



## Getwell Group of Companies

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# PRODUCT VISUAL GUIDE





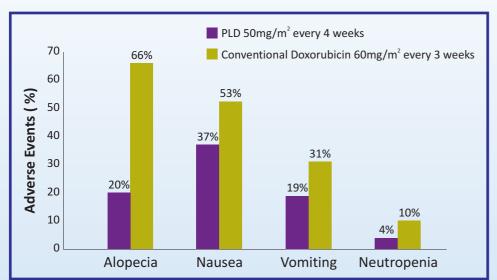


R. 20 mg / 10 ml Doxorubicin (2 mg / ml) Hydrochloride Liposome Injection sittik. Indilee (Pegylated Liposome Concentrate for Infu-LIPOSOMAL FORMULATION DO NOT SUBSTITUTE G Storile, single use vial Sichle, single use val GETWELL

Strengths – 20mg/10ml, 50mg/25ml

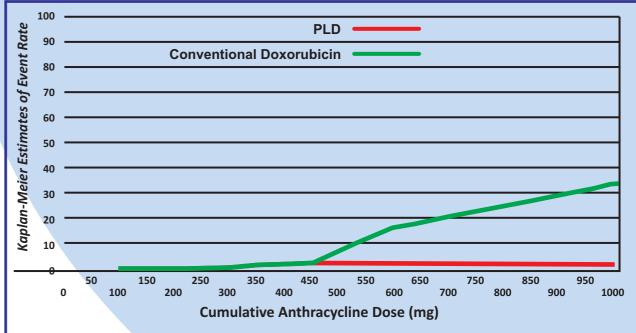
It is Indicated :-

- For metastatic carcinoma of the ovary, in patients with refractory disease to both paclitaxel and platinum based chemotherapy regimen.
- For the treatment of AIDS related Kaposi's sarcoma in patients showing disease progression.
- For the treatment of **Multiple Myeloma** in combination with bortezomib in patients who have not previously received bortezomib and have received at least one prior therapy.
- For the treatment of **metastatic Breast Cancer** patients with increased cardiac • risk.



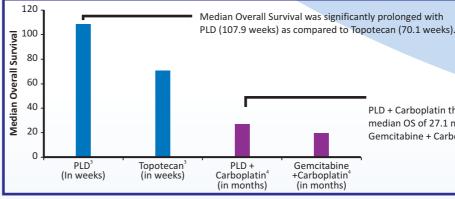
### ADVERSE EVENTS OF PLD VS CONVENTIONAL DOXORUBICIN

## **RATE OF CARDIAC EVENTS (DEFINED AS LAST LVEF < 35%) VS CUMULATIVE ANTHRACYCLINE DOSE<sup>2</sup>**

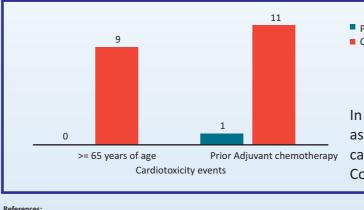


Risk of developing a cardiac event i.e. a resting LVEF value of 35% or less was lower with PLD than with Conventional Doxorubicin As cumulative lifetime anthracycline dose increases, the use of Conventional Doxorubicin is limited to 550 mg/m<sup>2</sup> due to an increased risk of developing cardiotoxicity.

## PLD IS THE DRUG OF CHOICE IN PLATINUM SENSITIVE RECURRENT OVARIAN CANCER<sup>4</sup>



PLD IS THE DRUG OF CHOICE IN HIGH RISK METASTATIC BREAST CANCER PATIENTS<sup>5</sup>



Annals of Oncology 15:440-449,2004 Stephen R D Johnston, "Caelyx (Pegylated Liposon Doxorubicin Hydrochloride)

Gynecol Oncol. 2004; 95: 1 – 8 Oncologist. 2010; 15(10):1073 - 82

- A Novel Anthracycline, " cited at http://www.touchbriefings.com/pdf/26/ept032\_t\_schering2.pdf Annals of Oncology 15: 440 - 449, 2004

I-DOX

PLD + Carboplatin therapy resulted in a longe median OS of 27.1 months as compared to Gemcitabine + Carboplatin therapy (19.7 months).

PLD 50mg/m<sup>2</sup> every 4 weeks Conventional Doxorubicin 60mg/m<sup>2</sup> every 3 weeks

In high risk MBC patients, PLD was associated with significantly less cardiotoxicity as compared to Conventional Doxorubicin<sup>5</sup>.

# **BENDAWEL**<sup>TM</sup> Bendamustine Hydrochloride for Injection (Lyophilized)

Strength – 100mg

It is indicated :-

- For the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established.
- For the treatment of indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab containing regimen.



