2. DACH ANCA VASKULITIS FORUM 2024
22. & 23. NOVEMBER 2024 | MÜNCHEN

CSL Vifor

Deutsche Avacopan-Kohorte: GC-Tapering unter Avacopan

Dr. Jonas Zimmermann

Berlin

CHARITÉ
UNIVERSITÄTSMEDIZIN BERLIN

Deutsche Avacopan-Kohorte: GC-Tapering unter Avacopan

2. DACH ANCA-Vaskulitis Forum 2024

Dr. med. Jonas Zimmermann| 23. November 2024 | München

Conflict of Interest

CSL Vifor

Agenda

1. Vorstellung der Studie „**Avacopan in ANCA-associated Vasculitis in a real-world setting"**

2. Diskussion des **Glukokortikoid-Tapering** unter **Avacopan** anhand eines Beispiels

Warum Avacopan?

- Notwendigkeit von effektiveren Therapieoptionen
- Toxizität von Glucocorticoiden (GC) mit langem Tapering und hoher kumulativer Dosis
- Alternativer Komplement-Pathway mit Aktivierung von Anaphylatoxin C5a mit zentraler Rolle in AAV-Pathogenese

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Avacopan for the Treatment of ANCA-Associated Vasculitis

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Avacopan in Anti-Neutrophil Cytoplasmic Autoantibodies–Associated Vasculitis in a Real-World Setting

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Methoden

Studienaufbau:

- Multizentrische Beobachtungsstudie in 5 deutschen Vaskulitis-Zentren

Einschlusskriterien:

- >18 Jahre, rezidivierende/neu diagnostizierte AAV
- Avacopan mind. 3 Monate zwischen 02/2022 und 06/2023 (intention to treat)

Kombinierter primärer Endpunkt:

- Remission (BVAS von 0 und ≤7,5 mg Prednisolon/Tag nach 6 Monaten)
- Erhaltene Remission (BVAS von 0 nach 6 und 12 Monaten ohne Relapse)

Sekundäre Endpunkte:

- Subgruppenanalyse: eGFR < 15 ml/min, Diffuse alveoläre Hämorrhagie (DAH)
- ANCA-Titer, Hämaturie, Proteinurie, Serum-Kreatinin/eGFR
- kumulative Dosis von GC
- UAWs
- Gründe der Therapieentscheidung für Avacopan (Fragebogen)

