2. DACH ANCA VASKULITIS FORUM 2024

22. & 23. NOVEMBER 2024 | MÜNCHEN

CSL Vifor

Fokus Avacopan bei eGFR<15 / Dialyse

Univ.-Prof. PD Dr. Kathrin Eller

Graz

Medical University of Graz

KLINISCHE ABTEILUNG FÜR NEPHROLOGIE
MEDIZINISCHE UNIVERSITÄT GRAZ LKH UNIV KLINIKUM GRAZ

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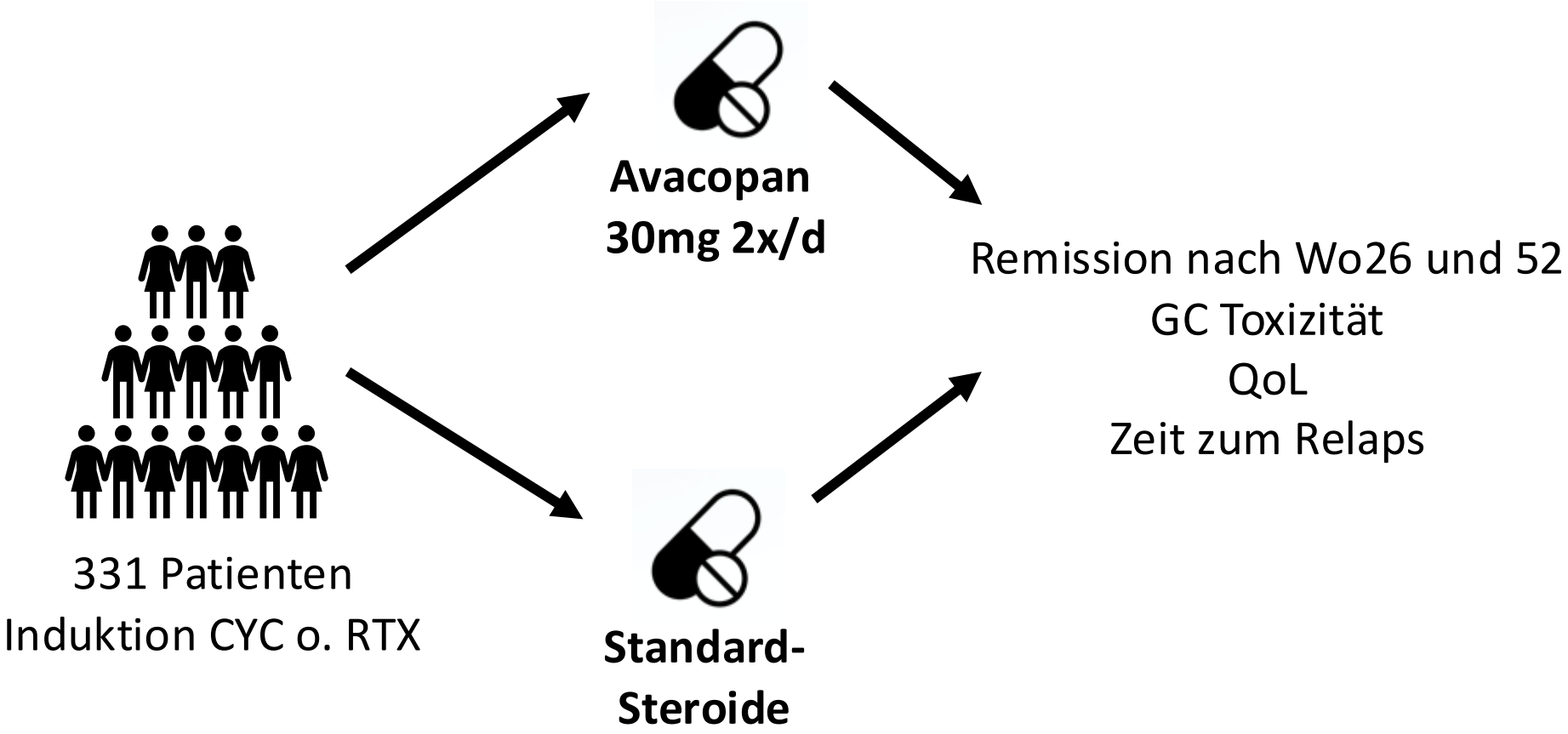
Interessenskonflikt

- Vifor, Otsuka, Alexion, Sanofi Aventis, AstraZeneca, Novartis, Astellas, Chiesi - Referentenhonorar, Advisory board Honorar
- Neovi, AstraZeneca, Novartis, Astellas, Chiesi - Kongressunterstützung

ADVOCATE Trial



Jayne DRW et al. Avacopan for the Treatment of ANCA-Associated Vasculitis. **N Engl J Med. 2021** Feb 18;384(7):599-609. doi: 10.1056/NEJMoa2023386.

