

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

Docetaxel Ebewe 10 mg/ml concentrate for solution for infusion

### **Docetaxel**

#### **Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **What is in this leaflet:**

1. What Docetaxel Ebewe is and what it is used for
2. What you need to know before you use Docetaxel Ebewe
3. How to use Docetaxel Ebewe
4. Possible side effects
5. How to store Docetaxel Ebewe
6. Content of the pack and other information

### **1. WHAT DOCETAXEL EBEWE IS AND WHAT IT IS USED FOR**

The name of this medicine is Docetaxel Ebewe. Its common name is docetaxel. Docetaxel is a substance derived from the needles of yew trees. Docetaxel belongs to the group of anti-cancer medicines called taxoids.

Docetaxel Ebewe has been prescribed by your doctor 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:

- for the treatment of advanced breast cancer, Docetaxel Ebewe could be administered either alone or in combination with doxorubicin, or trastuzumab, or capecitabine.
- for the treatment of early breast cancer with or without lymph node involvement, Docetaxel Ebewe could be administered in combination with doxorubicin and cyclophosphamide.
- for the treatment of lung cancer, Docetaxel Ebewe could be administered either alone or in combination with cisplatin.
- for the treatment of prostate cancer, Docetaxel Ebewe is administered in combination with prednisone or prednisolone.
- for the treatment of metastatic gastric cancer, Docetaxel Ebewe is administered in combination with cisplatin and 5-fluorouracil.
- for the treatment of head and neck cancer, Docetaxel Ebewe is administered in combination with cisplatin and 5-fluorouracil.

### **2. WHAT YOU NEED TO KNOW BEFORE YOU USE DOCETAXEL EBEWE**

#### **Do not use Docetaxel Ebewe**

- if you are allergic to docetaxel or any of the other ingredients of Docetaxel Ebewe.
- if the number of white blood cells is too low.
- if you have a severe liver disease.

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### **Warnings and Precautions Docetaxel Ebewe**

Before each treatment with Docetaxel Ebewe, you will have blood tests to check that you have enough blood cells and sufficient liver function to receive Docetaxel Ebewe. In case of white blood cells disturbances, you may experience associated fever or infections.

Tell your doctor, hospital pharmacist or nurse if you have vision problems. In case of vision problems, in particular blurred vision, you should immediately have your eyes and vision examined.

If you develop acute or worsening problems with your lungs (fever, shortness of breath or cough), please tell your doctor, hospital pharmacist or nurse immediately. Your doctor may stop your treatment immediately.

You will be asked to take premedication consisting of an oral corticosteroid such as dexamethasone, one day prior to Docetaxel Ebewe administration and to continue for one or two days after it in order to minimise certain undesirable effects which may occur after the infusion of Docetaxel Ebewe in particular allergic reactions and fluid retention (swelling of the hands, feet, legs or weight gain).

During treatment, you may be given other medicines to maintain the number of your blood cells.

Docetaxel Ebewe contains alcohol. Discuss with your doctor if you suffer from alcohol dependency or liver impairment. See also section "Important information about some of the ingredients of Docetaxel Ebewe" below.

### **Other medicines and Docetaxel Ebewe**

Please tell your doctor or hospital pharmacist if you are taking or have recently taken any other medicine, including medicines obtained without a prescription.

This is because Docetaxel Ebewe or the other medicine may not work as well as expected and you may be more likely to get a side effect.

### **Docetaxel Ebewe with food and drink:**

Grapefruit (fruit or juice) should not be consumed while taking Docetaxel. It can interfere with the usual effect of your medicine and you may be more likely to get a side effect.

### **Pregnancy, breast-feeding and fertility**

Ask your doctor or pharmacist for advice before taking any medicine.

Docetaxel Ebewe must NOT be administered if you are pregnant unless clearly indicated by your doctor..

You must not become pregnant during treatment with this medicine and must use an effective method of contraception during therapy, because docetaxel may be harmful for the unborn baby. If pregnancy occurs during your treatment, you must immediately inform your doctor.

You must NOT breast-feed while you are treated with Docetaxel Ebewe.

If you are a man being treated with Docetaxel Ebewe you are advised not to father a child during and up to 6 months after treatment and to seek advice on conservation of sperm prior to treatment because docetaxel may alter male fertility.

Docetaxel Ebewe

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### **Driving and using machines**

No studies on the effects on the ability to drive and use machines have been performed.

### **Important information about some of the ingredients of Docetaxel Ebewe**

This medicinal product contains 4100 mg alcohol per 160 mg (average dose), equivalent to less than 100 ml beer.