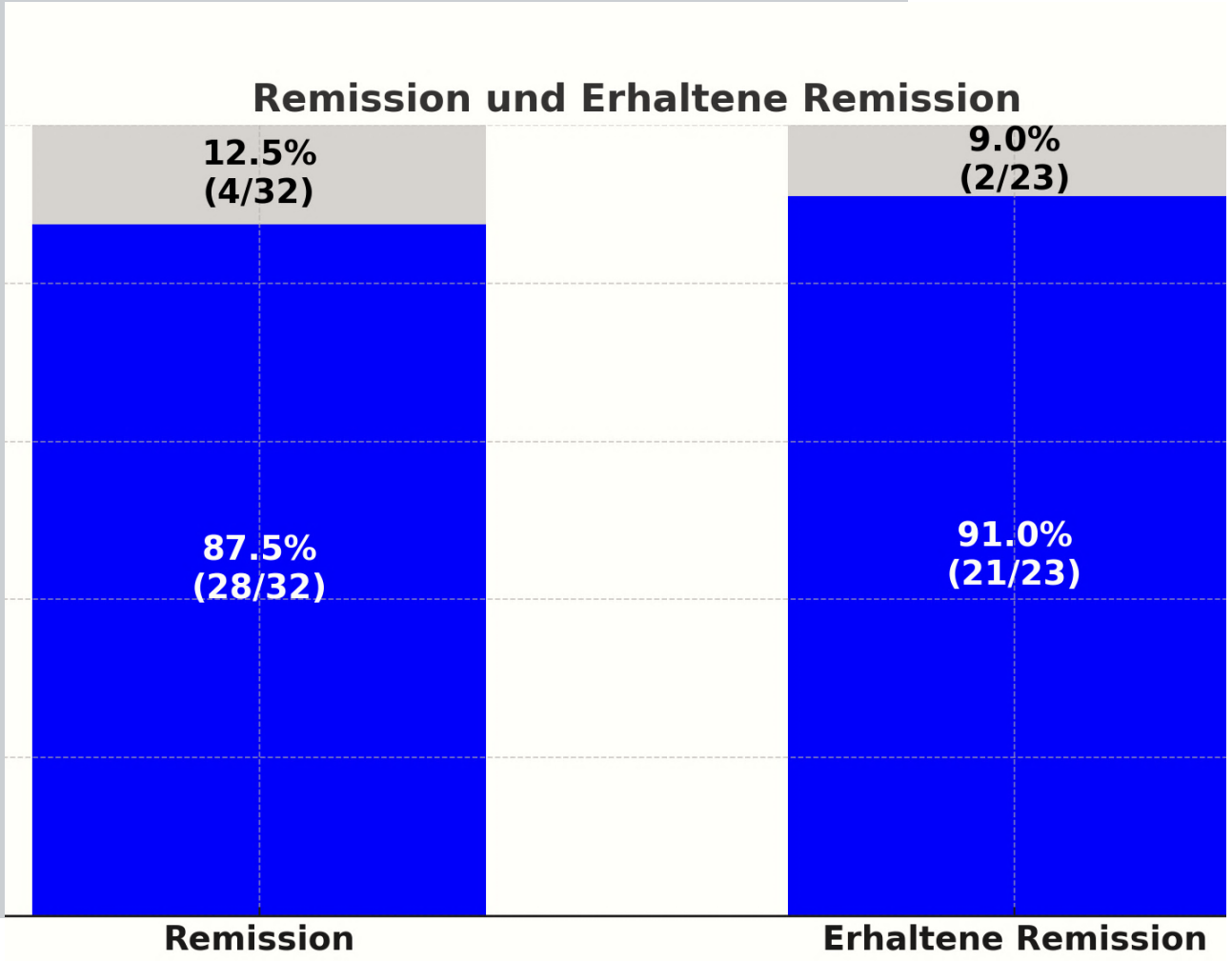
Patientencharakteristika

Table 1: Patient and clinical characteristics and treatment

Characteristic		Treatment	
Sex – No. (%)		**Induction therapy** – No. (%)	
Female	18/39 (46)	Methylprednisolone pulse	30/39 (77)
Male	21/39 (54)	Rituximab (initially)+	24/39 (62)
Age – years (mean; IQR)	64 (51, 72)	Cyclophosphamid (initially)*	15/39 (38)
Diagnosis/Antibody – No. (%)		Plasma exchange	11/39 (28)
GPA / PR3-ANCA	22/39 (56)	**Maintenance therapy** – No. (%)	
MPA / MPO-ANCA	15/39 (38)	Avacopan	39/39 (100)
MPA / MPO + anti-GBM	2/39 (5)	Prednisolone	37/39 (95)
Newly diagnosed/Relapse – No. (%)		Rituximab#	21/27 (78)
Newly diagnosed	20/39 (51)	Mycophenolate mofetil	3/27 (11)
Relapsed	19/39 (49)	Azathioprine	2/27 (7)
BVAS (at time of diagnosis) – mean	17	Methotrexate	1/27 (4)
Kidney involvement – No. (%)	33/39 (85)	**eGFR <15ml/min** – No. (%)	15/39 (38)
Kidney replacement therapy – No. (%)	7/39 (18)	**Diffuse alveolar hemorrhages**	7/39 (18)

→ **2 Pat. mit mechanischer Beatmung**

Primärer Endpunkt



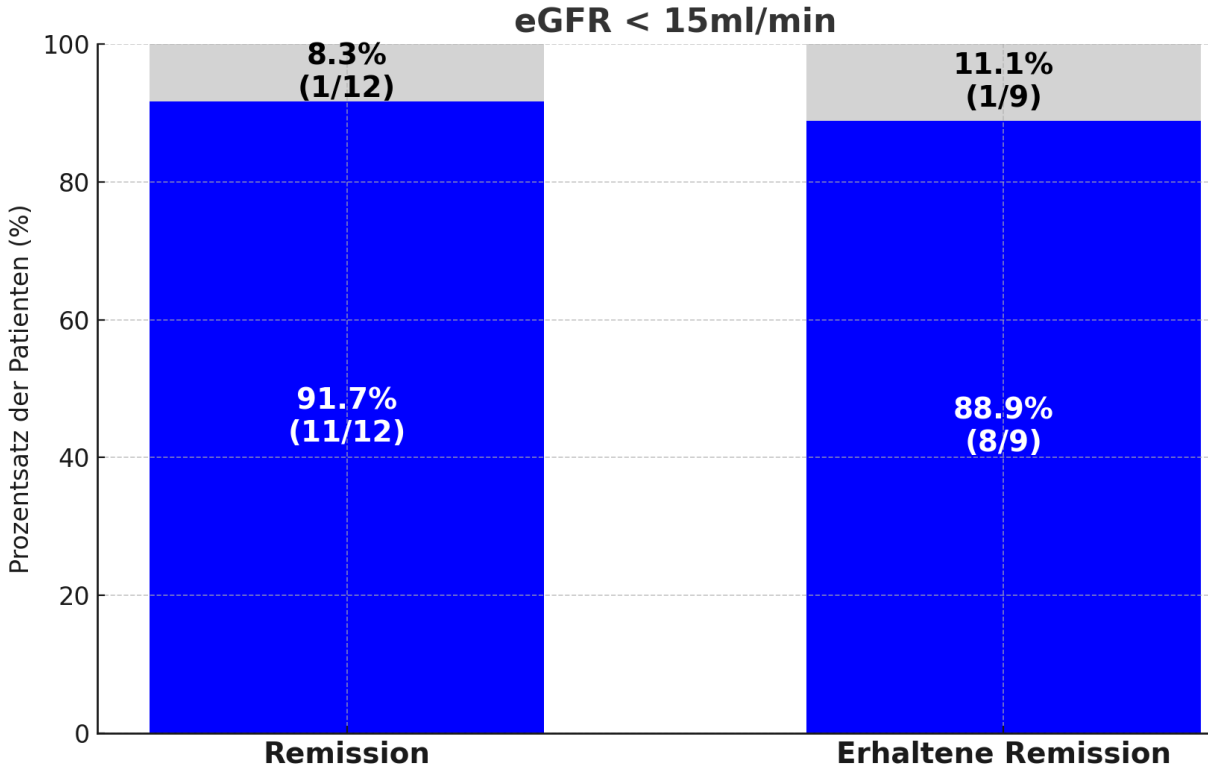
Remission: BVAS von 0 und ≤7,5 mg Prednisolon/Tag nach 6 Monaten
Erhaltene Remission: BVAS von 0 nach 6 und 12 Monaten ohne Relapse

