Docetaxel Kabi 20 mg/ml
Trusted Generics: Total Care

Docetaxel Kabi 20 mg/ml
Concentrate for solution
for infusion
Docetaxel Kabi

Therapeutic class
Taxane – mitotic inhibitor

Indications
Treatment of:
- Locally advanced and metastatic breast cancer
- Locally advanced and metastatic non small cell lung cancer
- Locally advanced and metastatic gastrointestinal cancers
- Advanced head and neck cancers
- Hormone refractory metastatic prostate cancer

Docetaxel Kabi is available as follows:

<table>
<thead>
<tr>
<th>Strength</th>
<th>Volume</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>20 mg</td>
<td>1 ml</td>
<td>Vial</td>
</tr>
<tr>
<td>80 mg</td>
<td>4 ml</td>
<td>Vial</td>
</tr>
<tr>
<td>120 mg</td>
<td>6 ml</td>
<td>Vial</td>
</tr>
<tr>
<td>160 mg</td>
<td>8 ml</td>
<td>Vial</td>
</tr>
<tr>
<td>180 mg</td>
<td>9 ml</td>
<td>Vial</td>
</tr>
</tbody>
</table>

Composition
1 ml of concentrate contains 20 mg docetaxel anhydrous

Pharmaceutical form
Concentrate for solution for infusion (sterile concentrate). The concentrate is a colourless Type-I glass vial, closed with fluorotec rubber stopper and a blue flip-off aluminium over seal.

Excipients
Polysorbate 80, ethanol anhydrous, anhydrous citric acid (ph-adjustment)

Shelf life
2 years (before opening the vial)

The colour of the packaging is designed to improve patient and user safety and to distinguish between different products in our range.
Stability

Each vial is for single use and should be used immediately after opening. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Once added as recommended into the infusion bag, the docetaxel infusion solution, if stored below 25 °C, is stable for 6 hours. It should be used within 6 hours (including the one hour infusion intravenous administration).

Docetaxel Kabi in focus

- Proven mitotic inhibitor for cancer chemotherapy*
- Inhibits depolymerization of microtubules twice as effectively as Paclitaxel
- Established survival profile


Manufacturing and safety

Docetaxel Kabi is made by Fresenius Kabi from our own raw materials giving us full control of the manufacturing and supply chain. Our state of the art cleaning process for finished vials guarantees the removal of all external contamination.

Fresenius Kabi sleeved vials (OncoShield®) offers maximum protection for people working with cytotoxic drugs.
Abridged SPC of Docetaxel Kabi 20 mg/ml concentrate solution for infusion (Docetaxel)

**Composition:** The solution contains 20 mg of docetaxel. Each vial of 1 ml contains 20 mg, each vial of 2 ml contains 40 mg, each vial of 3 ml contains 60 mg, each vial of 6 ml contains 120 mg, each vial of 8 ml contains 160 mg and each vial of 9 ml contains 180 mg of docetaxel.

**Indication:** Docetaxel is indicated for the treatment of breast cancer as follows: in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer. In combination with doxorubicin for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition. As monotherapy in the treatment of patients with locally advanced or metastatic breast cancer after failure of previous cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent. In combination with trastuzumab for the treatment of patients with metastatic breast cancer whose tumours over express HER2 and who previously have not received chemotherapy for metastatic disease. In combination with docetaxel for the treatment of patients with hormone refractory metastatic prostate cancer.

**Dosage and Administration:** Docetaxel is administered as a one-hour infusion every three weeks. For breast, NSCLC, gastric, and head and neck cancers premedication consisting of an oral corticosteroid, such as dexamethasone 16 mg per day (e.g. 8 mg b.i.d) for 3 days starting 1 day prior to docetaxel administration, unless contraindicated, can be used. Prophylactic G-CSF may be used to mitigate the risk of haematological toxicities. For prostate cancer, due to the concurrent use of prednisone or prednisolone, the recommended prophylactic dose of G-CSF is 500 micrograms/m² every 3 weeks for 4 cycles. For patients with locally advanced metastatic breast cancer, the recommended dose of docetaxel is 100 mg/m² in monotherapy. In first-line treatment, docetaxel 75 mg/m² is given in combination with doxorubicin (50 mg/m²). In combination with trastuzumab the recommended dose of docetaxel is 100 mg/m² every three weeks. In combination with capecitabine, the recommended dose of docetaxel is 75 mg/m² every three weeks, combined with capcetabine at 1250 mg/m² twice daily (within 30 minutes after a meal) for 2 weeks followed by a 1 week rest period. For capecitabine dose calculation according to body surface area, see capcetabine summary of product characteristics. In combination with capecitabine, the recommended dose regimen is docetaxel 75 mg/m² every 3 weeks, combined with capecitabine at 1250 mg/m² twice daily (within 30 minutes after a meal) for 2 weeks followed by a 1 week rest period. For capecitabine dose calculation according to body surface area, see capcetabine summary of product characteristics. In combination with trastuzumab, particularly following anthracycline-containing chemotherapy. Others: contraceptive measures must be taken by both men and women during treatment and for men at least 6 months after cessation of therapy. Gastrointestinal reactions: symptoms such as early abdominal pain and tenderness, fever, diarrhoea, with or without neutropenia, may be early manifestations of congestive heart failure. Although most cases are not related to docetaxel, the risk of congestive heart failure should be considered if patients develop symptoms of congestive heart failure during therapy and during the follow up period. Pregnancy and lactation: DOCETAXEL KABI must NOT be administered if you are pregnant unless clearly indicated by your doctor. You must not become pregnant during treatment with Docetaxel. Docetaxel should be avoided in pregnant women as it has been shown to cause birth defects and fetal death. There are no reports of overdose. There is no known antidote for docetaxel overdose. In case of overdose, the patient should be kept in a specialised unit and vital functions closely monitored. In cases of overdose, exacerbation of adverse events may be expected. The primary anticipated complications of overdose would consist of bone marrow suppression, peripheral neurotoxicity and mucositis. Patients should receive therapeutic G-CSF as soon as possible after discovery of overdose. Other appropriate symptomatic measures should be taken, as needed. List of excipients: Polysorbate 80, ethanol anhydrous, anhydrous citric acid (pH adjustment) Shell Life: 2 years (before opening the vial)

Registered product information may differ in your country. Before prescribing please refer to nationally approved prescribing information.