# ΤM PEMETRA Pemetrexed for Injection (Lyophilized)

Strengths - 100mg, 500mg

It is indicated :-

- As a single agent for the treatment of patients with advanced nonsquamous non-small cell lung cancer (NSCLC), after prior chemotherapy.
- For the treatment for malignant pleural mesothelioma along with cisplatin, when surgery is not an option.





#### PEMETRA

# **PACLIVEL** Paclitaxel Injection

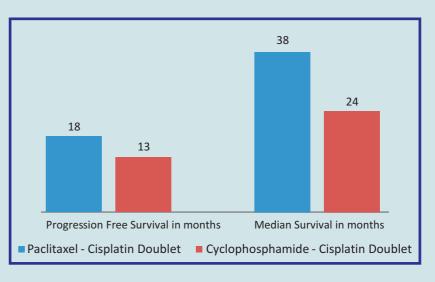
Strengths - 30mg / 5ml, 100mg / 16.7ml, 260mg / 43.4ml, 300mg / 50ml

#### It is indicated :-

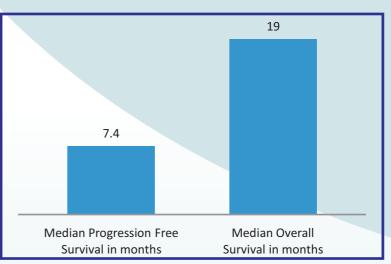
- As first line and subsequent therapy for the treatment of advanced carcinoma of the ovary.
- For the **adjuvant treatment** of **node-positive breast cancer** administered sequentially to standard doxorubicin containing combination chemotherapy.
- In combination with Cisplatin is indicated for the **first line** treatment of **NSCLC** cancer in patients who are not candidates for potentially curative surgery or radiation therapy.
- For the second-line treatment of AIDS related Kaposi's



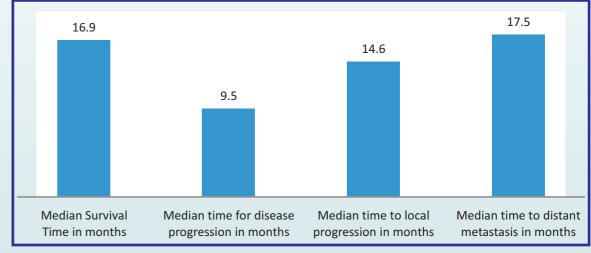
#### Paclitaxel in Stage III & IV Ovarian Cancer<sup>1</sup>



## Weekly Paclitaxel/Gemcitabine in Metastatic Breast Cancer or Locally advanced Breast Cancer<sup>2</sup>



## Induction Paclitaxel- Carboplatin followed by concurrent radiation therapy and weekly Paclitaxel and consolidation Paclitaxel-Carboplatin in stage III NSCLC<sup>3</sup>



Reference

1. International Journal of Women's Health 2010:2411-427

2. Jpn J Clin Oncol. 2011 Apr;41(4):455-61

J Thorac Oncol. 2011 Jan;6(1):79-85.

PACLIWEL

#### **Inoperable Pancreatic Cancer<sup>1</sup>**

## R TAXEWELL

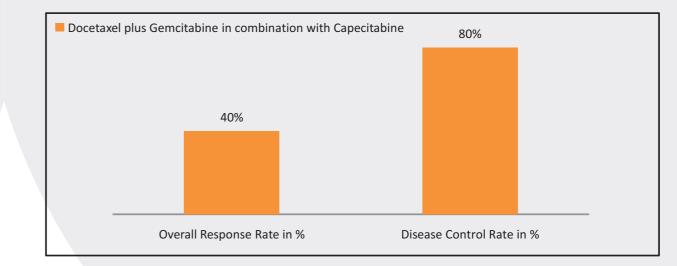
## **Docetaxel Injection** Concentrate with Solvent

Strengths - 20mg / 0.5ml, 80mg / 2ml, 120mg / 3ml

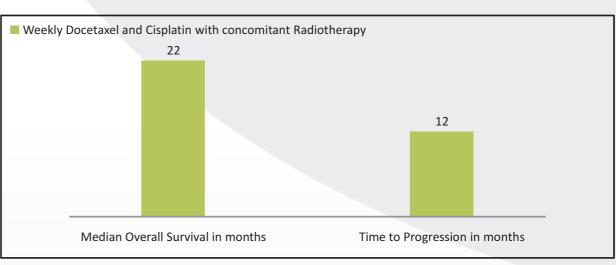
It is indicated for the treatment of :-

- NSCLC
- Metastatic Breast Cancer
- Hormone Refractory Prostate Cancer (HRPC)
- Gastric Adenocarcinoma (GC)
- Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN).