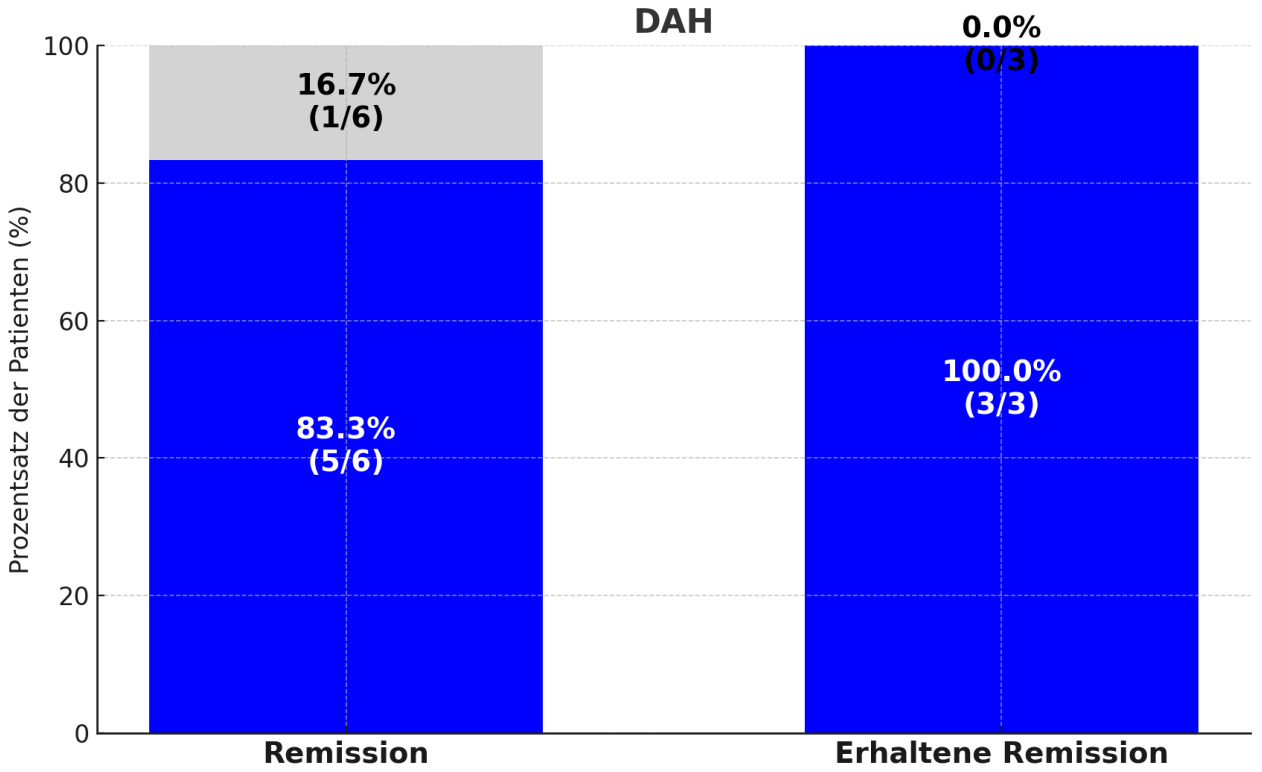
Hohe Remissions- und Erhaltene Remissionsraten trotz kränkerem Patientenkollektiv im Vergleich zu ADVOCATE

Erhaltungstherapie für alle Patienten (zumeist **Rituximab**)

