

# modified FOLFOX-6 - Oxaliplatin 85 / Folinic Acid 400 / Fluorouracil 2400, colon carcinoma adjuvant

Protocol-ID: 644 V1.1 (Complete), mFOLFOX-6 (OXAL85/CFOL400/FU2400), Colon Ca, adj.

# Indication(s)

• Colon Cancer; ICD-10 C18.0, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C19

## **Protocol classification**

· Classification: current standard

· Intensity: Standard dose

Therapy phase:

· Therapy intention: curative

## **Cycles**

Cycle length 14 days, recommended cycles: 12

#### **Risks**

• Emetogenicity (MASCC/ESMO): moderate (30-90%)

• Neutropenia: high (21-40%)

• Febrile Neutropenia: low (<10%)

Thrombocytopenia below 50 000/μl: low (<10%) °3-4: 3.4%</li>

Diarrhea: CTC AE °3-4: 9.7%Fatigue: CTC AE °3-4: 7.2%

• Thromboembolic Event: CTC AE °3-4: 4.6%

• Neuropathy: CTC AE °3-4: 14.4%, sensory

• Dehydration: CTC AE °3-4: 4.0%

• Allergic Reaction: CTC AE °3-4: 4.7%

• Pain: CTC AE °3-4: 6.3%

## **Therapy**

Hydr	ation: Balanced Crystalloid Solution						HYD
Acce	ss: peripheral venous						
Hydra	ation before, during, or after antitumor therapy						
Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure	
1	Balanced Crystalloid Solution	500 ml		i.v.	60 min	60 min before Oxaliplatin (d1)	

ΑE

## Antiemesis: Emetogenicity moderate, GRAN i.v., DEXA i.v.

Access: peripheral venous

ASCO 2015, DGHO 2016, DKG 2016, MASCC/ESMO 2016, if palonosetron not available

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	Dexamethasone	8 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Oxaliplatin (d1)
1	Granisetron	1 mg	NaCl 0.9% 50 ml	i.v.	5 min	15 min before Oxaliplatin (d1)
or oth	er 5-HT3 receptor antagonist					
2-3	Dexamethasone	8 mg		p.o.		1-0-0-0

Antineoplastic therapy: mFOLFOX6								
Acces	ss: central venous, port							
Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure		
1	Oxaliplatin	85 mg/m² BSA	Dextrose 5% 500 ml	i.v.	2 h	Sequence		
1	Folinic acid	400 mg/m <sup>2</sup> BSA	NaCl 0.9% 250 ml	i.v.	2 h	Sequence		
1	Fluorouracil	400 mg/m² BSA	none	i.v.	1 min	Sequence		
Bolus	application							
1	Fluorouracil	2400 mg/m <sup>2</sup> BSA	NaCl 0.9% 500 ml	i.v.	46 h	Sequence		

The volume of the carrier solution refers to inpatient therapy with infusion pumps. When using syringe pumps or ambulatory systems, a different volume (e.g. 100 ml) can be used.

## **Substance links**

Links to substances are found here.

## **Notes**

Oxaliplatin is administered before folinic acid for pharmacological reasons.

## Cycle diagram

## **Hydration: Balanced Crystalloid Solution**

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

## Antiemesis: Emetogenicity moderate, GRAN i.v., DEXA i.v.

	Week 1 / d						
Substance	1	2	3	4	5	6	7
Dexamethasone (i.v.)							
Granisetron (i.v.)							
Dexamethasone (p.o.)							

# Antineoplastic therapy: mFOLFOX6

	Week 1 / d						
Substance	1	2	3	4	5	6	7
Oxaliplatin (i.v.)							
Folinic acid (i.v.)							
Fluorouracil (i.v.)							
Fluorouracil (i.v.)							

# **Cycles**

Cycle length 14 days, recommended cycles: 12

#### **Controls:**

- Blood count: on day 1 and subsequently weekly
- DPD Exclude deficiency: Uracil levels or DPD gene mutations.
- Day 1: GOT, GPT, GGT, Bilirubin, AP, Cholinesterase Fluorouracil: dose reduction is necessary in the presence of concomitant impaired hepatic and renal function.
- Day 1: Creatinine, glomerular filtration rate (GFR) Oxaliplatin

## **Pharmacokinetics**

Fluorouracil: 90% metabolische Elimination, 10% renal

Oxaliplatin: renale Elimination der Metabolite

## Original indication

adjuvant treatment of colon carcinoma, stage 2/3, ECOG 0-1

## **Original author**

Allegra CJ (2009)

## **Origin**

University of Florida, Division of Hematology and Oncology, Gainsville, Florida, NSABP

#### References

- Allegra CJ, Initial safety report of NSABP C-08: A randomized phase III study of modified FOLFOX6 with or without bevacizumab for the adjuvant treatment of patients with stage II or III colon cancer. J Clin Oncol 2009 Jul 10;27(20):3385-90. doi: 10.1200/JCO.2009.21.9220. PMID: 19414665. [PMID]
- Allegra CJ, Phase III trial assessing bevacizumab in stages II and III carcinoma of the colon: results of NSABP protocol C-08. J Clin Oncol 2011 Jan 01;29(1):11-6. doi: 10.1200/JCO.2010.30.0855. PMID: 20940184. [PMID]

#### Recommendations

- 07/2020: European Society for Medical Oncology
- 11/2023: National Comprehensive Cancer Network

## **Status**

Valid since 2024-01-04, Version 1.1, last updated 2024-10-27

Last modification: V1.1: Title correction V1.0: Cato test done with cycle count and ICD-10 codes. Dexamethasone for prophylaxis of delayed emesis analogous to the guidelines on day 4 deleted. V0.1: Durations according to primary literature, sequence Oxaliplatin before Fluorouracil according to summary of product characteristics.

## Important notice

The copyrighted protocols are treatment recommendations. The information contained in this compilation on cytostatic drugs, concomitant medication and other therapeutic procedures, as well as dosage and application information, is continuously reviewed with all due care by the authors and editors involved. Nevertheless, the publishers and authors do not assume any liability for the correctness - also with regard to possible printing errors.

The protocols may not be changed in terms of content. Any further use of the protocols in physical or non-physical form, such as copying, distribution, disclosure, export to other media, or publication, even in excerpt form, is not permitted.

Diagnosis, indication for therapy and treatment of malignant diseases must be carried out in each individual case by the hematologist and oncologist on his or her own responsibility. The treating physician is obligated to this personal responsibility to weigh in each case before a diagnostic or therapeutic measure, indication, contraindications, dosage and application under consideration of the specialized information or other documents of the manufacturers. This applies in particular to rarely used preparations or preparations that are new to the market.



The publishers and authors assume no liability for the accuracy of the contents. The application is at the own responsibility of the treating physician. ©Onkopti.