# PRODUCT PROFILE

## Class

Antimicrotubule Agents (Taxanes)

From FEAR To FAITH

## MOA

Docetaxel is believed to have a twofold mechanism of antineoplastic activity: (1) inhibition of microtubular depolymerization and (2) attenuation of the effects of bcl-2 and bcl-xL gene expression.

## Indications

- Breast cancer
- Non-small cell lung cancer
- Prostate cancer
- Gastric adenocarcinoma
- Head and neck cancer

## Side Effects

- Infections
- Anemia
- Febrile
- Neutropenia
- Hypersensitivity
- Thrombocytopenia
- Constipation
- Anorexia
- Nail disorders
- Fluid retention
- Asthenia pain
- Nausea diarrhea
- Vomiting
- Mucositis
- Alopecia
- Skin reactions and
- myalgia

## DOSE:

Administer in a facility equipped to manage possible complications (e.g., anaphylaxis). Administer intravenously (IV) over 1 hr every 3 weeks. PVC equipment is not recommended.

**BC locally advanced or metastatic:** 60 mg/m2 to 100 mg/m2 single agent.

**BC adjuvant:** 75 mg/m2 administered 1 hour after doxorubicin 50 mg/m2 and cyclophosphamide 500 mg/m2 every 3 weeks for 6 cycles.

**NSCLC after platinum therapy failure:** 75 mg/m2 single agent.

**NSCLC chemotherapy naive:** 75 mg/m2 followed by cisplatin 75 mg/m2.

**HRPC:** 75 mg/m2 with 5 mg prednisone twice a day continuously.

**GC:** 75 mg/m2 followed by cisplatin 75 mg/m2 (both on day 1 only) followed by fluorouracil 750 mg/m2 per day as a 24-hr IV (days 1–5), starting at end of cisplatin infusion.

**SCCHN:** 75 mg/m2 followed by cisplatin 75 mg/m2 IV (day 1), followed by fluorouracil 750 mg/m2 per day as a 24-hr IV (days 1–5), starting at end of cisplatin infusion; for 4 cycles.

**SCCHN:** 75 mg/m2 followed by cisplatin 100 mg/m2 IV (day 1), followed by fluorouracil 1000 mg/m2 per day as a 24-hr IV (days 1–4); for 3 cycles.

**Pack Size:** 1's

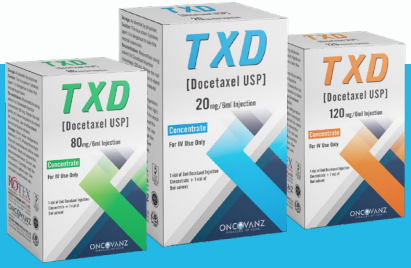
**Storage (°C.):** Below 25° C

**Strength:**

20mg /6ml Injection

80mg /6ml Injection

120mg /6ml Injection




# TXD

Docetaxel

## Class
Antimicrotubule Agents

# Comfort them with THE RIGHT START

## MOA
Promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing de-polymerization This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions In addition, paclitaxel induces abnormal arrays or "bundles" of microtubules throughout the cell cycle and multiple asters of microtubules during mitosis.

## Indications
- Ovarian carcinoma
- Breast cancer
- Non-small cell lung cancer
- AIDS-related Kaposi's sarcoma

## Side Effects
- Neutropenia
- Alopecia
- Anemia
- Arthralgia/myalgia
- Neuropathy
- Leukopenia
- Nausea/vomiting
- Opportunistic infections
- Peripheral
- Thrombocytopenia
- Hypersensitivity
- Diarrhea
- Renal impairment
- Hypotension

## DOSE:
**NOTE:** Contact of the undiluted concentrate with plasticized PVC equipment or devices used to prepare solutions for infusion is not recommended.

**Ovarian Carcinoma**

For previously untreated patients with carcinoma of the ovary, one of the following recommended regimens may be given every 3 weeks.

**a.** Paclitaxel administered intravenously over 3 hours at a dose of 175 mg/m2 followed by cisplatin at a dose of 75 mg/m2; or

**b.** Paclitaxel administered intravenously over 24 hours at a dose of 135 mg/m2 followed by cisplatin at a dose of 75 mg/m2.