Sekundäre Endpunkte

Subgruppenanalyse: eGFR<15ml/min + DAH





Remission: BVAS von 0 und ≤7,5 mg Prednisolon/Tag nach 6 Monaten
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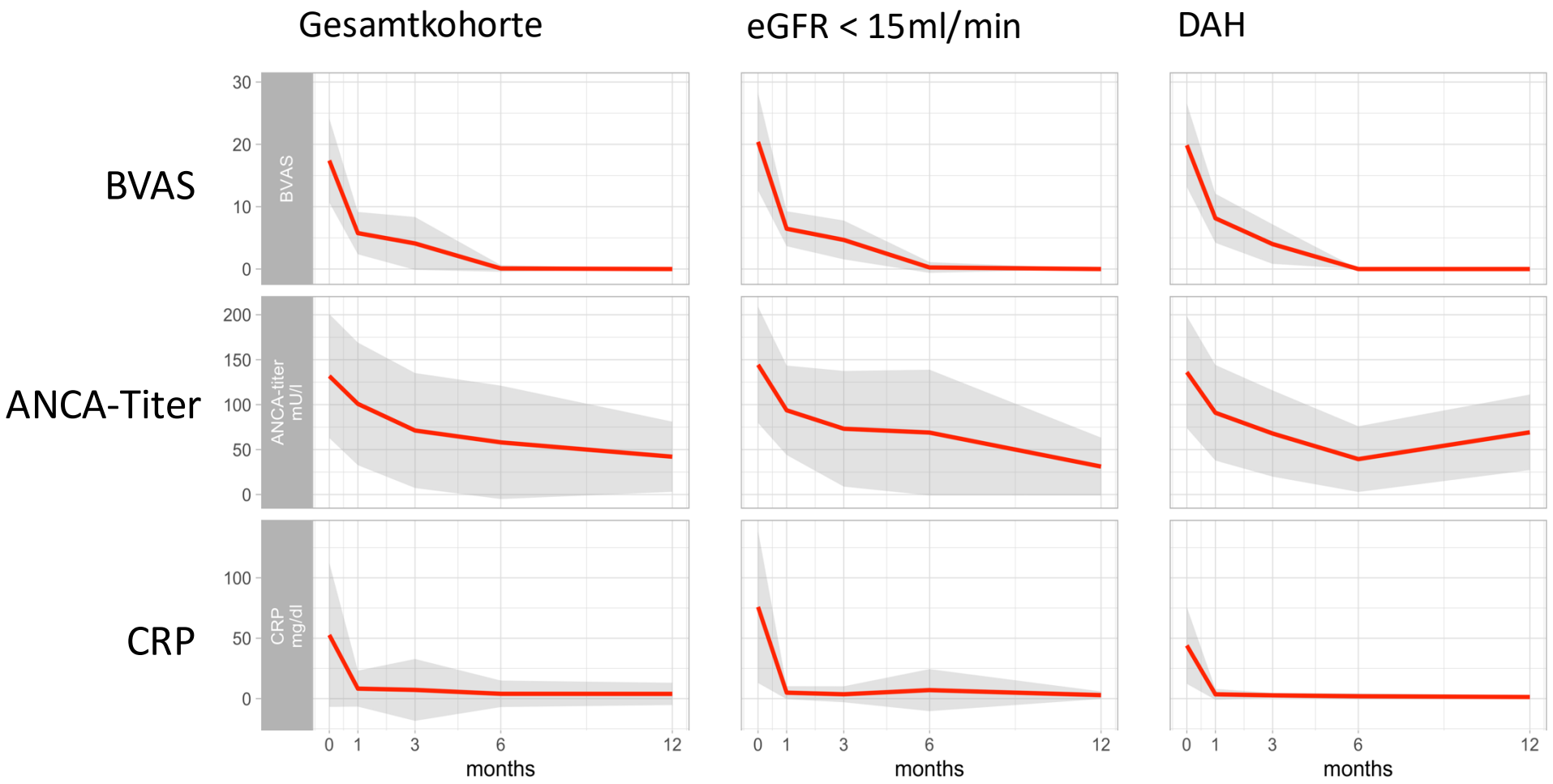
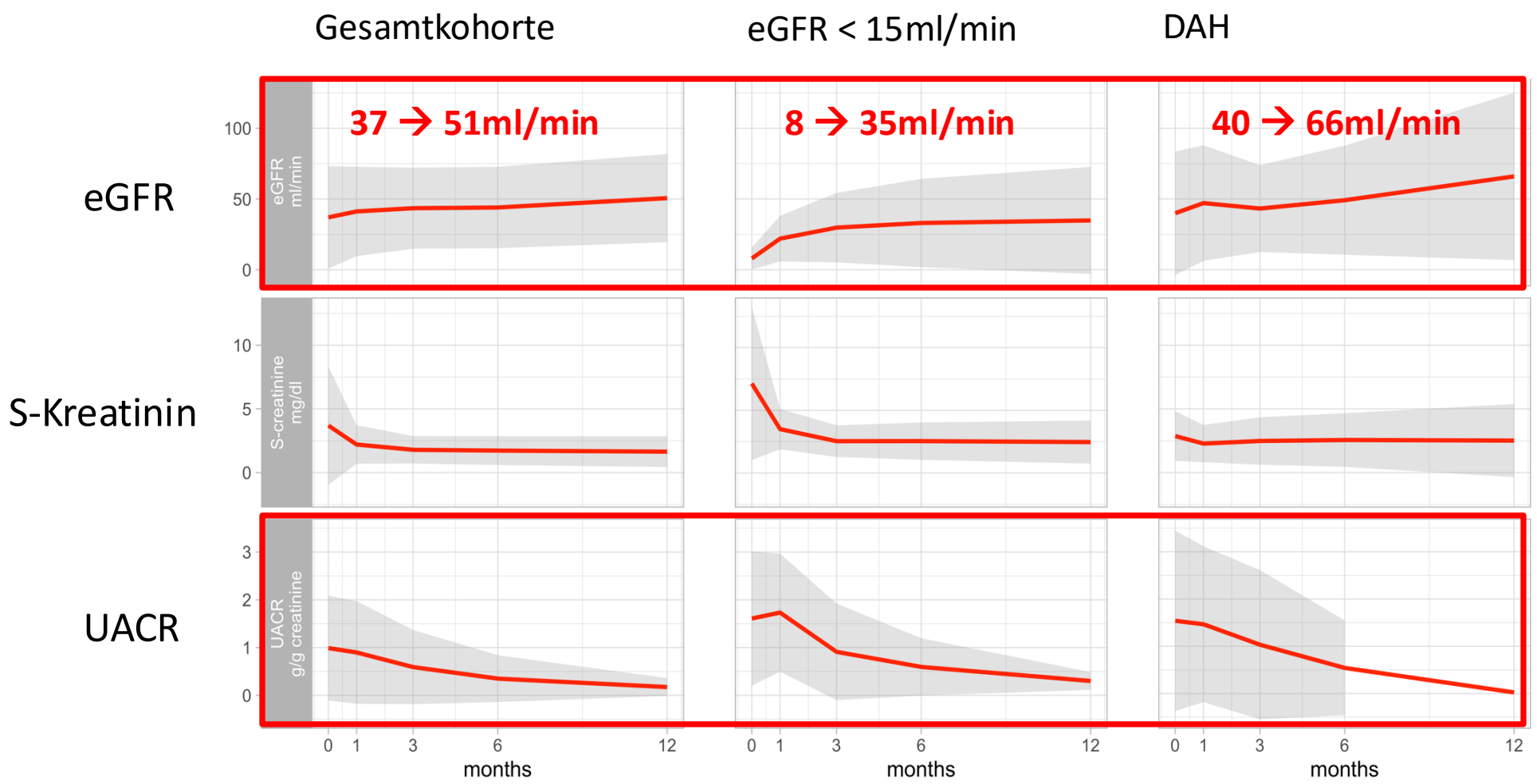
→ **Niedrige Fallzahlen**

