



## 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. \(PID581\)](#)
- [EC \(EPIR90/CYCL600\), Breast Ca, adj., dd \(PID2702\) -|- PACL80, adj. \(PID581\)](#)
- [SWOG S0221: AC \(DOXO60/CYCL600\), Breast Ca, adj., dd, var. 1 \(PID478\) -|- PACL80, adj. \(PID581\)](#)
- [AC \(DOXO60/CYCL600\), Breast Ca, adj. \(PID599\) -|- PACL80, 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	<b>Balanced Crystalloid Solution</b>	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	<b>Dexamethasone</b>	20 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Paclitaxel (d1)
1	<b>Dimetinden</b>	4 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Paclitaxel (d1)
1	<b>Cimetidine</b>	300 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Paclitaxel (d1)

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

ANTX

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

## Substance links

Links to substances are found [here](#).

## 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.)							

### Antineoplastic 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 < 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. doi: 10.1056/NEJMoa0707056. PMID: 18420499. [\[PMID\]](#)
- De Laurentiis M, Taxane-based combinations as adjuvant chemotherapy of early breast cancer: a meta-analysis of randomized trials. J Clin Oncol 2008 Jan 01;26(1):44-53. doi: 10.1200/JCO.2007.11.3787. PMID: 18165639. [\[PMID\]](#)
- Budd GT, SWOG S0221: a phase III trial comparing chemotherapy schedules in high-risk early-stage breast cancer. J Clin Oncol 2015 Jan 01;33(1):58-64. doi: 10.1200/JCO.2014.56.3296. PMID: 25422488. [\[PMID\]](#)
- Shulman LN, Comparison of doxorubicin and cyclophosphamide versus single-agent paclitaxel as adjuvant therapy for breast cancer in women with 0 to 3 positive axillary nodes: CALGB 40101 (Alliance). J Clin Oncol 2014 Aug 01;32(22):2311-7. doi: 10.1200/JCO.2013.53.7142. PMID: 24934787. [\[PMID\]](#)

## 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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