In patients previously treated with chemotherapy for carcinoma of the ovary, paclitaxel has been used at several doses and schedules; The recommended regimen is paclitaxel 135 mg/m2 or 175 mg/m2 administered intravenously over 3 hours every 3 weeks.

**Breast Cancer**

1) Adjuvant treatment of node-positive breast cancer, the recommended regimen is paclitaxel, at a dose of 175 mg/m2 intravenously over 3 hours every 3 weeks for 4 courses administered sequentially to doxorubicin-containing combination chemotherapy.

2) After failure of initial chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy, paclitaxel at a dose of 175 mg/m2 administered intravenously over 3 hours every 3 weeks has been shown to be effective.

**Non-Small Cell Lung Carcinoma:** The recommended regimen, given every 3 weeks, is paclitaxel administered intravenously over 24 hours at a dose of 135 mg/m2 followed by cisplatin, 75 mg/m2.

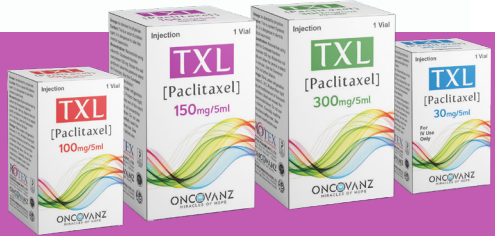
**Pack Size:** 1's

**Storage (°C.):** 2°-8° C

**Strength:**

30mg /5ml Inj
100mg /16.7ml Inj
150mg /25ml Inj
300mg /50ml Inj

# TXL
Paclitaxel



## Class
Anthracyclines

Bounce back **STRONGER**

## MOA
Damages DNA by intercalating between base pairs resulting in uncoiling of the helix ultimately inhibiting DNA synthesis and DNA-dependent RNA synthesis Daunorubicin may also act by inhibiting polymerase activity affecting the regulation of gene expression and generating free radicals' Cytotoxic activity is cell cycle phase non-specific although it exerts maximal cytotoxic effects in the S-phase.

## Indications
- Acute myelogenous leukemia
- Acute non-lymphocytic leukemia
- lymphocytic leukemia

## Side Effects
- Myelosuppression
- Alopecia
- Facial flushing with rapid Injection
- Hyperpigmentation
- Flare reaction (histamine release)
- Nail changes
- Pain on injection
- Diarrhea
- Vomiting
- Rash

## DOSE:
**Remission Induction in Adult Acute Non-Lymphocytic Leukemia:**
In Combination:
For patients under age 60, daunorubicin hydrochloride injection 45 mg/m 2/day IV on days 1, 2, and 3 of the first course and on days 1, 2 of subsequent courses AND cytosine arabinoside 100 mg/m 2/day IV infusion daily for 7 days for the first course and for 5 days for subsequent courses.
For patients 60 years of age and above, daunorubicin hydrochloride injection 30 mg/m 2/day IV on days 1, 2, and 3 of the first course and on days 1, 2 of subsequent courses AND cytosine arabinoside 100 mg/m 2/day IV infusion daily for 7 days for the first course and for 5 days for subsequent courses.
**Remission Induction in Pediatric Acute Lymphocytic Leukemia:**
In Combination:
Daunorubicin hydrochloride injection 25 mg/m 2 IV on day 1 every week, vincristine 1.5 mg/m 2 IV on day 1 every week, prednisone 40 mg/m 2 PO daily. Generally, a complete remission will be obtained within four such courses of therapy; however, if after four courses the patient is in partial remission, an additional one or, if necessary, two courses may be given in an effort to obtain a complete remission.
In children less than 2 years of age or below 0.5 m2 body surface area, it has been recommended that the daunorubicin hydrochloride injection dosage calculation should be based on weight (1 mg/kg) instead of body surface area.
**Remission Induction in Adult Acute Lymphocytic Leukemia:**
In Combination:
Daunorubicin hydrochloride injection 45 mg/m 2/day IV on days 1, 2, and 3 AND vincristine 2 mg IV on days 1, 8, and 15; prednisone 40 mg/m 2/day PO on days 1 through 22, then tapered between days 22 to 29; L-asparaginase 500 IU/kg/day x 10 days IV on days 22 through 32.