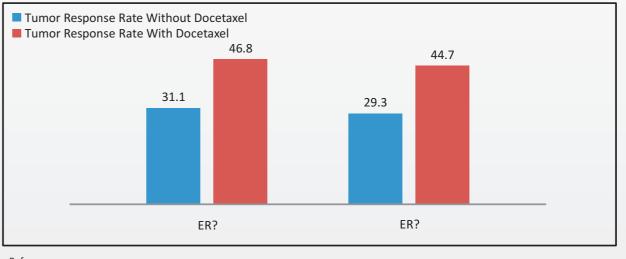




## Stage III NSCLC<sup>2</sup>



## **Docetaxel produces a higher response rate in both ER<sup>+</sup> & ER<sup>-</sup> Metastatic Breast Cancer Patients<sup>3</sup>**



Reference

1. Cancer Chemother Pharmacol. 2011 Aug 20.

Cancer Chemother Pharmacol, 2011 Apr 17. 2.

3. The Oncologist 2010; 15:476-483



#### TAXEWELL

# DOCETEL **Docetaxel for Injection** (Lyophilized) with Diluent

Strengths – 20mg, 80mg, 120mg

It is indicated for the treatment of :-

- NSCLC
- Metastatic Breast Cancer
- Hormone Refractory Prostate Cancer (HRPC)
- Gastric Adenocarcinoma (GC)
- Squamous Cell Carcinoma of the Head and Neck Cancer (SCCHN).

Docetaxel Injection IP

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Docetaxel Injection IP

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• Better storage & stability than conventional formulation, thereby improving efficacy.

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DOCETE

• Improved solubility, thereby reducing the reconstitution time with minimal efforts.

# TM **EPIRUBA** Epirubicin Hydrochloride for Injection (Lyophilized)

Strengths – 10mg, 50mg It is indicated :-

- As a component of adjuvant therapy in patients with evidence of **axillary** node tumor involvement following resection of primary breast cancer.
- 1. 65% of patients with Invasive Breast Cancer achieved a complete response which enabled them to undergo breast conserving surgery after being undergone treatment with **Paclitaxel and Epirubicin**<sup>1</sup>.
- 2. Epirubicin plus CMF (Cyclophosphamide, Methotrexate and Fluorouracil) is superior to CMF alone as adjuvant treatment for early breast cancer with Relapse-free and overall survival rates being significantly higher in the Epirubicin–CMF groups than in the CMF-alone groups<sup>2</sup>.
  - 2-year relapse-free survival, 91% vs.85%
  - 5-year relapse-free survival, 76% vs. 69%
  - 2-year overall survival, 95% vs. 92%
  - 5-year overall survival, 82% vs. 75%



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References

1. Clin Drug Invest. 2006; 26(12):691-701

N Engl J Med 2006; 355:1851-1862



#### **EPIRUBA**



# TM GEMWEL

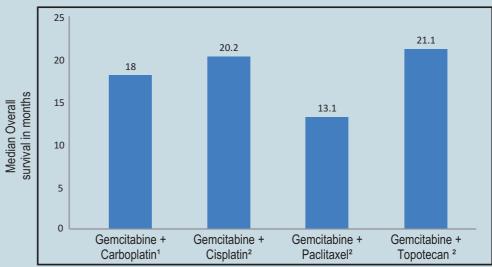
# Gemcitabine for Injection (Lyophilized)

Strengths – 200mg, Igm It is indicated :-

- For the treatment of relapsed advanced ovarian cancer in combination with Carboplatin.
- In combination with Paclitaxel for the first-line treatment of metastatic breast cancer patients after failure of prior anthracycline containing adjuvant therapy.
- In combination with Cisplatin for the **first-line treatment** of inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer.
- For the first-line treatment of locally advanced or metastatic Adenocarcinoma of the pancreas.



### **Gemcitabine combinations in Recurrent Ovarian Cancer**



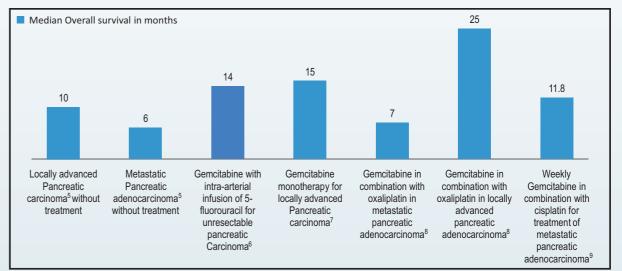
## Gemcitabine in Advanced Stage NSCLC<sup>3</sup>

	Overall Survival in Adenocarcinoma in months	Overall Survival in Squamous cell carcinoma in months	Overall Survival in Large cell carcinoma in months
Gemcitabine /CDDP	8.1	9.4	9.7
Paclitaxel/CDDP	9.1	6.9	6.1
Docetaxel/CDDP	7.7	8.1	6.8

### Gemcitabine combinations in patients with pretreated MBC

	Overall Response rates	Median Progression Free Survival in months	Median Survival times in months
Gemcitabine - Vinorelbine	39%	5.7	17.5
Gemcitabine - Cisplatin	47.70%	6.9	13
Gemcitabine - Capecitabine	34.70%	8.3	19.4

### **Gemcitabine in Pancreatic Cancer**



6.