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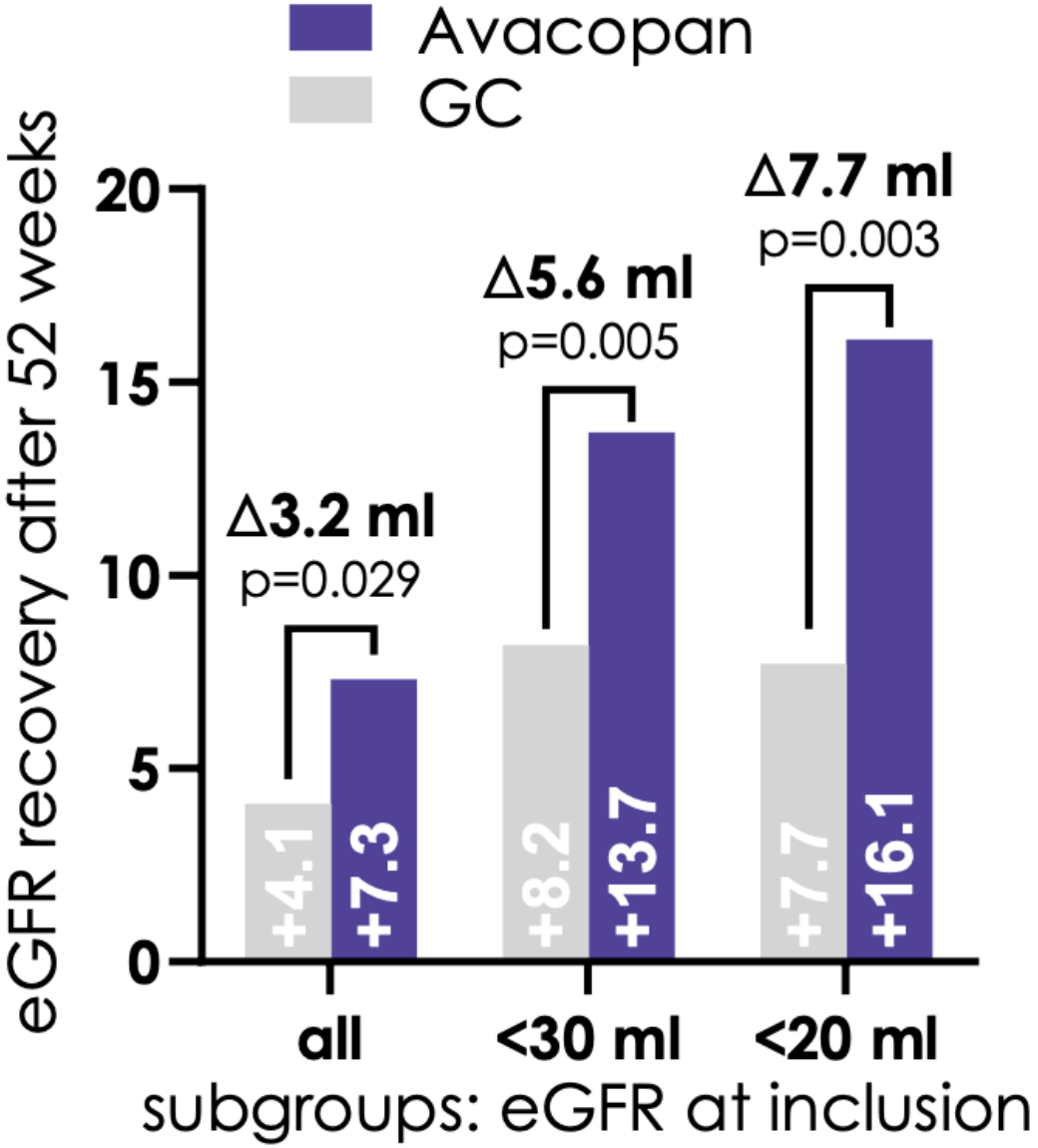

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ADVOCATE Trial - Inklusionskriterien

