CSL Vifor

1. DACH ANCA VASKULITIS FORUM 2023
12. & 13. MAI 2023

Interdisziplinäre Sicht auf die AAV - AAV aus der Sicht des Nephrologen

Priv. Doz. Dr. Michael Rudnicki
Innsbruck

ACH ANCA VASKULITIS FORUM 2023
MAI 2023 | WIEN, HOTEL SAVOYEN
Rudnicki

AT-AVA-2300038
DE-AVA-2300050

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0:00 / 24:15

AAV aus der Sicht des Nephrologen

Michael Rudnicki

Medizinische Universität Innsbruck
Univ. Klinik für Innere Medizin IV
Nephrologie und Hypertensiologie

1st DACH ANCA VASKULITIS FORUM 2023
12.-13. Mai 2023

Disclosure

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Sanofi, Amicus, Otsuka, Chiesi, Baxter, Fresenius Medical Care, Vifor, Alnylam, Hansa Biopharma, Astra Zeneca, Amgen

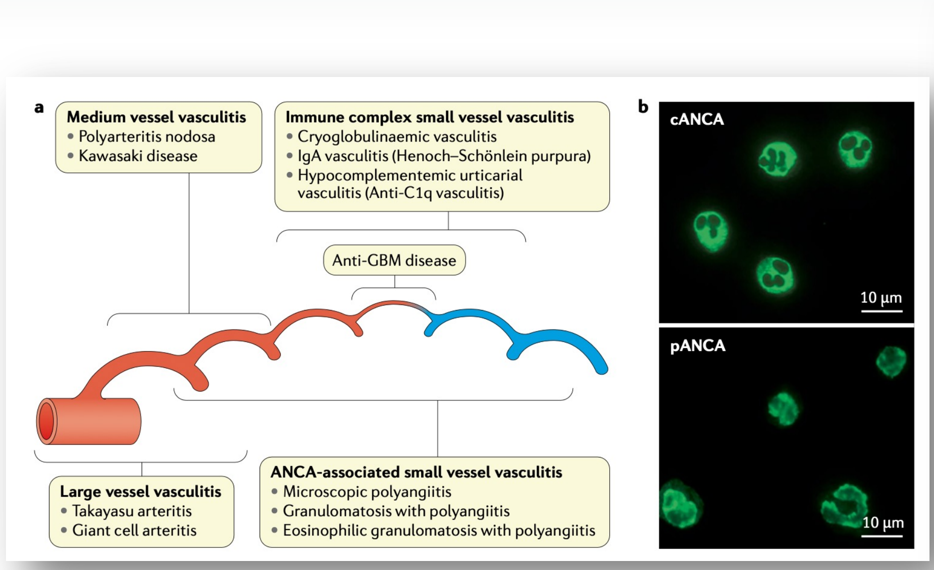
Consultancy-cooperation:

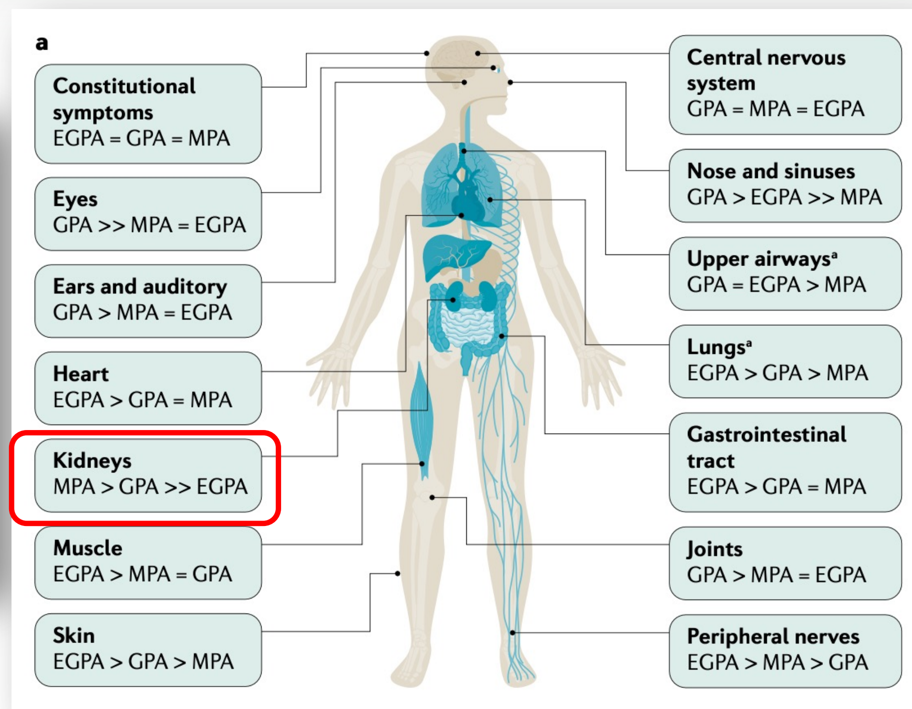
Delta4, AOP

Nierenbeteiligung bei AAV

- Pathologie
- Klinische Manifestation und ihre Bedeutung
- Therapie
- Therapieansprechen
- Dialyse
- Der alte Patient
- Infektionen

ANCA-assoziierte Vasculitis und die Niere

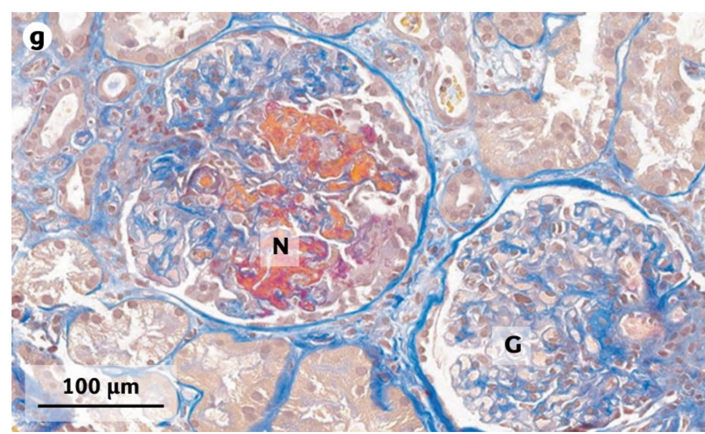




Kitching et al., Nat Rev Dis Primers. 2020 Aug 27;6(1):71.

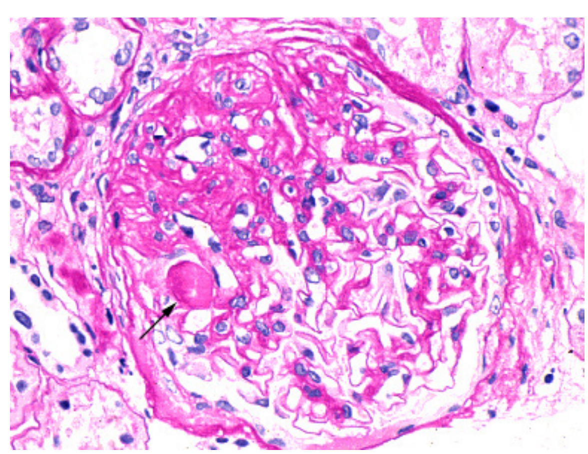
Pathologie der Nierenbeteiligung bei AAV

Nekrotisierende pauci-immune Glomerulonephritis



Hämaturie +++
Proteinurie +/-

(sekundäre) Fokal-segmentale Glomerulosklerose



Hämaturie +/-
Proteinurie +/++/+++

Kitching et al., Nat Rev Dis Primers. 2020 Aug 27;6(1):71.