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#### Reference

- Annals of Oncology12: 1115-1120,2001. 1
- Annals of Oncology 17 (Supplement 5); v188-v194, 2006 7.
- Clinical Medicine Insights: Oncology 2011:5; 177-184
- Br J Cancer. 2011 Mar 29;104(7):1071-8.
- Hu et al. Journal of Hematology & Oncology 2011, 4:11

Pancreas, 2005 Apr:30(3):223-6 Jpn J Clin Oncol. 2010 Jun;40(6):573-9 Gastroenterol Clin Biol. 2005 Oct;29(10):1006-9. Pancreatology. 2006;6(6):635-41.

#### **GEMWEL**

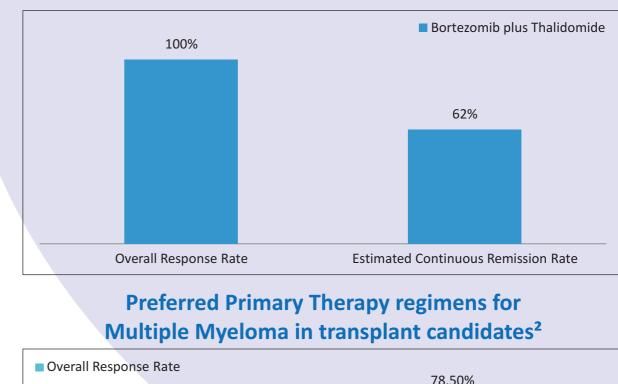
### Newly Diagnosed Multiple Myeloma<sup>1</sup>

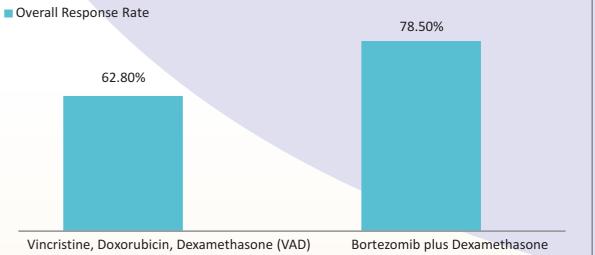
# NEOMIB Bortezomib for Injection (Lyophilized)

Strengths – 2mg, 3.5mg It is indicated :-

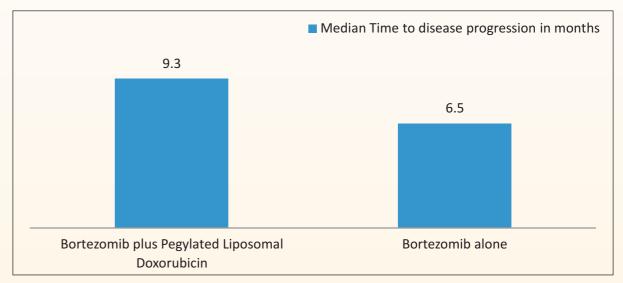
- In the treatment of **Multiple Myeloma**.
- In the treatment of Mantle Cell Lymphoma who have received at least 1 prior therapy.







## **Treatment of Progressive or Relapsed Myeloma<sup>3</sup>**



Reference

Zhonghua Nei Ke Za Zhi. 2011 Apr;50(4):291-4.

J Clin Oncol 2010; 28: 4621-4629

J Clin Oncol 2007; 25: 3892-3901 3.

#### NEOMIB



Strengths - 150mg/15ml, 450mg/45ml

It is indicated :-

- For the **initial treatment** of **advanced ovarian carcinoma** in combination with Cyclophosphamide.
- For the **palliative treatment** of patients with **recurrent ovarian carcinoma**.





Strengths - 10mg/10ml, 50mg/50ml

It is indicated :-

- For metastatic testicular tumors as combination therapy.
- For metastatic ovarian tumors in combination with Cyclophosphamide.
- As a single agent for patients with transitional cell bladder cancer.



#### bination therapy. nation with Cyclophosphamide. **nal cell bladder cancer**.

#### CARBOWEL

#### CISWEL

# **FOSFA**<sup>TM</sup> Ifosfamide for Injection with Mesna Injection

Ifosfamide for Injection Strengths - Igm, 2gm, 3gm It is indicated :-

- As the first line single agent therapy in Soft tissue sarcoma.
- As a single agent or in combination with Cisplatin and Bleomycin in advanced or recurrent cervical carcinoma.

Mesna Injection

Strengths - 2ml, 4ml

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It is indicated :-

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• As a prophylatic agent in reducing the incidence of ifosfamide induced hemorrhagic cystitis.