- Klinische Diagnose eine GPA oder MPA nach Chapel-Hill Konsensus Konferenz Definition
- 18 Jahre oder älter mit der Diagnose einer neuen oder relapsierten AAV mit einer Behandlungsnotwendigkeit mit Cyclophosphamid oder Rituximab. Auch Adoleszente (12-17 Jahre) konnten in Zentren mit entsprechender Ethikfreigabe eingeschlossen werden.
- Positiver Test für anti-PR3 oder anti-MPO Antikörper
- Mind 1 major Kriterium im BVAS oder 3 minor Kriterien oder mind. 2. renale Kriterien wie Proteinurie und Hämaturie im BVAS
- GFR $\geq$ 15ml/min zum Zeitpunkt des Screenings nach MDRD
- Informed consent
- Fit for study

ADVOCATE Trial – Exklusionskriterien

- Schwangerschaft oder Stillen
- Akute alveoläre Hämorrhagien, die eine invasive Beatmung benötigen
- Vorhandensein einer andere systemische Autoimmunerkrankung
- Dialysepflichtigkeit oder Plasmaaustausch in den 12 Wochen vor Screening
- Nierentransplantation

ADVOCATE Trial – Was wir jetzt Wissen … und welche Fragen bleiben offen?

- Avacopan hilft bei der Steroidreduktion und kann damit Lebensqualität verbessern sowie Steroidnebenwirkungen reduzieren.
- Avacopan verbessert das renale Outcome. V.a. bei Patient*innen mit GFR 15-30 ml/min
- Was tun mit Patient*innen mit GFR < 15 ml/min?
- Avacopan auch bei Patient*innen mit Dialysepflichtigkeit?
- Avacopan auch bei Patient*innen mit pulmonaler Blutung?
- Wie sehen die Nebenwirkungen und das Avacopan Potential im real-life Setting aus?

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Avacopan bei Patienten mit Dialyse-Pflichtigkeit

Avacopan in Patients With Rapidly Progressive Glomerulonephritis Requiring Dialysis