Harmful for those suffering from alcoholism.

To be taken into account in high risk groups such as patients with liver disease, or epilepsy.

The amount of alcohol in this medicinal product may alter the effects of other medicinal products.

The amount of alcohol in this medicinal product may impair the patient's ability to drive or use machines.

## **3. HOW TO USE DOCETAXEL EBEWE**

Docetaxel Ebewe will be administered to you by a healthcare professional.

### **Usual dose**

The dose will depend on your weight and your general condition. Your doctor will calculate your body surface area in square meters (m<sup>2</sup>) and will determine the dose you should receive.

### **Method and route of administration**

Docetaxel Ebewe will be given by infusion into one of your veins. The infusion will last approximately one hour during which you will be in the hospital.

### **Frequency of administration**

You should usually receive your infusion once every 3 weeks.

Your doctor may change the dose and frequency of dosing depending on your blood tests, your general condition and your response to Docetaxel Ebewe. In particular, please inform your doctor in case of diarrhoea, sores in the mouth, feeling of numbness or pins and needles, fever and give her/him results of your blood tests. Such information will allow her/him to decide whether a dose reduction is needed.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Your doctor will discuss these with you and will explain the potential risks and benefits of your treatment.

The most commonly reported adverse reactions of Docetaxel Ebewe alone are: decrease in the number of red blood cells or white blood cells, alopecia, nausea, vomiting, sores in the mouth, diarrhoea and tiredness.

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The severity of adverse events of Docetaxel Ebewe may be increased when Docetaxel Ebewe is given in combination with other chemotherapeutic agents.

During the infusion at the hospital the following allergic reactions (may affect more than 1 in 10 people):

- flushing, skin reactions, itching
- chest tightness; difficulty in breathing
- fever or chills
- back pain
- low blood pressure.

More severe reactions may occur.

The hospital staff will monitor your condition closely during treatment. **Tell them IMMEDIATELY if you notice any of these effects.**

Between infusions of Docetaxel Ebewe the following may occur, and the frequency may vary with the combinations of drugs that are received:

**Very common** (affects more than 1 user in 10):

- infections, decrease in the number of red (anaemia), or white blood cells (which are important in fighting infection) and platelets
- fever: if this happens you must tell your doctor immediately
- allergic reactions as described above
- loss of appetite (anorexia)
- unable to sleep (insomnia)
- feeling of numbness or pins and needles or pain in the joints of muscles
- headache
- alteration in sense of taste
- inflammation of the eye or increased tearing of the eyes
- swelling caused by faulty lymphatic drainage
- shortness of breath
- nasal drainage; inflammation of the throat and nose; cough
- bleeding from the nose
- sores in the mouth
- stomach upsets including feeling sick (nausea), vomiting and diarrhoea, constipation
- abdominal pain
- indigestion
- hair loss (in most cases normal hair growth should return)
- redness and swelling of the palms of your hands or soles of your feet which may cause your skin to peel (this may also occur on the arms, face, or body)
- change in the colour of your nails, which may detach
- muscle aches and pains; back pain or bone pain
- change or absence of menstrual period
- swelling of the hands, feet, legs
- tiredness; or flu-like symptoms
- weight gain or loss.

**Common** (affects 1 to 10 users in 100):

- oral candidiasis
- dehydration
- dizziness

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- hearing impaired
- decrease in blood pressure; irregular or rapid heart beat
- heart failure
- oesophagitis
- dry mouth
- difficulty or painful swallowing
- haemorrhage
- raised liver enzymes (hence the need for regular blood tests).

**Uncommon** (affects 1 to 10 users in 1,000):

- fainting
- reaction at the injection site, skin reactions, phlebitis (inflammation of the vein) or swelling
- inflammation of the colon, small intestine; intestinal perforation
- blood clots.

**Frequency unknown:**

- interstitial lung disease (inflammation of the lungs causing coughing and difficulty breathing. Inflammation of the lungs can also develop when docetaxel therapy is used with radiotherapy)
- pneumonia (infection of the lungs)
- pulmonary fibrosis (scarring and thickening in the lungs with shortness of breath)
- blurred vision due to swelling of the retina within the eye (cystoid macular oedema)
- decrease of the sodium in your blood.

### Reporting of side effects

If you get any side effects talk to your doctor, hospital pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the IMB Pharmacovigilance Earlsfort Terrace, Dublin 2 Tel: +353 1 6764971 Fax: +353 1 6762517 Website: [www.imb.ie](http://www.imb.ie) e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE DOCETAXEL EBEWE

Keep this medicine out of the sight and reach of children.