# TM **XYLOTIN** Oxaliplatin Injection / Oxaliplatin for Injection (Lyophilized)

Oxaliplatin Injection Strengths - 50mg/25ml, 100mg/50ml

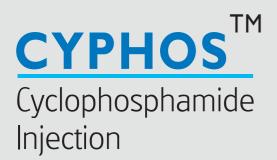
Oxaliplatin for Injection (Lyophilized) Strengths – 50mg, 100mg

It is indicated :-

- As a adjuvant treatment of stage III (Duke's C) colon cancer in patients who • have undergone complete resection of the primary tumor.
- In the treatment of advanced metastatic colorectal cancer.







Strengths - 200mg, 500mg, Igm It is indicated for the treatment of :-

- Hodgkin's lymphoma, Lymphocytic lymphoma, Mixed cell type lymphoma, Histocytic lymphoma, Burkitt's lymphoma?
- Multiple Myeloma
- Leukemia: Chronic lymphocytic leukemia, chronic granulocytic leukemia, acute myelogenous, monocytic leukemia and acute lymphoblastic leukemia in children
- Mycosis fungoides
- Neuroblastoma
- Adenocarcinoma
- Retinoblastoma
- Carcinoma of breast

Cyclophosphamide Injection IP tittise, an HI15 A AFTS HE end the ien bat CYPHOS Üvc ophosphamide in the second erst wirth Injection P 16.31(0) Ster. Lyclophosphamide rjection P Cyclophosphamice **CYPHOS**<sup>Th</sup> Injection P a conceptantice nadia R CYPHOS For I.V use only СҮРНО in in in in CYPHOS For I.V use only 10.10 For LV use only all' soulz GETWELL GETWELL GETWELL

# TM TINOWEL Dactinomycin for Injection (Lyophilized)

Strength – 0.5 mg

It is indicated :-

- For the treatment of Wilm's tumor, childhood rhabdomyosarcoma, Ewing's Sarcoma and metastatic nonseminomatous testicular cancer as a combination therapy.
- For the treatment of **gestational trophoblastic neoplastic** as a single agent or as a combination therapy.
- · For Palliative or adjunctive treatment of locally recurrent or locoregional solid malignancies.
- For the treatment of Germ cell tumors, Kaposi's sarcoma, Melanoma and Osteogenic sarcoma.



### **CYPHOS**



# **DOXORUBA**<sup>®</sup> Doxorubicin HCI Injection / Doxorubicin HCI for Injection (Lyophilized)

Doxorubicin HCl Injection Strengths - 10mg/5ml, 50mg/25ml

Doxorubicin HCl for Injection (Lyophilized) Strengths – 10mg, 50mg

It is indicated for the treatment of :-

- Carcinoma of the breast, lung, bladder, thyroid and also ovarian carcinoma
- Bone and soft tissue sarcoma
- Hodgkin's lymphoma and Non Hodgkin's lymphoma
- Neuroblastoma, Wilm's tumor
- Acute lymphoblastic leukemia and Acute myeloblastic leukemia

# **ETOPA**TM Etoposide Injection / Etoposide Capsules

Etoposide Injection Strength - 100mg/5ml

Etoposide capsules Strengths – 50mg, 100mg

It is indicated for the treatment of :-

- Small cell lung cancer
- Testicular cancer
- Bladder cancer
- Hodgkin's lymphoma
- Non-Hodgkin's lymphoma





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**DOXORUBA** 

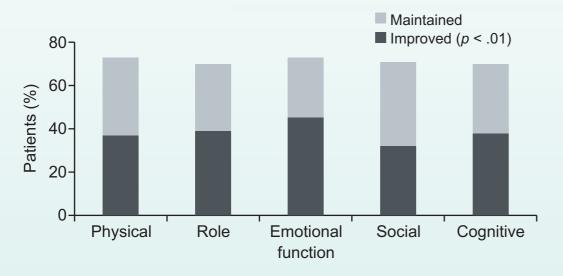


Strength – 500mg Pack-I x 10Tabs It is indicated :-

- For the treatment of Adjuvant Colorectal Cancer and Metastatic **Breast Cancer**.
- For the treatment of **Breast Cancer**.