Check for updates

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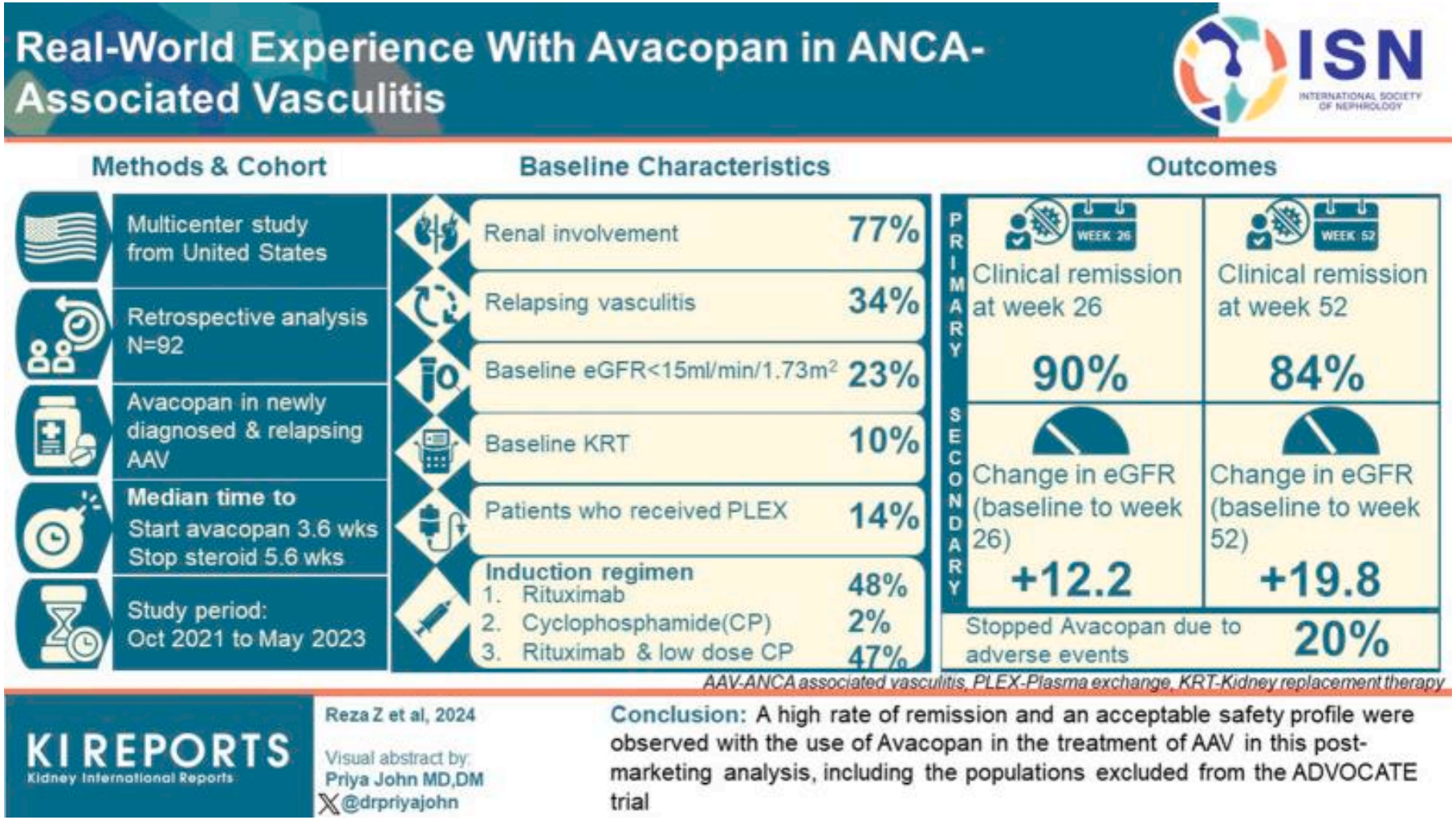
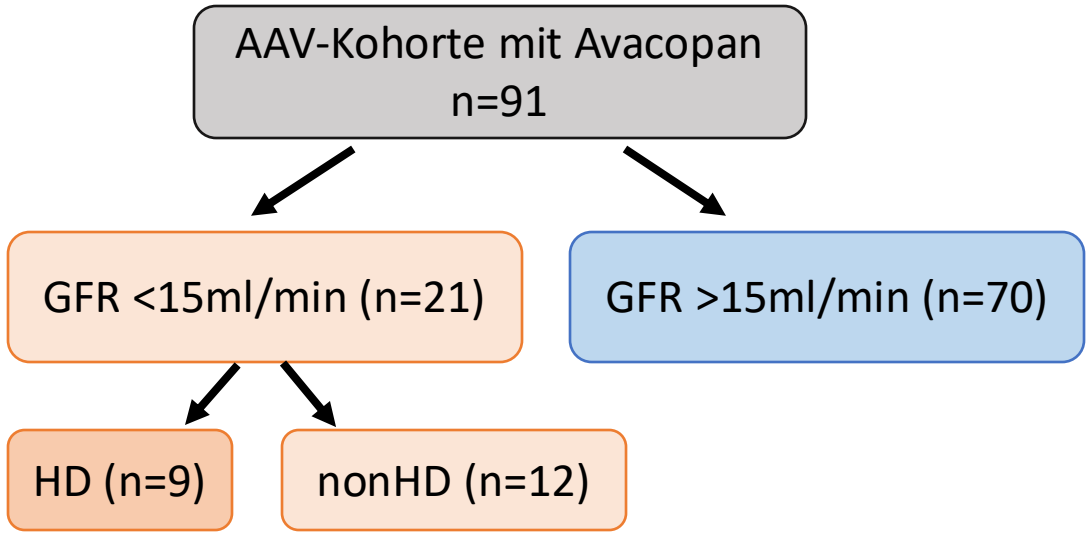
Real-life data Avacopan