Subgruppenanalyse: eGFR<15ml/min + DAH



Patientenanzahl: 39 32 23 15 12 9 7 6 3

Subgruppenanalyse: eGFR<15ml/min + DAH



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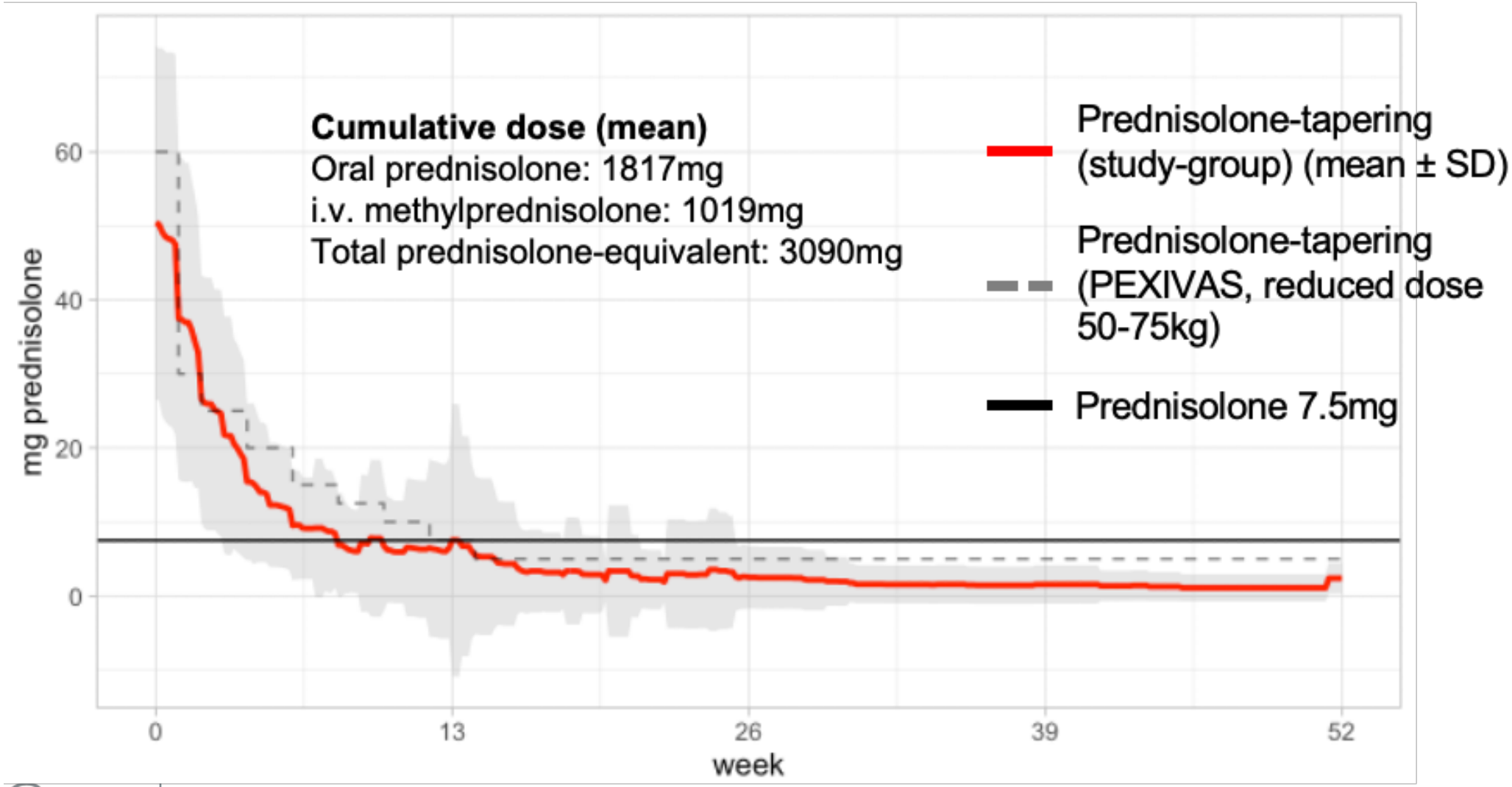
Kumulative Glukokortikoid-Dosis