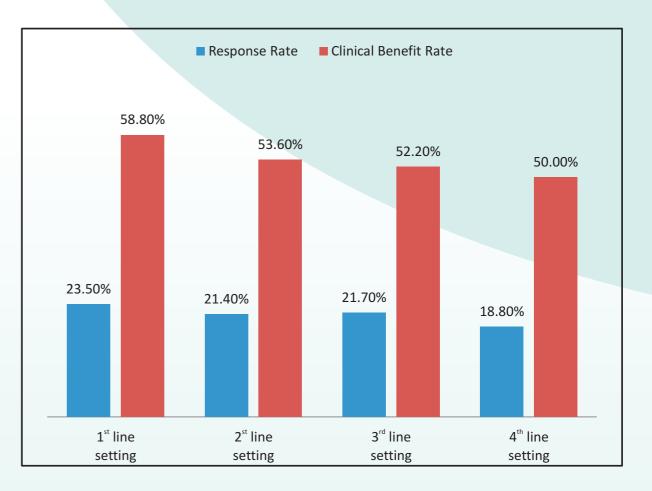


### **Capecitabine treatment improves quality of life** in women with breast cancer<sup>1</sup>.



### Capecitabine monotherapy is effective and well tolerated in all settings of chemotherapy in patients with metastatic or advanced breast cancer<sup>2</sup>

	1st line setting	2nd line setting	3rd line setting	4th line setting
Median number of cycles in each setting	12 cycles	11 cycles	9 cycles	11 cycles
Response Rate	23.50%	21.40%	21.70%	18.80%
Clinical Benefit Rate	58.80%	53.60%	52.20%	50.00%



Reference

- 1 Gelmon K, Chan A, Harbeck N; The Role of Capecitabine in First - Line Treatment for Patients with Metastatic Breast Cancer; The Oncologist2006; 11 (suppl 1):42 - 51
- 2. Jpn J Clin Oncol 2010; 40(3) 188-193

CABITA



Strengths – 20mg, 100mg, 250mg Pack – 1 x 5 Caps

It is indicated :-

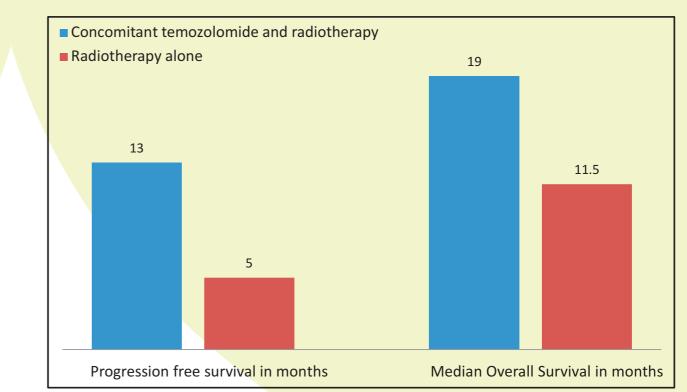
- For the treatment of **newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy** and then as maintenance treatment.
- For the treatment of **Refractory anaplastic** astrocytomas.



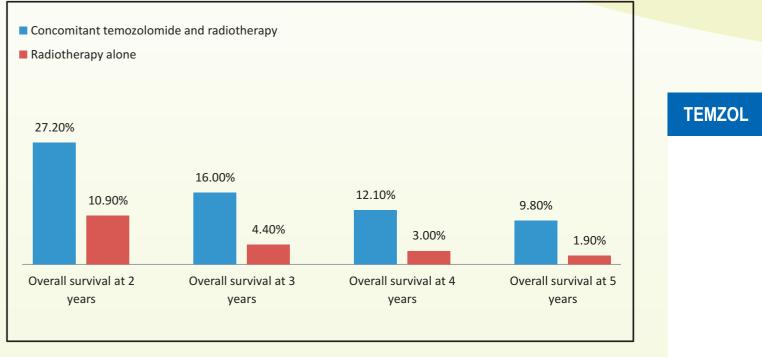




## Concurrent Temozolomide and Radiotherapy more effective than Radiotherapy alone for treatment of newly diagnosed glioblastoma multiforme<sup>1</sup>



## Effects of radiotherapy with concomitant and adjuvant temozolomide versus radiotherapy alone on survival in Glioblastoma in a randomised Phase III study<sup>2</sup>



Reference

1. J BUON. 2011 Jan-Mar;16(1):133-7.

2. Lancet Oncol 2009; 10: 459 - 66



Strengths – 100mg,400mg Pack – 1 x 10Tabs

It is indicated :-

- For the treatment of **Philadelphia chromosome positive myeloid leukemia** in **blast crisis**, **accelerated crisis** or in **chronic phase** after failure of interferon alpha therapy.
- For the treatment of Gastrointestinal Stromal Tumors (GIST).



Methods: A retrospective study of 171 CML-CP patients receiving imatinib monotherapy was done with 73 in the initial treatment group (disease course < / = 6 months) and 98 in the re-treatment group (disease courses > 6 months).







### RESULTS

RESULTS	Initial treatment group	Re-treatment group
Median time to major molecular response	15 months	36 months
Progression free survival at 84 months	97%	85%
Event free survival at 84 months	92%	70%

Conclusion: CML-CP patients benefits from early treatment with Imatinib.