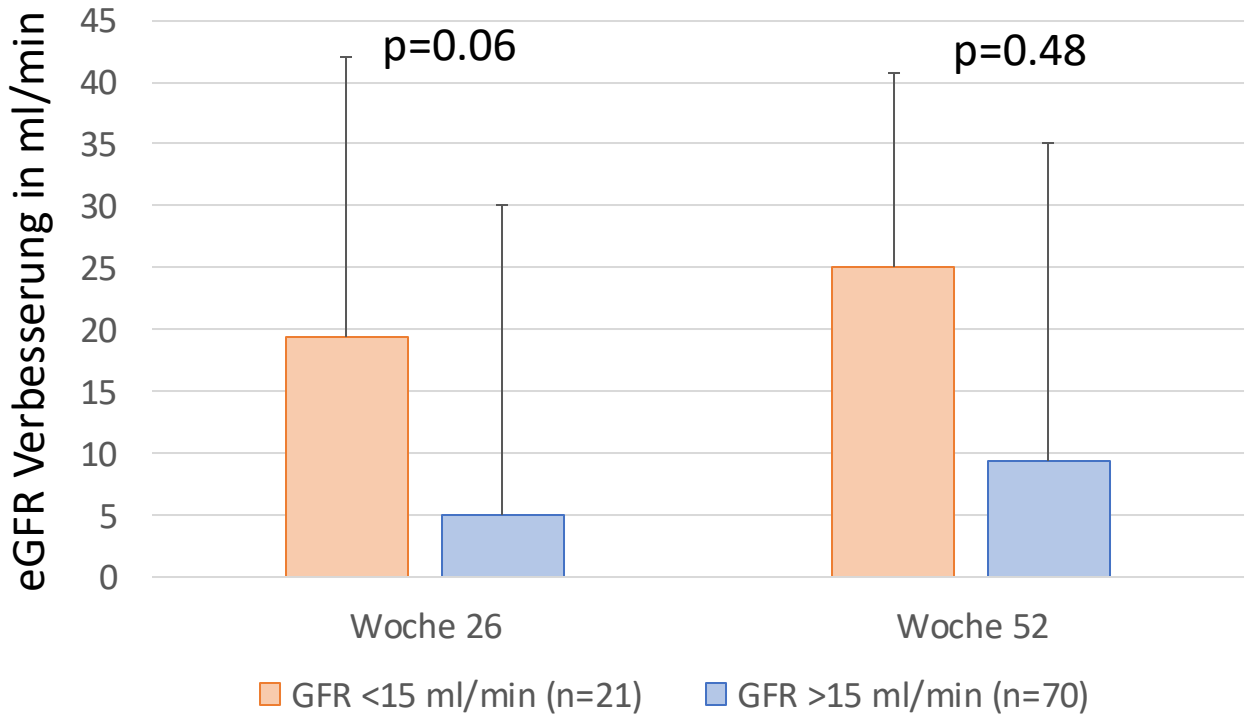
Zonozi R, et al. Real-World Experience With Avacopan in Antineutrophil Cytoplasmic Autoantibody-Associated Vasculitis. **Kidney Int Rep. 2024** Mar 26;9(6):1783-1791. doi: 10.1016/j.ekir.2024.03.022. PMID: 38899183

Real-life data Avacopan



	GFR <15 ml/min n=21	GFR >15ml/min n=70	Signifikanz
PLEX	9/21 (45%)	4/70 (5.7%)	p<0.01
Start Avacopan	47d (21-58)	21d (14-49)	p=0.02
ESKD	6/21 (30%)	0/70 (0%)	p<0.01

