



## Paclitaxel 80, Breast Cancer, adjuvant

Protocol-ID: 581 V1.2 (Complete), PACL80, Breast Ca, adj.

### Indication(s)

- Breast Cancer; ICD-10 C50.-

### Protocol classification

- Classification: alternative
- Intensity: Standard dose
- Therapy phase:
- Therapy intention: curative

### Cycles

Cycle length 7 days, recommended cycles: 12

### Protocol sequences

- [EC \(EPIR90/CYCL600\), Breast Ca, adj. \(PID579\) -|- PACL80, Breast Ca, adj. \(PID581\)](#)

### Risks

- Emetogenicity (MASCC/ESMO): low (10-30%)
- Neutropenia: low (<10%) °3-4: 2%
- Febrile Neutropenia: low (<10%) °3-4: 1%
- Infections: CTC AE °3-4: 3%
- Fatigue: CTC AE °3-4: 3%
- Neuropathy: CTC AE °2-4: 27%
- Myalgias: CTC AE °3-4: 2%

### Therapy

#### Hydration: Balanced Crystalloid Solution

HYD

Access: peripheral venous

Hydration before, during, or after antitumor therapy

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	Balanced Crystalloid Solution	500 ml		i.v.	30 min	30 min before Paclitaxel (d1)

#### Allergy prophylaxis: Paclitaxel Allergy Prophylaxis

AP

Access: peripheral venous

Dexamethasone, dimetinden maleate, cimetidine

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	Dexamethasone	20 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Paclitaxel (d1)
1	Dimetinden	4 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Paclitaxel (d1)
1	Cimetidine	300 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Paclitaxel (d1)

**Medical tumor therapy: Paclitaxel 80 mg/m<sup>2</sup>**
**CTX**

Access: peripheral venous

weekly therapy

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	<b>Paclitaxel</b>	80 mg/m <sup>2</sup> BSA	NaCl 0.9% 250 ml	i.v.	60 min	Sequence

## Concomitant therapy supplements

Dexamethasone for antiemesis is covered by dexamethasone of allergy prophylaxis.

## Notes

Paclitaxel administration over 60 minutes is only up to a dose of 100 mg/m<sup>2</sup>.

## Cycle diagram

### Hydration: Balanced Crystalloid Solution

Substance	Week 1 / d						
	1	2	3	4	5	6	7
Balanced Crystalloid Solution (i.v.)							

### Allergy prophylaxis: Paclitaxel Allergy Prophylaxis

Substance	Week 1 / d						
	1	2	3	4	5	6	7
Dexamethasone (i.v.)							
Dimetinden (i.v.)							
Cimetidine (i.v.)							

### Medical tumor therapy: Paclitaxel 80 mg/m<sup>2</sup>

Substance	Week 1 / d						
	1	2	3	4	5	6	7
Paclitaxel (i.v.)							

## Cycles

Cycle length 7 days, recommended cycles: 12

## Controls:

- Blood count: on day 1 and subsequently weekly
- ECG Risk of developing conduction disorder during paclitaxel therapy, regular ECG monitoring.
- Day 1: GOT, GPT, GGT, Bilirubin, AP, Cholinesterase Liver value monitoring before and during paclitaxel therapy.
- Day 1: Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>2+</sup>, Mg<sup>2+</sup>

## Pharmacokinetics

Paclitaxel: hepatischer Abbau, biliäre Elimination 25%, renal &lt; 10%

Cimetidin: CYP450 Inhibitor, vielschichtige Interaktionen möglich

## Original indication

Paclitaxel weekly, Breast Cancer, adjuvant

## Original author

Sparano JA (2008)

## Origin

Eastern Cooperative Oncology Group, Philadelphia, US

## References

- Sparano JA, Weekly paclitaxel in the adjuvant treatment of breast cancer., N Engl J Med 2008 Apr 17;358(16):1663-71 [[PMID](#)]
- De Laurentiis M, Taxane-based combinations as adjuvant chemotherapy of early breast cancer: a meta-analysis of randomized trials., J Clin Oncol 2008 Jan 1;26(1):44-53 [[PMID](#)]

## Recommendations

- 08/2019: [European Society for Medical Oncology](#)
- 03/2023: [National Comprehensive Cancer Network](#)

## Links

- One-hour paclitaxel infusions: review of safety and efficacy. [[PMID](#)]

## Status

**Valid** since 2023-09-16, Version 1.2, last updated 2023-09-16

Last modification: V1.2: Protocol name changed according to current standard V1.1: Cato test done. Revision of allergy prophylaxis according to summary of product characteristics, change of H2- antagonist for Paclitaxel from Ranitidine to Cimetidine according to DGHO recommendations 10/2019. V1.0: Cato test again due to correct cycle count and diagnoses. V0.1: Cato test successful. Application of this protocol after 4 cycles of EC, see EC x 4 followed by Pacl, Breast Ca, adjuvant, A. Duration according to primary literature. This protocol was established based on AGO and NCCN recommendation allowing extrapolation from AC+Paclitaxel to EC+Paclitaxel and recommending use in dose equivalent due to more favorable side effect profile.

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