa, ON: Canadian Pharmaceutical Association; 2005.

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3. Extra JM, Rousseau F, Bruno R, Clavel M, Le Bail N, Marty M. Phase I and pharmacokinetic study of taxotere (RP 56976; NSC 628503) given as a short intravenous infusion. Cancer Res 1993; 53:1037-42.

4. Adachi I, Watanabe T, Takashima S, Narabayashi M, Horikoshi N, Aoyama H, Taguchi T. A late phase II study of RP56976 (docetaxel) in patients with advanced or recurrent breast cancer. Br J Cancer 1996; 73:210-6.

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6. Kudo S, Hino M, Fujita A, Igarashi T, Arita K, Niitani H, Taguchi T. [Late phase II clinical study of RP56976 (docetaxel) in patients with non-small cell lung cancer]. [Japanese] Gan to Kagaku Ryoho 1994; 21(15):2617-23. (English abstract only).