Verbesserung der eGFR



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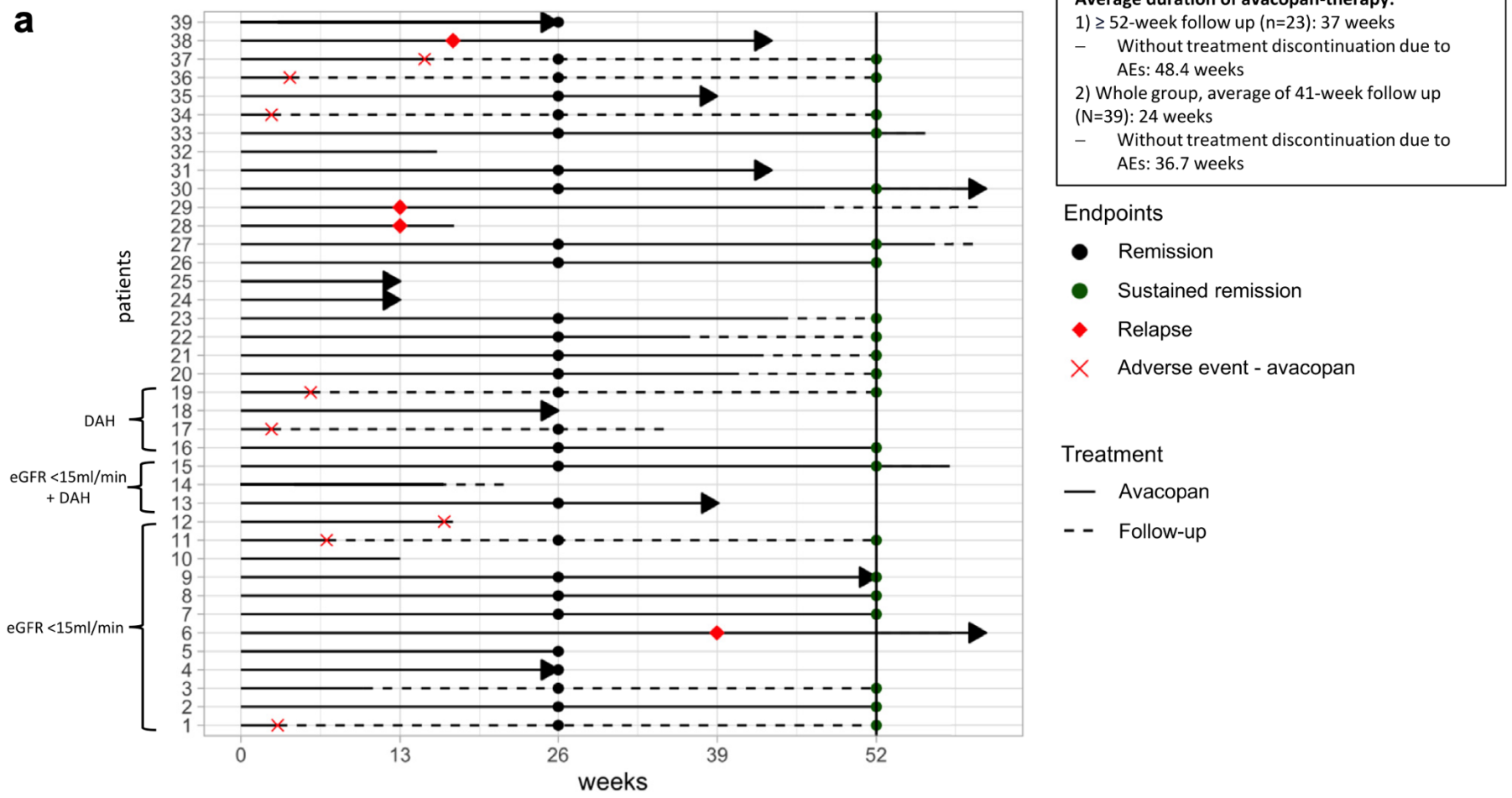

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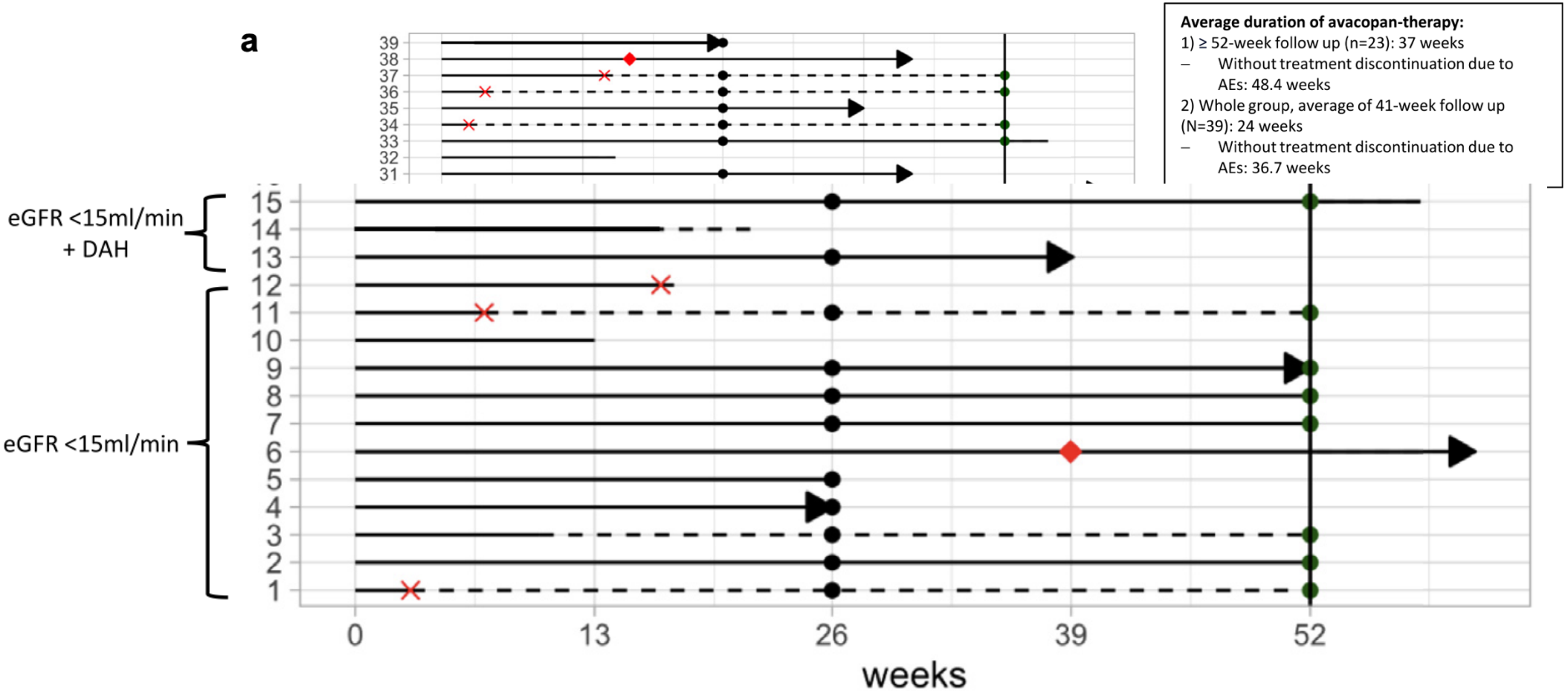