Seven year response to Imatinib as initial treatment versus re-treatment in Chinese patients with Chronic Myelogenous Leukemia in the chronic phase<sup>1</sup>.

MATNIB

#### **First line Gefitinib in NSCLC<sup>2</sup>**

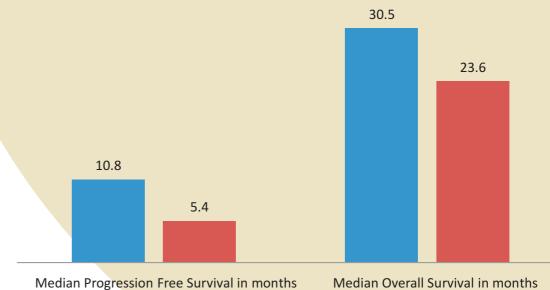


Strength – 250mg Pack-3x10Tabs

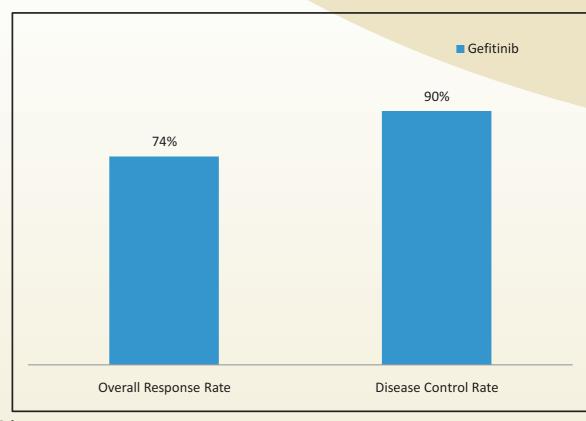
• It is indicated as monotherapy for locally advanced or metastatic NSCLC.



Gefitinib vs. Carboplatin / Paclitaxel was compared as a first line treatment in NSCLC, and it was concluded that this is the first time a targeted monotherapy has demonstrated significantly longer PFS than doublet chemotherapy<sup>1</sup>.



## **First-Line Gefitinib therapy for elderly advanced NSCLC patients** with Epidermal Growth Factor Receptor mutations<sup>3</sup>



Reference

http://www.ispub.com/journal/the\_internet\_journal\_of\_pulmonary\_medicine/volume\_11\_number\_2\_5/article/gefitinib-as-1. monotherapy-in-the-first-line-setting-in-non-small-cell-lung-cancer.html

N Engl J Med. 2010 Jun 24;362(25):2380-8

Journal of Clinical Oncology, Vol 28, No 15\_suppl (May 20 Supplement), 2010:7561 3.



Gefitinib Carboplatin - Paclitaxel

**GEFTIWEL** 



Strengths – 4mg, 8mg  $Pack - 5 \times 8 Tabs$ 

It is indicated :-

- For palliative management of Leukemias and lymphomas in adults and acute leukemias of childhood.
- As premedication in chemotherapy associated nausea and vomiting and taxane therapy.



Strengths – 50mg, 100mg Pack – 3 × 10 Caps

It is indicated for the treatment of :-

- Cutaneous manifestations of moderate to severe Erythema Nodosum Leprosum (ENL).
- Patients with newly diagnosed Multiple Myeloma in combination with Dexamethasone.

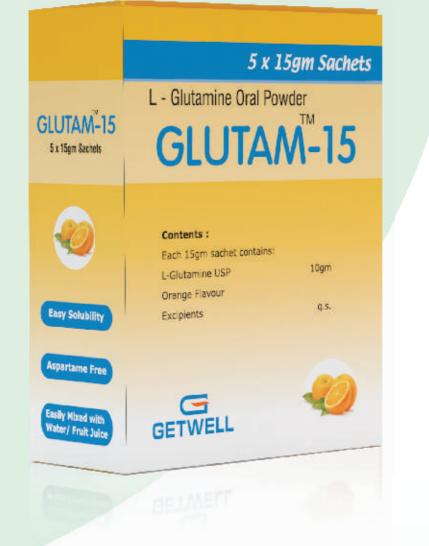


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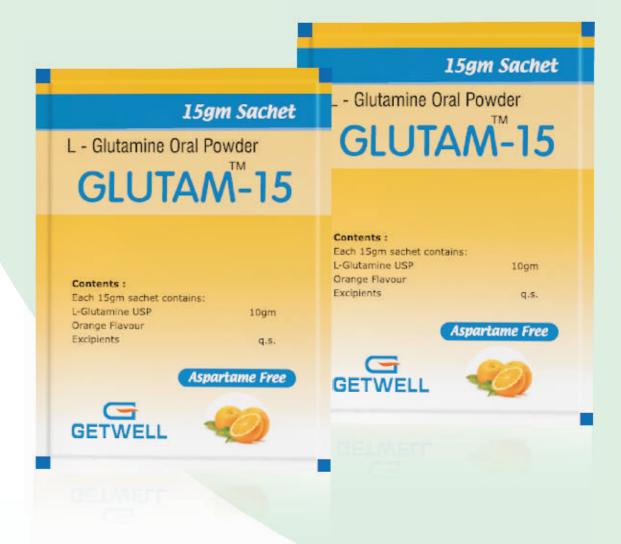


