Public Summary

Summary for ARTG Entry: 213037 CAPECITABINE AN capecitabine 500 mg film-coated tablet blister pack

ARTG entry for	Medicine Registered
Sponsor	Juno Pharmaceuticals Pty Ltd
Postal Address	Level 2 6 Bond Street, South Yarra, VIC, 3141 Australia
ARTG Start Date	22/07/2014
Product category	Medicine
Status	Active
Approval area	Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. CAPECITABINE AN capecitabine 500 mg film-coated tablet blister pack

Product Type Single Medicine Product **Effective date** 15/06/2017

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

Colon Cancer:,Capecitabine is indicated for the adjuvant treatment of patients with DukeÆs stage C and highrisk 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.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	PVC/PVDC/Al	3 Years	Store below 25 degrees Celsius	Not recorded	Store in a Dry Place
Blister Pack	Al/Al	3 Years	Store below 25 degrees Celsius	Not recorded	Store in a Dry Place

Pack Size/Poison information

Pack Size	Poison Schedule
120 Tablets in blister pack	(S4) Prescription Only Medicine
60 Tablets in blister pack	(S4) Prescription Only Medicine
30 Tablets in blister pack	(S4) Prescription Only Medicine

Components

1. CAPECITABINE AN capecitabine 500 mg film-coated tablet blister pack

Dosage Form	Tablet, film coated
Route of Administration	Oral
Visual Identification	Peach coloured, oblong shaped, biconvex, film-coated tablets, debossed

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with 500 on one side and plain on other side.

Active Ingredients	
Capecitabine	**500 mg**