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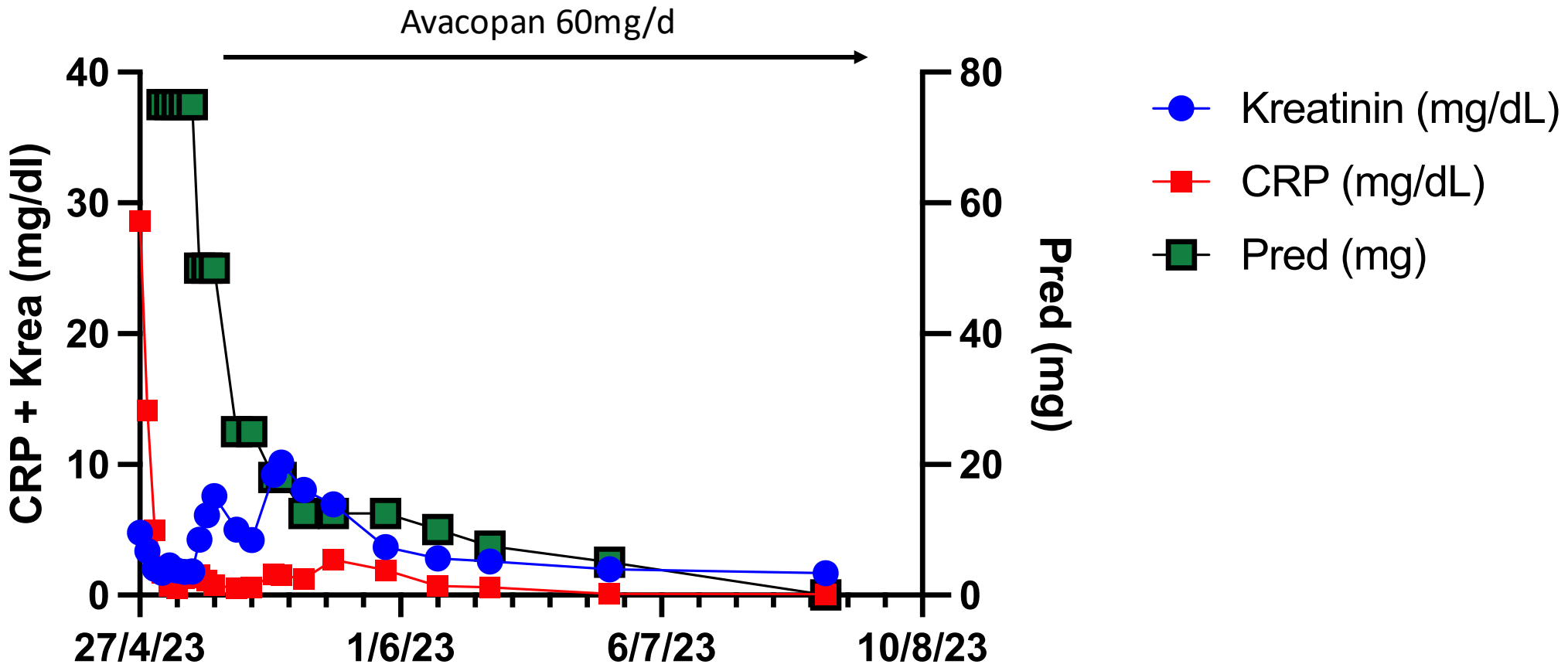
Patientenfall - Dialysepflichtigkeit