Do not use Docetaxel Ebewe after the expiry date which is stated on the label and on the carton. The expiry date refers to the last day of that month.

Do not store above 25°C.

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

The infusion solution should be used within 4 hours including the one hour infusion time. Chemical and physical in-use stability has been demonstrated at room temperature (below 25 °C) or refrigerated (2-8°C).

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. CONTENT OF THE PACK AND OTHER INFORMATION

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### What Docetaxel Ebewe contains

The active substance is docetaxel. 1 ml of the concentrate for solution for infusion contains 10 mg docetaxel.

The other ingredients are:

Citric Acid Anhydrous

Macrogol 300

Polysorbate 80

Ethanol 96%

One ml of the concentrate for solution for infusion contains 10 mg docetaxel.

Each vial of 2ml contains 20 mg docetaxel (10 mg/ml).

Each vial of 8 ml contains 80 mg docetaxel (10 mg/ml).

Each vial of 16 ml contains 160 mg docetaxel (10 mg/ml)

### What Docetaxel Ebewe looks like and contents of the pack

Docetaxel Ebewe **10 mg/ml** concentrate for solution for infusion **is a clear, colourless to pale yellow solution.**

*Docetaxel Ebewe is presented in clear glass vials containing 2 ml (20 mg/vial), 8 ml (80 mg/vial) or 16 ml (160mg/vial).*

Pack sizes:

**20 mg/2ml:** 1 vial, 5 and 10 vials

**80 mg/8ml:** 1 vial, 5 and 10 vials

**160 mg/16ml:** 1 vial, 5 and 10 vials

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

EbewePharmaGes.m.b.HNfg.KG

Mondseestrasse 11

A-4866 Unterach

Austria

**This medicinal product is authorised in the Member States of the EEA under the following names:**

**AT: Docetaxel Ebewe 10**

**BE: Docetaxel Sandoz 10**

**BG: Docetaxel Ebewe 10**

**CZ: Docetaxel Ebewe 10**

**DE: Docetaxel NC 10**

**EE: Docetaxel Ebewe 10**

**ES: Docetaxel Ebewe 10**

**FI: Docetaxel Ebewe 10**

**FR: DOCETAXEL EBEWE**

**GB: Docetaxel 10 mg/ml**

**GR: Docetaxel Ebewe 10**

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**HU: Docetaxel "Ebewe" 10**

**IE: Docetaxel Ebewe 10**

**IT: DOCETAXEL**

**LT: Docetaxel Ebewe 10**

**LU: Docetaxel Sandoz 10**

**LV: Docetaxel Ebewe 10**

**MT: Docetaxel Ebewe 10**

**NL: Docetaxel Sandoz 10**

**NO: Docetaxel Ebewe 10**

**PL: Docetaxel-Ebewe DOCETAXEL CONCENTRATE**

**PT: Docetaxel Sandoz DOCETAXEL CONCENTRATE**

**RO: Docetaxel Ebewe 10**

**SE: Docetaxel Ebewe 10**

**SI: Docetaxel Ebewe 10**

**SK: Docetaxel Ebewe 10**

**This leaflet was last approved in 02/2014**

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**The following information is intended for medical or healthcare professionals only:**

***Instructions for use and handling for disposal***

Inspection prior to use

Docetaxel Ebeweconcentrate for solution for infusion should be inspected visually for particulate matter and discoloration prior to dilution. If the concentrate is not clear or appears to have precipitation, it has to be discarded.

Preparation of the infusion solution

The concentrate must be diluted before use.

Infusion solutions have to be prepared with either 0.9% sodium chloride or with 5% glucose and administered as an intravenous infusion.

If the vials are stored under refrigeration, allow the required number of vials of Docetaxel Ebewe 10 mg/ml concentrate for solution for infusion to stand below 25°C until the solution has reached room temperature.

The required volume can be directly withdrawn from the vial.

More than one vial may be necessary to obtain the required dose for the patient. Based on the required dose for the patient expressed in mg, aseptically withdraw the corresponding volume containing 10 mg/ml docetaxel from the appropriate number of vials using graduated syringes fitted with a needle. For example, a dose of 140 mg docetaxel would require 14 ml docetaxel concentrate for solution for infusion.

The required volume of Docetaxel Ebewe 10 mg/ml concentrate for solution for infusion must be injected via a single injection (one shot) into a 250 ml infusion bag or bottle containing either 5% glucose solution or 0.9% sodium chloride solution for infusion.

If a dose greater than 200mg of docetaxel is required, use a larger volume of the infusion vehicle so that a concentration of 0.74 mg/ml docetaxel is not exceeded.