Therapiesicherheit

Events	Overall cohort N = 39 – No. (%)	eGFR <15ml/min N = 15 – No. (%)	DAH N = 7 – No. (%)
Any adverse event	34 (87)	13 (87)	6 (86)
Any serious adverse event*	14 (36)	6 (40)	2 (28)
Life-threatening adverse event+	3 (8)	1 (7)	1 (14)
Death#	1 (3)	0 (0)	0 (0)
Any infection	14 (36)	9 (60)	3 (43)
Any serious infection§	6 (15)	4 (27)	1 (14)
Any potential glucocorticoid-associated adverse event&	24 (62)	11 (73)	4 (57)
Cardiovascular	15 (38)	6 (40)	2 (29)
Infectious	10 (26)	7 (47)	2 (29)
Gastrointestinal	4 (10)	3 (20)	0 (0)
Psychological	1 (3)	0 (0)	0 (0)
Endocrine/metabolic	10 (26)	4 (27)	1 (14)
Dermatological	1 (3)	1 (7)	0 (0)
Musculoskeletal	0 (0)	0 (0)	0 (0)
Ophthalmological	0 (0)	0 (0)	0 (0)
Discontinuation of avacopan therapy due to adverse event	8 (21)	3 (20)	2 (29)

Allgemein:

1. Raten an AEs, SAEs vergleichbar
2. GC-assoziierte AEs vergleichbar (mit Ausnahme der Infektionen)

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1. Gesamtkohorte: schwere Infektionen ↑; Infektionsrate ↓
2. eGFR<15ml/min: (schwere) Infektionsrate ↑
   Grund: Plasmapheresen 53%?

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Therapieabbruch:

1. vergleichbar zu ADVOCATE und zwischen Subgruppen

2x Fieber+Leukozytopenie, 2 Transaminasen, 2x GI-Symptomatik, 2x schwerer Husten und Mukusproduktion

Therapieentscheidung für Avacopan

Therapy decision*	**N = 39 – No. (%)**
Improving therapeutic response / overall outcome	21 (54)
Improving renal response / outcome	23 (59)
Diabetes mellitus or adipositas	11 (28)
Reduction in the cumulative dose of glucocorticoids	30 (77)
Contraindications for glucocorticoids	1 (3)
Intensification of therapy for uncontrolled disease / desire for higher immunosuppressive efficacy / relapse	20 (51)

Take Home Message

1. Hohe Remissions- und erhaltene Remissionsraten
2. Patienten mit eGFR<15ml/min weisen deutliche Verbesserung der GFR auf
3. Prospektive Studien notwendig, insb. für Pat. mit eGFR < 15ml/min, DAH
4. Alle Patienten erhielten Erhaltungstherapie (meistens Rituximab) – im Gegensatz zu ADVOCATE
5. Keine „Safety-Signals“, Monitoring für AEs dennoch wichtig – können zu Therapieabbruch führen
6. Schnelleres Prednisolon-Tapering empfohlen, um Nebenwirkungen zu verringern und Wirksam zu erhalten

Was bedeutet „schnelleres Glukokortikoid Tapering“?

ADVOCATE

Pre-Screening (4 Wochen)

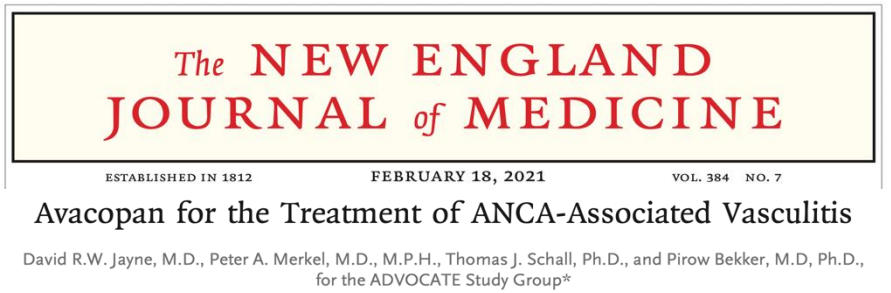
- Bis zu 3g i.v. Methylprednisolon
- Glukokortikoide p.o. (jedoch nicht >6 Wochen >10mg!)