- 71 Jahre alte Frau
- PR3-ANCA Vaskulitis mit pulmorenalem Syndrom, Nierenbiopsie mit 100% aktiven Crescents
- Therapie: 5x Plasma-Austausch, Kombination CYC/RTX, Pred.-Bolus 1g/d 3x
- Avacopan-Start after 1 week

Patientenfall - Dialysepflichtigkeit



4 Patient*innen mit Dialysepflichtigkeit

- 4 Patienten mit GFR < 15 ml/min
- 2 Männer (76 und 47a), 2 Frauen (60 und 71a)
- 2 MPO-ANCA, 2 PR3-ANCA
- Beteiligte Organe: Niere (4/4 Pat.), Lunge (3/4 Pat.), Haut (1/4 Pat.), Nerven (1/4 Pat.), Herz (2/4 Pat.), HNO (1/4 Pat.).
- Therapie: PLEX (3/4 Pat.), komb. CYC/RTX, Steroid-Bolus, Avacopan, Dialyse (4/4 Pat.)
- 3/4 Patients ohne HD. 2 Patienten mit GFR>30 ml/min, 1 Patient CKDG5 ohne HD, 1 Patient HD 2x/week
- Komplikationen und Stop von Avacopan: Pat. CKDG5 – LFP Anstieg (gGT 800 IU/ml, AST 180 IU/ml, ALT 564 IU/ml) mit Gyrase-Inhibitor Antibiotika (2 Monate nach Th-Start), Pat. mit HD – Neutropenie (500/l – 2,5 Mo nach Th-Start)

Grenzen der Therapie mit Avacopan

Table 3. Safety Results.*

Event	Avacopan (N=166)	Prednisone (N=164)
Any adverse event		
No. of patients (%)	164 (98.8)	161 (98.2)
No. of events	1779	2139
Any serious infection¶		
No. of patients (%)	22 (13.3)	25 (15.2)
No. of events	25	31
Any serious opportunistic infection — no. (%)	6 (3.6)	11 (6.7)
Death due to infection — no. (%)	1 (0.6)	2 (1.2)
Life-threatening infection — no. (%)	1 (0.6)	2 (1.2)
Serious adverse event of abnormality on liver-function testing — no. (%)	9 (5.4)	6 (3.7)

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Grenzen der Therapie mit Avacopan

Dosismanagement

Die Behandlung muss klinisch neu beurteilt und vorübergehend unterbrochen werden wenn:

- der Alanin-Aminotransferase (ALT)- oder Aspartat-Aminotransferase (AST)-Spiegel über dem 3-Fachen des oberen Normwerts (ULN) liegt.

Die Behandlung muss vorübergehend unterbrochen werden, wenn:

- ALT oder AST > 5 × ULN,
- der Patient eine Leukopenie (Leukozytenzahl < 2×10^9/l), Neutropenie (Neutrophile < 1×10^9/l) oder Lymphopenie (Lymphozyten < $0{,}2 \times 10^9$/l) entwickelt,
- der Patient eine aktive, schwerwiegende Infektion hat (d. h., wenn eine stationäre Aufnahme oder eine längere Hospitalisierung erforderlich ist).

Die Behandlung kann wiederaufgenommen werden:

- nach Normalisierung der Werte und auf Grundlage einer individuellen Nutzen-Risiko-Bewertung.

Wird die Behandlung wiederaufgenommen, sind die Lebertransaminase- und Gesamtbilirubin-Spiegel engmaschig zu überwachen.

Take home message

- Im real-world Setting ist ein Einsatz von Avacopan auch in Patienten mit einer GFR<15 ml/min oder Dialysepflichtigkeit erfolgt.
- Die Datenlage ist überschaubar. Es dürfte aber auch in diesem Kollektiv zu einer GFR-Verbesserung kommen.
- Die Nebenwirkungshäufigkeit ist aktuell nicht abschätzbar. Engmaschiges Monitoring der Transaminasen und des Blutbilds sind wichtig.
- Zentrumsvorgehen: Start von Avacopan auch bei GFR<15ml/min oder Dialysepflichtigkeit. Absetzen von Avacopan nach 2-3 Monaten bei fehlender Erholung der Nierenfunktion.

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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.