Mix the infusion bag or bottle manually by gentle inversion and rotation in a controlled manner and avoid foaming. Shaking or vigorous agitation has to be avoided during preparation and transportation to the patient for administration.

The prepared Docetaxel infusion solution is stable for up to 4 hours and should be used within these 4 hours, including storage and the one hour infusion time to the patient. The infusion should be aseptically administered under room temperature (below 25 °C) and normal lighting conditions.

The infusion solution prepared using Docetaxel Ebewe 10 mg/ml concentrate for solution for infusion, should be visually inspected carefully for precipitation prior to use. If the infusion solution is not clear or appears to have precipitation it has to be discarded. From a microbiological point of view, the product should be used immediately.

Contact of the Docetaxel Ebewe concentrate with plasticized PVC equipment or devices used to prepare solutions for infusion is not recommended. In order to minimize patient exposure to the plasticizer DEHP (di-2-ethylhexyl phthalate), which may be leached from PVC infusion bags or sets, the final Docetaxel Ebewe dilution for infusion should be stored in bottles or plastic bags (polypropylene, polyolefin) and administered through polyethylene-lined administration sets.

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To minimize the potential for precipitation of the infusion solution, the use of bags is recommended. Glass bottles are not recommended for use.

*pH and osmolality of reconstituted solution*

0.3 mg/mL in Glucose 5%: pH  $\approx$  3.6; 517 mOsm/kg

0.74 mg/mL in NaCl 0.9%: pH  $\approx$  3.3 – 3.6; 849 mOsm/kg

*Guidelines for the Safe Handling of Antineoplastic Agents*

Cytotoxic preparations should not be handled by pregnant staff. Trained personnel should dilute the drug. This should be performed in a designated area. The work surface should be covered with disposable plastic-backed absorbent paper.

Adequate protective gloves, masks and clothing should be worn. Precautions should be taken to avoid the drug accidentally coming into contact with skin or mucous membranes, the affected area should be cleaned thoroughly with soap and water. If accidental contamination occurs with the eyes, they should be washed with water thoroughly and immediately.

Use Luer-lock fittings on all syringes and sets. Large bore needles are recommended to minimise pressure and the possible formation of aerosols. The latter may also be reduced by the use of a venting needle.

Any unused contents should be discarded. Adequate care and precaution should be taken in the disposal of items used to dilute Docetaxel Ebewe. Any unused product or contaminated materials should be placed in a high-risk waste bag. Sharp objects (needles, syringes, vials, etc) should be placed in a suitable rigid container. Personnel concerned with the collection and disposal of this waste should be aware of the hazard involved. Any unused product or waste material should be disposed of in accordance with standard procedures applicable to cytotoxic agents. Any excess drug solution should be flushed directly into a drain with copious amounts of water.

The medicinal product is capable for multiple use, please refer to section “storage and shelf life”.

***Incompatibilities***

This medicinal product must not be mixed with other medicinal products.

***Administration***

Docetaxel Ebewe is for intravenous use only.

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**BG: Docetaxel Ebewe 10**

**CZ: Docetaxel Ebewe 10**

**DE: Docetaxel NC 10**

**EE: Docetaxel Ebewe 10**

**ES: Docetaxel Ebewe 10**

**FI: Docetaxel Ebewe 10**

**FR: DOCETAXEL EBEWE**

**GB: Docetaxel 10 mg/ml**

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**NL: Docetaxel Sandoz 10**  
**NO: Docetaxel Ebewe 10**  
**PL: Docetaxel-Ebewe DOCETAXEL CONCENTRATE**  
**PT: Docetaxel Sandoz DOCETAXEL CONCENTRATE**  
**RO: Docetaxel Ebewe 10**  
**SE: Docetaxel Ebewe 10**  
**SI: Docetaxel Ebewe 10**  
**SK: Docetaxel Ebewe 10**

### *Storage and shelf life*

#### **Shelf life of medicinal product as packaged for sale:**

Unopened: 24 months  
 After first opening: 28 days at 2°C – 8°C and at room temperature with and without light protection.

#### **Shelf life after dilution:**

Chemical and physical in-use stability has been demonstrated up to 4 hours at 2°C to 8°C with light protection and at below 25°C without light protection in Glucose 5% or Sodium Chloride 0.9%. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

### *Special precautions for storage*

#### **As packaged for sale:**

Do not store above 25°C.  
 Do not freeze.  
 Keep the vial in the outer carton in order to protect from light.  
 For storage condition of the diluted medicinal product, see section ‘Shelf life after dilution’.