Screening Periode (14 Tage)

- Tapering Prednisolon-Dosis auf ≤20mg

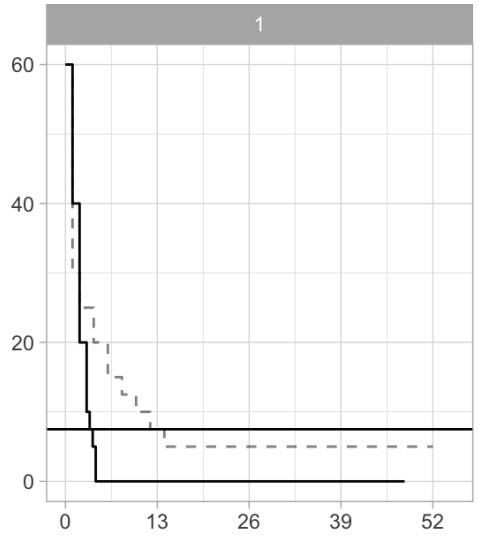
Studien Periode (4 Wochen)

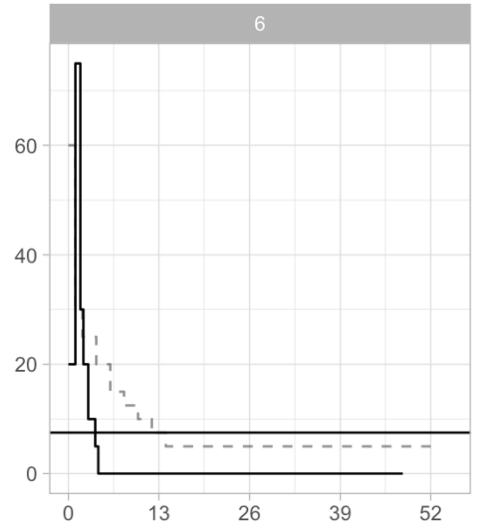
- i.v. Prednisolon für Rituximab-Prämedikation
- Ausschleichen innerhalb von 4 Wochen

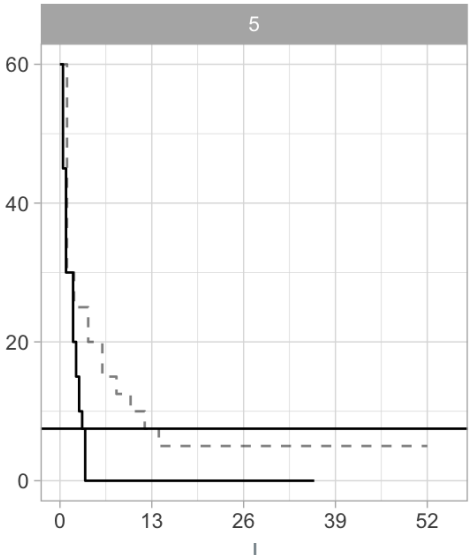


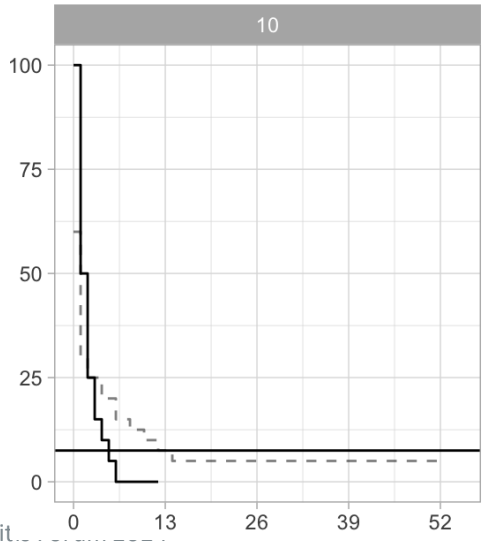
1676mg Prednisolon-Äquivalenz

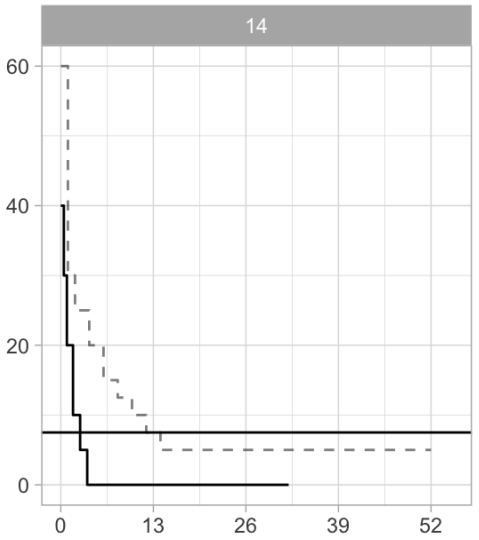
Positivbeispiele – Tapering

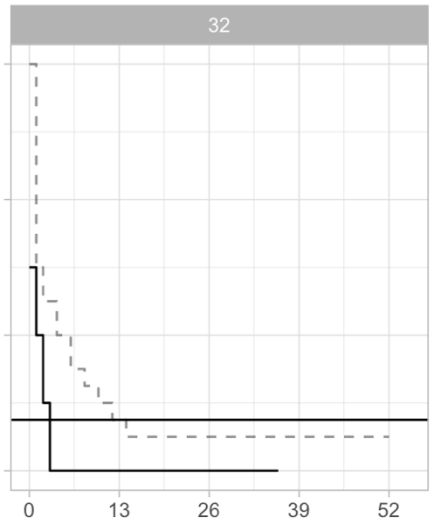












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→ **Prednisolon nach 4 Wochen ausgeschlichen**

→ **Remission erreicht, kein Relapse im Follow-up**

Diskussion Tapering-Schema

Study day	Daily prednisolone dose (mg)
Day 1-3 (methylprednisolone i.v.)	250
Day 4-6	60
Day 7-9	30
Day 10-12	25
Day 13-15	20
Day 16-18	15
Day 19-21	10
Day 22-24	7,5
Day 25-27	5
Day 28-30	2.5
> day 30	0
Cumulative i.v. dose (prednisolone-equivalent)	937.5
Cumulative p.o. dose	547.5
Total cumulative dose (prednisolone-equivalent)	1485.0

Vielen Dank für die Aufmerksamkeit!