**Pack Size:** 1's
**Storage (°C.):** Below 25° C
**Strength:** 20 mg


# Daunotec
Daunorubicin

## Class
Anthracyclines

LIVE LIFE Everyday

## MOA
Intercalation inhibits nucleotide replication and the action of DNA and RNA polymerases. The interaction of doxorubicin with topoisomerase II to form DNA-cleavable complexes appears to be an important mechanism of doxorubicin hydrochloride cytocidal activity.

## Indications
- Adjuvant breast cancer
- Acute lymphoblastic leukemia
- Acute myeloblastic leukemia
- Hodgkin lymphoma
- Non-Hodgkin lymphoma (NHL)
- Metastatic breast cancer
- Metastatic Wilms' tumor
- Metastatic neuroblastoma
- Metastatic bone sarcoma
- Metastatic ovarian carcinoma
- Metastatic transitional cell bladder carcinoma
- Metastatic thyroid carcinoma
- Metastatic gastric carcinoma
- Metastatic bronchogenic carcinoma
- Metastatic soft tissue sarcom

## Side Effects
- Nausea
- Vomiting
- Mouth pain or sores
- Heart problems
- Alopecia
- Red-colored urine (patient may have red-colored urine for 1 to 2 days after infusion of doxorubicin.
- Risk of new cancers
- Skin damage at or near the vein where doxorubicin is given
- Decreased blood cell counts

## DOSE:
**Recommended Dosage for Adjuvant Breast Cancer**

Recommended dosage of Doxorubicin HCL Injection is 60 mg/m2 administered as an intravenous bolus on day 1 of each 21-day treatment cycle, in combination with cyclophosphamide, for a total of four cycles.

**Recommended Dosage for Other Cancers**

The recommended dosage of Doxorubicin Hydrochloride Injection/for Injection when used as a single agent is 60 mg/m2 to 75 mg/m2 intravenously every 21 days.

The recommended dosage of Doxorubicin HCL Injection, when administered in combination with other chemotherapy drugs, is 40 mg/m2 to 75 mg/m2 intravenously every 21 to 28 days.

Consider use of the lower Doxorubicin dose in the recommended dosage range or longer intervals between cycles for heavily pretreated patients, elderly patients, or obese patients.

Cumulative doses above 550 mg/m2 are associated with an increased risk of cardiomyopathy.

**Pack Size:** 1's
**Storage (°C.):** 2°-8° C
**Strength:**
10mg/5ml Injection
50mg/25ml Injection


# Rubidox
Doxorubicin Hcl

## Class
Glycopeptide antibiotic

Add **VALUE** to **LIFE**

## MOA
Although bleomycin's exact mechanism of action is unknown, available evidence indicates that the main mode of action is the inhibition of DNA synthesis with some evidence of lesser inhibition of RNA and protein synthesis Bleomycin is known to cause single, and to a lesser extent, double-stranded breaks in DNA In vitro and in vivo experiments, bleomycin has been shown to cause cell cycle arrest in G2 and mitosis.

## Indications
- Squamous cell carcinoma
- Lymphoma
- Testicular carcinoma
- Malignant pleural effusion.

## Side Effects
- Pulmonary adverse reactions
- Idiosyncratic reactions
- Erythema
- Rash
- Vesiculation
- Hyperpigmentation
- Tenderness of the skin
- Hyperkeratosis
- Nail changes
- Alopecia
- Pruritus
- Stomatitis
- Scleroderma-like skin changes
- Vascular toxicities
- Fever
- Chills

## DOSE:
Because of the possibility of an anaphylactic reaction, lymphoma patients should be treated with 2 units or less for the first 2 doses. If no acute reaction occurs, then the regular dosage schedule may be followed.
**Squamous cell carcinoma, non-Hodgkin's lymphoma, testicular carcinoma -** O.25 to O.5O units/kg (1O to 2O units/m2) given intravenously, intramuscularly, or subcutaneously weekly or twice weekly.
**Hodgkin's Disease -** O.25 to O.5O units/kg (1O to 2O units/m2) given intravenously, intramuscularly, or subcutaneously weekly or twice weekly. After a 5O% response, a maintenance dose of 1 unit daily or 5 units weekly intravenously or intramuscularly should be given.
Pulmonary toxicity of bleomycin appears to be dose-related with a striking increase when the total dose is over 4OO units. Total doses over 4OO units should be given with great caution. Improvement of Hodgkin's disease and testicular tumors is prompt and noted within 2 weeks. If no improvement is seen by this time, improvement is unlikely. Squamous cell cancers respond more slowly, sometimes requiring as long as 3 weeks before any improvement is noted.

