Pro Pharmaceuticals Group Pty LTD
ABN: 20 605 457 430
www.propg.com.au

Dear Healthcare Professional,

Shortage of XELABINE capecitabine 500 mg film-coated tablet blister pack (AUST R: 213045)

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in the supply status of XELABINE capecitabine 500 mg film-coated tablet blister pack (AUST R: 213045) in Australia.

The Australian registered medicine, XELABINE capecitabine 500 mg film-coated tablet blister pack (AUST R: 213045) is currently in shortage due to an unexpected increase in consumer demand.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **Capecitabine Tablets USP 500mg (Camber Pharmaceuticals, USA)**. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **31st July 2025** for the following indication(s):

- ***Colon Cancer:*** *Capecitabine is indicated for the adjuvant treatment of patients with Dukes' stage C and high-risk stage B, colon cancer, either as monotherapy or in combination with oxaliplatin.*
- ***Colorectal Cancer:*** *Capecitabine is indicated for the treatment of patients with advanced or metastatic colorectal cancer.*
- ***Oesophagogastric Cancer:*** *Capecitabine is indicated for the first-line treatment of patients with advanced oesophagogastric cancer in combination with a platinum-based regimen.*
- ***Breast Cancer:*** *Capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of taxanes and an anthracycline containing chemotherapy regimen unless therapy with these and other standard agents are clinically contraindicated. Capecitabine in combination with docetaxel is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior anthracycline containing chemotherapy.*

Capecitabine Tablets USP 500mg (Camber Pharmaceuticals, USA) has the same active ingredient, strength and formulation as the Australian registered **XELABINE capecitabine 500 mg film-coated tablet blister pack (AUST R: 213045).** It is registered and marketed in USA and therefore all labelling is in English.

Please note: Both the s19A and Australian approved capecitabine 500mg tablet products **contain lactose**. However, this excipient is not declared on the s19A product label. Prior to dispensing, pharmacists should determine if this product is appropriate for the patient.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing for the above approved indications. This is available at: https://www.ebs.tga.gov.au

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **Capecitabine Tablets USP 500mg (Camber Pharmaceuticals, USA**) must be reported by healthcare professionals, pharmacists, and patients to the TGA at https://www.tga.gov.au/reporting-problems or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with **Capecitabine Tablets USP 500mg (Camber Pharmaceuticals, USA)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email orders@propg.com.au

Please forward this information to relevant staff members in your organisation.
For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,
Sandip Manku – Director Pro Pharmaceuticals Group