Fragen?

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Gekürzte Verschreibungsinformationen

Schweiz:

Tavneos®. Z: Avacopan. **I:** Tavneos, als ergänzende Therapie zu einer immunsuppressiven Standardbehandlung auf Basis von Rituximab oder Cyclophosphamid mit Glukokortikoiden, ist für die Behandlung erwachsener Patienten mit schwerer aktiver ANCA Vaskulitis (GPA/MPA) indiziert. **D:** Orale Einnahme morgens und abends 2x täglich 30 mg (3 Kapseln zu je 10 mg) mit Nahrung. **KI:** Überempfindlichkeit gegen den Wirkstoff oder einen der Hilfsstoffe. **VM:** Hepatotoxizität; Angioödem; Überwachung des Blutbildes (weisse Blutkörperchen); Schwere Infektionen; Reaktivierung des Hepatitis-B-Virus; Herzbeschwerden; Bösartige Tumore; Macroglycerinhydroxystearat. **S/S:** Eine Anwendung während der Schwangerschaft und bei Frauen im gebärfähigen Alter, die keine Verhütungsmethode anwenden, ist nicht empfohlen. Es ist nicht bekannt, ob Avacopan in die Muttermilch ausgeschieden wird. Der Nutzen des Stillens für das Kind sollte gegen den Nutzen der Behandlung für die Patientin abgewogen werden. **UW:** Sehr häufig: Infektion der oberen Atemwege, Nasopharyngitis; Kopfschmerzen; Erbrechen, Durchfall, Übelkeit; erhöhter Lebertest; verminderte Anzahl weisser Blutkörperchen. Häufig: Lungenentzündung, Infektion der unteren Atemwege, Influenza, Bronchitis, Zellulitis, Infektion der Harnwege, Herpes zoster, Sinusitis, orale Candidose, Herpes im Mundbereich, Otitis media, Rhinitis, Gastroenteritis; Neutropenie; Oberbauchschmerzen; Anstieg der Kreatinphosphokinase im Blut. Gelegentlich: Angioödeme. **IA:** Avacopan ist ein Substrat von CYP3A4. Die gleichzeitige Verabreichung von Induktoren oder Inhibitoren dieses Enzyms kann die Pharmakokinetik von Avacopan beeinflussen. Siehe Fachinformation. **P:** Tavneos 10 mg: 30 und 180 Hartkapseln. **Liste B**. Detaillierte Informationen**:** www.swissmedicinfo.ch. Stand der Information**:** Januar 2024. **Zulassungsinhaberin:** Vifor Fresenius Medical Care Renal Pharma Ltd., St. Gallen. **Vertrieb:** Vifor Pharma Switzerland AG, CH-1752 Villars-sur-Glâne |

▼Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung. Für weitere Informationen, siehe Fachinformation TAVNEOS® auf www.swissmedicinfo.ch.

Gekürzte Verschreibungsinformationen

Österreich:

Tavneos® Fachkurzinformation
Tavneos®10mg Hartkapsel

Zusammensetzung: Jede Hartkapsel enthält 10 mg Avacopan. Sonstige Bestandteile mit bekannter Wirkung:245 mg Macrogolglycerolhydroxystearat(Ph.Eur). **Anwendungsgebiete:** Tavneos® ist in Kombination mit einem Rituximab- oder Cyclophopamid-Dosierungsschema indiziert zur Behandlung erwachsener Patienten mit schwerer aktiver Granulomatose mit Polyangiitis (GPA) oder mikroskopischer Polyangiitis (MPA). **Gegenanzeigen:** Überempfindlichkeit gegen den Wirkstoff oder einen der sonstigen Bestandteile. **Pharmakotherapeutische Gruppe:** Komplement-Inhibitoren **ATC- Code:** L04AJ05 **Inhaber der Zulassung:** Vifor France, 100-101 Terrasse Boieldieu Tour Franklin La Defense 8 92042 Paris La Defense Cedex, Frankreich. Rezept- und apothekenpflichtig. Weitere Angaben zu Warnhinweisen und Vorsichtsmaßnahmen für die Anwendung, Wechselwirkungen mit anderen Arzneimitteln oder sonstigen Wechselwirkungen, Schwangerschaft und Stillzeit und Nebenwirkungen sowie Gewöhnungseffekten sind der veröffentlichten Fachinformation zu entnehmen. Stand der Information: Mai 2023

▼Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung. Dies ermöglicht eine schnelle Identifizierung neuer Sicherheitsdaten. Angehörige der Gesundheitsberufe werden gebeten, alle Verdachtsfälle von unerwünschten Wirkungen zu melden.