**Pack Size:** 1's
**Storage (°C.):** 2°-8° C
**Strength:** 15 Units Powder for INJ


# Bleotex
Bleomycin (As Sulphate)

## Class
Bisphosphonate

# STRENGTH makes you UNBREAKABLE

## MOA
The principal pharmacologic action of zoledronic acid is inhibition of bone resorption Although the antiresorptive mechanism is not completely understood, several factors are thought to contribute to this actionIn vitro, zoledronic acid inhibits osteoclastic activity and induces osteoclast apoptosis Zoledronic acid also blocks the osteoclastic resorption of mineralized bone and cartilage through its binding to bone It inhibits the increased osteoclastic activity and skeletal calcium release induced by various stimulatory factor sreleased by tumors.

## Indications
- Hypercalcemia of malignancy
- Multiple myeloma
- Bone metastases of solid tumors

## Side Effects
- Fever
- Progression of cancer
- Constipation
- Nausea
- Diarrhea
- Vomiting
- Anorexia
- Insomnia
- Anxiety
- Confusion
- Agitation
- Abdominal pain
- Skeletal pain
- Anemia
- Moniliasis
- Hypophosphatemia
- Hypokalemia
- Hypomagnesemia

## DOSE:
**Hypercalcemia of Malignancy**

The maximum recommended dose of zoledronic acid is 4 mg. The 4 mg dose must be given as a single-dose intravenous infusion over no less than 15 minutes.

Retreatment with zoledronic acid 4 mg may be considered if serum calcium does not return to normal or remain normal after initial treatment. It is recommended that a minimum of 7 days elapse before retreatment, to allow for full response to the initial dose.

**Multiple Myeloma and Bone Metastases of Solid Tumors**

The recommended dose in patients with multiple myeloma and metastatic bone lesions from solid tumors for patients with creatinine clearance (CrCl) greater than 60 mL/min is 4 mg infused over no less than 15 minutes every 3 to 4 weeks. The optimal duration of therapy is not known.

**Pack Size:** 1's
**Storage (°C.):** 2°-8° C
**Strength:** 4mg/5ml Injection


# Inibco
Zoledronic Acid

## Class
Kinase Inhibitor

# GET UP for the MIRACLE

## MOA
Sorafenib is a kinase inhibitor that decreases tumor cell proliferation in vitro Sorafenib was shown to inhibit multiple intracellular (c-CRAF, BRAF and mutant BRAF) and cell surface kinases (KIT, FLT- 3 RET, RET/ PTC, VEGFR-1, VEGFR- 2, VEGFR- 3, and PDGFR-β) Several of these kinases are thought to be involved in tumor cell signaling, angiogenesis and apoptosis.

## Indications
- Hepatocellular carcinoma
- Renal cell carcinoma
- Differentiate thyroid carcinoma.

## Side Effects
- Diarrhea
- Fatigue
- Infection
- Alopecia
- Hemorrhage
- Hand-foot skin reaction
- Rash
- Weight loss
- Decreased appetite
- Gastrointestinal and abdominal pains
- Nausea
- Hypertension

## DOSE:
400 mg orally twice daily without food (at least 1 hourbefore or 2 hours after a meal) until the patient is no longer clinically benefiting from therapy or until unacceptable toxicity.

**Pack Size:** 60's, 120's
**Storage (°C.):** 25°-30° C
**Strength:** 200 mg Tablets


# Nexaget
Sorafenib (As Tosylate)

## Class
Kinase Inhibitor

We have got your BEC

## MOA
Experimental data indicate that the action of Vinblastine sulfate is different from that of other recognized antineoplastic agents. Tissue-culture studies suggest an interference with metabolic pathways of amino acids leading from glutamic acid to the citric acid cycle and to urea.