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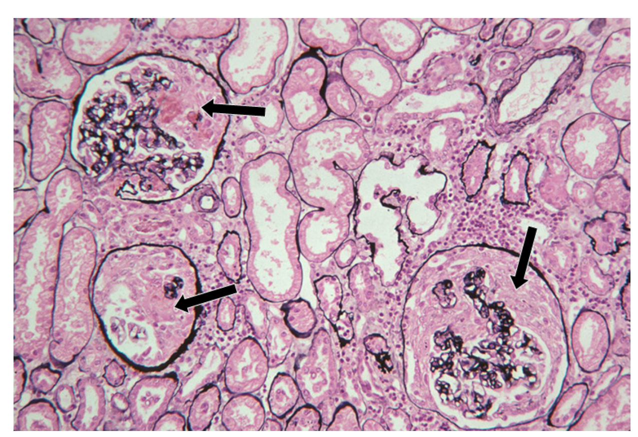
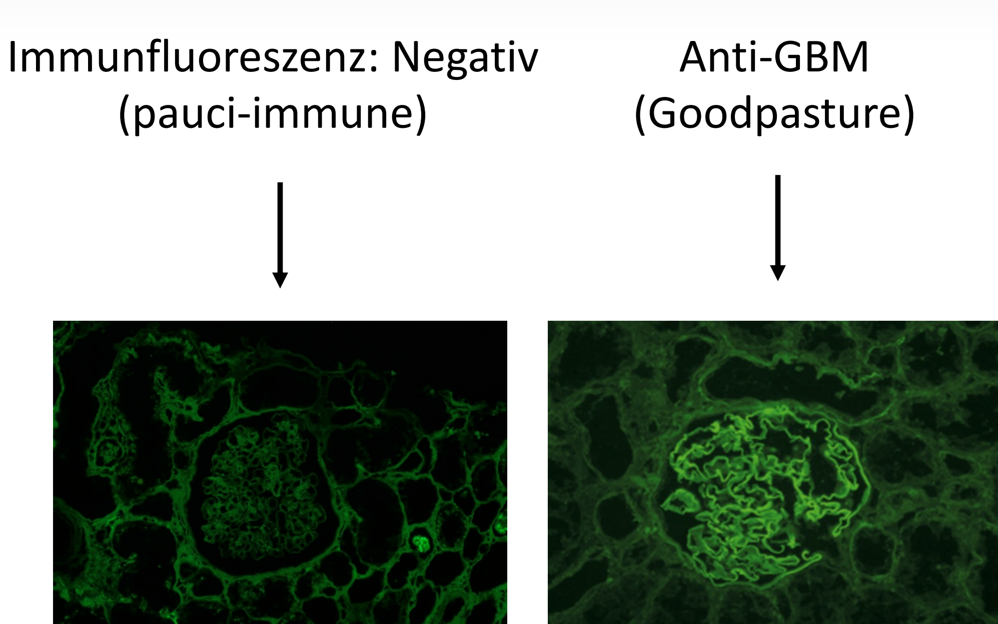
Pathologie der Nierenbeteiligung bei AAV

Crescentic pauci-immune Glomerulonephritis (Halbmonde)



Immunfluoreszenz: Negativ (pauci-immune)

Anti-GBM (Goodpasture)



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RPGN: Rapid-progressive Glomerulonephritis

- Klinische Definition:

  "rapidly declining kidney function"

  (ca.) -50% eGFR in <3 Monaten

- Häufig mit crescentic GN assoziiert
- Aber: Halbmonde bedeuten nicht automatisch RPGN
- RPGN: Therapeutische Konsequenzen!

KDIGO 2021 Guideline for the Management of Glomerular Diseases
Rovin et al., Kidney Int. 2021 Oct;100(4):753-779.

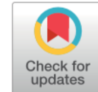
Clinical associations of renal involvement in ANCA-associated vasculitis

Andreas Kronbichler[a,b,*,1], Jae Il Shin[c,d,1], Keum Hwa Lee[c,d], Daiki Nakagomi[a,e], Luis F. Quintana[a,f], Martin Busch[g], Anthea Craven[h], Raashid A. Luqmani[h], Peter A. Merkel[i], Gert Mayer[b], David R.W. Jayne[a,j], Richard A. Watts[k]

- 1230 Patienten aus 31 Ländern
- 59% zeigten eine Nierenbeteiligung
  - 82% bei MPA
  - 58% bei GPA
  - 26% bei EGPA

Kronbichler et al., Autoimmun Rev. 2020 Apr;19(4):102495.