# **GLUTAM**<sup>TM</sup> 15 L-Glutamine Oral Powder

Strength – 15gm



- Glutamine supplements decrease the incidence and severity of adverse effects due to radiation in cancer patients such as dermatitis in breast cancer patients', **Stomatitis & Oesophagitis<sup>2,3</sup>** & intestinal permeability<sup>4</sup>.
- · Glutamine prevents chemotherapy associated mucositis, diarrhea associated Irinotecan, nervous system damage caused by Paclitaxel, Cardiotoxicity caused by anthracycline<sup>4</sup>. It is given concomitantly along with Methotrexate to enhance it tumorocidal activity.
- In surgery, glutamine decreases infections and **improves recovery after surgery**. Glutamine supplementation attenuated the negative postoperative nitrogen balance and supports muscle protein synthesis<sup>6</sup>. Glutamine **boosts the immune system** by increasing levels of lymphocytes<sup>7</sup>.
- Glutamine enhances selectivity of chemotherapy by protecting normal tissue from chemotherapy and by sensitizing tumor cells to chemotherapy.
- Oral glutamine reduce incidence of gastrointestinal, Nervous system, heart complications, diarrhea due to chemotherapy.

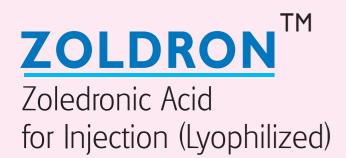


- · Glutamine supplementations reduce tumor growth by 40% and stimulate natural killer cell activity.8
- Glutamine nutrition decreases infections and shortens hospital stay in Bone marrow transplant patients.
- GLN supplementation reduced length of hospital stay on an average of 4 d.

#### References

- 1. Oral glutamine curbs radiation dermatitis in breast cancer patients; Internal Medicine News, March 1, 2005; cited at http://findarticles.com/p/articles/mi\_hb4365/is\_5\_38/ai\_n29173335/.
- Skubitz, Keith M., Anderson, Peter M. Oral glutamine to reduce Stomatitis, 1996, US 5545668.
- Savarese DM, Savy G, Vahdat L, Wischmeyer PE, Corey B; Prevention of chemotherapy and radiation toxicity with glutamine; Cancer Treat Rev. 2003; 29(6): 501-13.
- Nutritional Supplements That Support Cancer Chemotherapy; cited at http://www.powershow.com/view/11ba7-ZjEzO/Nutritional\_Supplements\_That\_Support\_Cancer\_Chemotherapy; cited on July 30, 2010, 10am
- Rouse K, Nwokedi E, Woodliff JE, Epstein J, Klimberg VS; Glutamine Enhances Selectivity of Chemotherapy Through Changes in Glutathione Metabolism; Annals of Surgery; 1995; 221(4): 420-426.
- Wilmore DW; The Effect of Glutamine Supplementation in Patients Following Elective Surgery and Accidental Injury; JN The Journal of Nutrition; 2001; 131: 2543S-2549S
- Rouse K, Nwokedi E, Woodliff JE, Epstein J, Klimberg VS; Glutamine Enhances Selectivity of Chemotherapy Through Changes in Glutathione Metabolism; Annals of Surgery; 1995; 221(4): 420-426.
- 8. Klimberg VS; Is Glutamine Effective in Enhancing Host Immune Response to Tumor?; JN The Journal of Nutrition; 135: 2920S, 2005
- Souba WW; Glutamine and Cancer; Annals of Surgery; 1993; 218(6): 715-728 9.

#### **GLUTAM-15**



Strength - 4mg

It is indicated :-

- For the treatment of **hypercalcemia of malignancy**. •
- For treatment of bone metastasis in patients with multiple myeloma and solid tumors in conjunction with antineoplastic therapy.
- To preserve bone mineral density in premenopausal women who have develop ovarian failure due to adjuvant chemotherapy.\*

\* Eur J Cancer. 2011 Mar;47(5):683-9. Epub 2011 Feb 14.



Strengths - I5mg/2ml, 50mg/5ml

It is indicated :-

- After high dose Methotrexate therapy in osteosarcoma to diminish the toxicity caused by Methotrexate.
- In the treatment of **megaloblastic anemia** due to folic acid therapy when oral therapy is not • recommended.
- For use in combination with 5-fluorouracil to prolong survival in the **palliative treatment** • patients with advanced colorectal cancer.