## Indications
Frequently responsive malignancies:

- Generalized hodgkin's disease
- Lymphocytic lymphoma
- Histiocytic lymphoma
- Mycosis fungoides
- Advanced carcinoma of testis
- Kaposi's sarcoma
- Letterer-siwe disease

Less frequently responsive malignancies:

- Choriocarcinoma resistant to other chemotherapeutic agents
- Breast cancer-unresponsive to endocrine surgery and hormonal therapy

## Side Effects

- Anemia
- Thrombocytopenia
- Alopecia
- Constipation
- Anorexia
- Nausea
- Vomiting
- Abdominal pain
- Ileus
- Vesiculation of the mouth pharyngitis
- Diarrhea
- Enterocolitis
- Bleeding from an old peptic ulcer and rectal bleeding
- Numbness of digits
- Loss of deep tendon reflexes
- Peripheral neuritis
- Mental depression
- Headache
- Convulsions
- Hemorrhagic

## DOSE:
**Adult Patients:** It is wise to initiate therapy for adults by administering a single intravenous dose of 3.7 mg/m 2 of body surface area (bsa). Thereafter, white blood cell counts should be made to determine the patient's sensitivity to vinblastine sulfate. A simplified and conservative incremental approach to dosage at weekly intervals for adults may be outlined as follows:

**First dose** ..... 3.7 mg/m 2 bsa
**Second dose** ..... 5.5 mg/m 2 bsa
**Third dose** ..... 7.4 mg/m 2 bsa
**Fourth dose** ..... 9.25 mg/m 2 bsa
**Fifth dose** ..... 11.1 mg/m 2 bsa

The above-mentioned increases may be used until a maximum dose not exceeding 18.5 mg/m 2 bsa for adults is reached. The dose should not be increased after that, reducing the white cell count to approximately 3,000 cells/mm 3. In some adults, 3.7 mg/m 2 bsa may produce this leukopenia; other adults may require more than 11.1 mg/m 2 bsa; and, very rarely, as much as 18.5 mg/m 2 bsa may be necessary. For most adult patients, however, the weekly dosage will prove to be 5.5 to 7.4 mg/m 2 bsa.

**Pediatric Patients:** As a single agent for Letterer-Siwe disease (histiocytosis X), the initial dose of vinblastine sulfate was reported as 6.5 mg/m 2. When vinblastine sulfate was used in combination with other chemotherapeutic agents for the treatment of Hodgkin's disease, the initial dose was reported as 6 mg/m 2. For testicular germ cell carcinomas, the initial dose of vinblastine sulfate was reported as 3 mg/m 2 in a combination regimen.

**Pack Size:** 1's
**Storage (°C.):** 2°-8° CB
**Strength:** 10mg Injection


# Vinbec
Vinblastine Sulphate

## Class
Vinca Alkaloids

You are born to **VIN**

## MOA
The mechanisms of action of vincristine sulfate remain under investigation The mechanism of action of vincristine sulfate has been related to the inhibition of microtubule formation in mitotic spindle, resulting in an arrest of dividing cells at the metaphase stage.

## Indications
- Acute leukemia

Useful in combination with other oncolytic agents in:
- Hodgkin's disease
- Neuroblastoma Wilm's tumor
- Rhabdomyosarcoma
- Non-hodgkin's malignant lymphomas

## Side Effects
- Hair loss
- Leukopenia
- Neuritic pain
- Abdominal cramps
- Nausea
- Vomiting
- Oral ulceration
- Diarrhea
- Paralytic ileus
- Intestinal necrosis and/or perforation
- Anorexia

## DOSE:
The usual dose of Vincristine Sulfate Injection, USP for pediatric patients is 1.5–2 mg/m2.
For pediatric patients weighing 10 kg or less, the starting dose should be 0.05 mg/kg, administered once a week. The usual dose of Vincristine Sulfate Injection, USP for adults is 1.4 mg/m2. A 50% reduction in the dose of Vincristine Sulfate Injection, USP is recommended for patients having a direct serum bilirubin value above 3 mg/100 mL. The drug is administered intravenously at weekly intervals.

**Pack Size:** 10's
**Storage (°C.):** 2°-8° C
**Strength:**
1mg Injection
2mg Injection


# Vincris
Vincristine Sulfate


# LAUNCHING SOON...

Plot D-7, Block 10-A Center Govt. Society, Gulshan -E-Iqbal,
Stadium Road, Karachi, Pakistan