Clinical associations of renal involvement in ANCA-associated vasculitis



Andreas Kronbichler[a,b,*,1], Jae Il Shin[c,d,1], Keum Hwa Lee[c,d], Daiki Nakagomi[a,e], Luis F. Quintana[a,f], Martin Busch[g], Anthea Craven[h], Raashid A. Luqmani[h], Peter A. Merkel[i], Gert Mayer[b], David R.W. Jayne[a,j], Richard A. Watts[k]

- Faktoren **eher assoziiert** mit renaler Beteiligung:

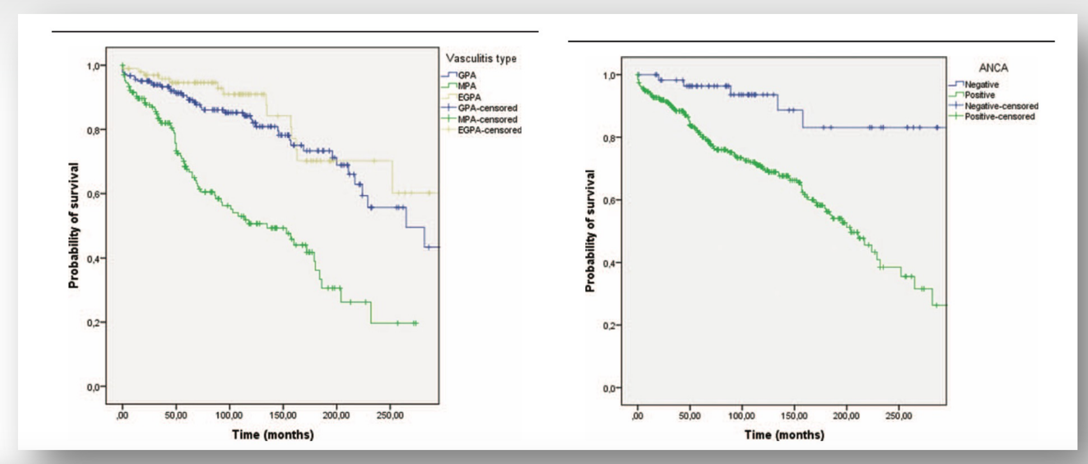
  Alter, Fieber, Gewichtsverlust, Polyarthritis, Petechien/Purpura, pulmonale Hämorrhagie, GI-Symptome, Epi-Anfall, S-Albumin ↓, C3↓, CRP↑, MPO/PR3-ANCA +

- Faktoren **seltener** assoziiert mit renaler Beteiligung:

  Mononeuritis multiplex, Proptosis/Exophthalmus, nasale Polypen, Septumdefekte, Asthma, Lungenfibrose, obstruktive Lungenerkrankung

Kronbichler et al., Autoimmun Rev. 2020 Apr;19(4):102495.

Renale Beteiligung bei AAV ist assoziiert mit schlechterem Überleben



Factor	Univariate analysis					Multivariate analysis		
	Death (n, %)	Alive (n, %)	OR	95% CI	*P*	OR	95% CI	*P*
Age at diagnosis >65 y	83 (64.3)	75 (23.4)	5.9	3.8–9.2	<0.001	3.1	1.8–5.4	<0.001
Renal involvement	111 (85.3)	168 (52.3)	5.6	3.3–9.7	<0.001	2.5	1.2–4.9	0.010
Cardiac failure	17 (13.2)	16 (5.0)	2.8	1.4–5.9	0.002			
Stroke	11 (8.5)	11 (34.3)	2.6	1.1–6.2	0.030			
Anemia	103 (79.9)	204 (63.6)	2.3	1.4–3.7	0.001			
Proteinuria >1 g	38 (29.5)	61 (19.0)	1.8	1.1–2.9	0.021			
Positive ANCA	124 (96.1)	266 (82.7)	5.1	2.0–13.1	<0.001	4.9	1.0–23	0.049
Bacterial infections	75 (58.1)	100 (34.6)	3.1	2.1–4.8	<0.001	3.7	2.1–6.6	<0.001
Opportunistic infections	23 (17.8)	33 (10.3)	2.3	1.3–4.2	0.008			

