

# Palbociclib

## Indication

Treatment of hormone receptor positive, Her2 negative locally advanced or metastatic breast cancer

- In combination with an aromatase inhibitor
- In combination with fulvestrant in women who have received prior endocrine therapy

In pre or perimenopausal women, the endocrine therapy should be combined with a LHRH agonist

## Regimen details

Palbociclib 125mg orally once daily for 21 days

## Cycle frequency

Every 28 days (i.e. three weeks on treatment with a week off)

See under "Administration" below for details of the 3-monthly supply cycle

## Number of cycles

Until disease progression or unacceptable toxicity

## Administration

Palbociclib is available as 125mg, 100mg and 75mg capsules.

The capsules should be swallowed whole and not chewed, crushed or opened. The dose should be taken with food, preferably a meal. Grapefruit and grapefruit juice should be avoided whilst taking palbociclib. Patients should be advised to take the dose at approximately the same time each day.

If a patient vomits or misses a dose an additional dose should not be taken that day but the next prescribed dose should be taken as planned

## 3-monthly supply:

For patients who experience a maximum of grade 1 or 2 neutropenia in the first 6 cycles, patients may be changed to the 3-monthly regimen. Patients will be supplied with a pack of 63 capsules and instructed to take them in a "three weeks on, one week off" cycle.

## Pre-medication

None

## Emetogenicity

Mild

## Additional supportive medication

Supply metoclopramide and loperamide with first cycle

## Extravasation

N/A

## Investigations – pre first cycle

Investigation	Validity period
FBC	14 days
U+E (including creatinine)	14 days
LFT (including AST)	14 days

## Investigations –pre subsequent cycles

FBC, U+E (including creatinine), LFT (including AST)

Clinical toxicity assessment for infection, bleeding, thromboembolism, fatigue, GI effects and neuropathy

For patients who experience a maximum of grade 1 or 2 neutropenia in the first 6 cycles, reduce the frequency of checks to every 3 months

## Standard limits for administration to go ahead

If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant.

Investigation	Limit
Neutrophil count	$\geq 1.0 \times 10^9/L$ (discuss with consultant if 1-1.2)
Platelet count	$\geq 50 \times 10^9/L$
Creatinine clearance	$\geq 30$ mL/min
Bilirubin	$\leq 1.5 \times$ ULN
AST	$\leq 3 \times$ ULN

## Dose modifications

Dose reductions should follow the table below:

Dose level	Dose
Full dose	125mg daily
First reduction	100mg daily
Second reduction	75mg daily

## Haematological Toxicity Grades

Neutropenia	
Grade	Neutrophils ( $\times 10^9/L$ )
1	$\geq 1.5-2$
2	$\geq 1-1.5$
3	$\geq 0.5-1$
4	$<0.5$

Thrombocytopenia	
Grade	Platelets ( $\times 10^9/L$ )
1	$\geq 75-150$
2	$\geq 50-75$
3	$\geq 25 - 50$
4	$< 25$

## Haematological Toxicity:

Grade	Dose
1-2	No dose modification required
3	Withhold and repeat FBC. When recovered to $\leq$ grade 2 start next cycle at the same dose Consider dose reduction if not recovered within 7 days or recurrent neutropenia
3 with fever +/- infection	Withhold until recovered to $\leq$ grade 2 Resume with one dose level reduction
4	Withhold until recovered to $\leq$ grade 2 Resume with one dose level reduction

## Non-haematological Toxicity

Grade	Dose
1 or 2	No change
3 or 4	Delay until recovery to $\leq$ grade 2. Restart at next lower dose level

## Renal impairment

Palbociclib should be administered with caution and close monitoring for signs of toxicity in severe renal impairment (CrCl < 30ml/min)

## Hepatic impairment

No dose adjustment of palbociclib is required for patients with mild or moderate hepatic impairment (Child-Pugh classes A and B). For patients with severe hepatic impairment (Child-Pugh class C), the recommended dose of palbociclib is 75 mg once daily

## Adverse effects –

[for full details consult product literature/ reference texts](#)

- **Serious side effects**

Neutropenia, anaemia, leukopenia  
Infections

- **Frequently occurring side effects**

Neutropenia, anaemia, leukopenia  
Thrombocytopenia  
Infections  
Fatigue  
Nausea and vomiting  
Stomatitis  
Rash, dry skin  
Alopecia  
Diarrhoea

- **Other side effects**

Reduced appetite  
Dysgeusia  
Blurred vision  
Dry eyes  
Increased transaminases

## Significant drug interactions

– [for full details consult product literature/ reference texts](#)

**Strong CYP3A4 inhibitors** (e.g. clarithromycin, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, posaconazole, saquinavir, telaprevir, telithromycin, voriconazole, grapefruit): Concomitant use of strong inhibitors should be avoided due to increased risk of toxicity. If co-administrated is deemed essential the dose of palbociclib should be reduced to 75mg daily and patients closely monitored.

**Strong CYP3A4 inducers** (e.g. carbamazepine, enzalutamide, phenytoin, rifampin, and St. John's Wort): Concomitant use may reduce the exposure of palbociclib and should therefore be avoided

## Additional comments

Women of childbearing potential or their male partners must use a highly effective method of contraception.

This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine

## References

Ibrance SPC - <https://www.medicines.org.uk/emc/product/7945/smpc>

SWCN protocols - <http://www.swscn.org.uk/guidance-protocols/cancer-protocols/>

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**THIS PROTOCOL HAS BEEN DIRECTED BY DR EATON, CONSULTANT ONCOLOGIST**

**RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE**

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