LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Docetaxel Seacross
# (docetaxel)

# SE/H/1049/01/E/01

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# Summary Public Assessment Report

Docetaxel Seacross
docetaxel (anhydrous)

Concentrate for solution for infusion, 20 mg/ml

This is a summary of the public assessment report (PAR) for Docetaxel Seacross. It explains how Docetaxel Seacross was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Docetaxel Seacross.

For practical information about using Docetaxel Seacross, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Docetaxel Seacross and what is it used for?**
Docetaxel Seacross is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Taxotere.

Docetaxel belongs to the group of anti-cancer medicines called taxoids. Docetaxel Seacross is used for for the treatment of breast cancer, special forms of lung cancer (non-small cell lung cancer), prostate cancer, gastric cancer or head and neck cancer. Depending on type of cancer, Docetaxel Seacross could be administered either alone or in combination with other medicines.

**How is Docetaxel Seacross used?**

The pharmaceutical form of Docetaxel Seacross is concentrate for solution for infusion.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

**What benefits of Docetaxel Seacross have been shown in studies?**

No additional studies were needed as Docetaxel Seacross is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Taxotere.

**What are the possible side effects from Docetaxel Seacross?**

Because Docetaxel Seacross is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

**Why is Docetaxel Seacross approved?**

It was concluded that, in accordance with EU requirements, Docetaxel Seacross has been shown to have comparable quality and similar to the reference medicine Taxotere. Therefore, the Swedish

Medical Products Agency decided that, as for Taxotere, the benefits are greater than its risks and recommended that it can be approved for use.

**What measures are being taken to ensure the safe and effective use of Docetaxel Seacross?**

A risk management plan has been developed to ensure that Docetaxel Seacross is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Docetaxel Seacross, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

**Other information about Docetaxel Seacross**

The full PAR for Docetaxel Seacross can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Docetaxel Seacross, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-06.