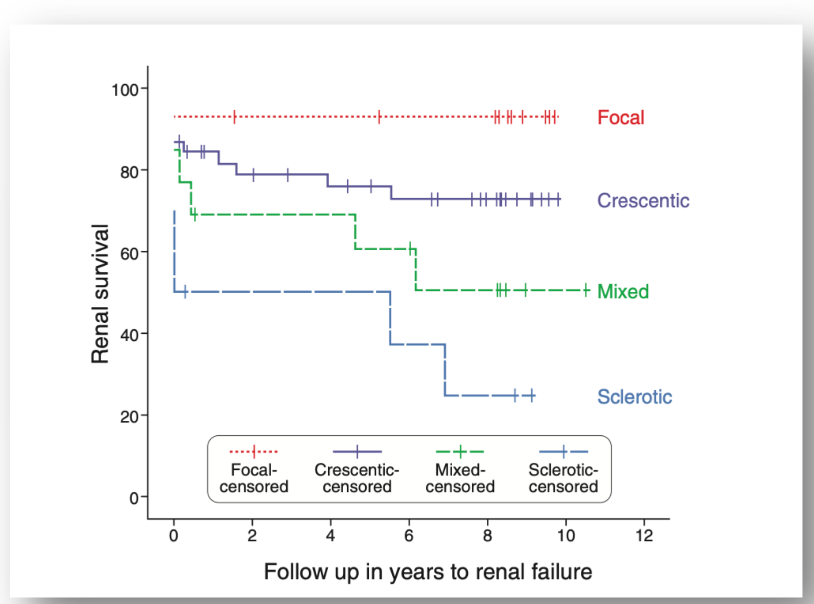
Solanse-Laque et al., Medicine (Baltimore). 2017 Feb;96(8):e6083

eGFR bei der Diagnose und die Histologie sind Prädiktoren für Dialyse

Table 4. Independent predictors of renal outcome

Multiple Linear Model	eGFR at 1 Year		eGFR at 5 Years	
	β	*P*	*β*	*P*
eGFR at entry	0.554	<0.001	0.530	0.002
Classification	−0.256	0.003	−0.289	0.031

Adjusted R^2 model eGFR 1 year = 0.61; adjusted R^2 model eGFR at 5 years = 0.49.



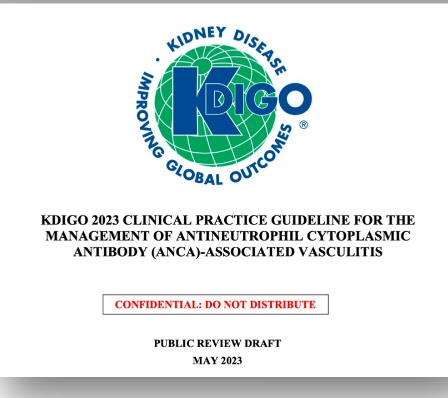
Berden et al., J Am Soc Nephrol. 2010 Oct;21(10):1628-36.

Viele Patienten mit AAV und Nierenbeteiligung erreichen die Dialysepflicht

- 15-38% der Patient:innen erreichen in 5 Jahren das Stadium einer terminalen Nierenerkrankung
- 29-72% der Patienten sind nach 3-6 Monaten noch immer dialysepflichtig oder sind verstorben
- Therapieziel: Verhinderung der Progression und der Dialyse

Corral-Gudino et al., Rheumatology (Oxford) 2011; Takala et al., Scand J Rheumatol 2011; Flossmann et al., Ann Rheum Dis 2011;
de Joode et al., Clin J Am Soc Nephrol 2013; Lee et al., Clin J Am Soc Nephrol 2014

Therapie



Diagnosis of AAV

Disease assessment

Induction of remission

No organ-threatening involvement

Vital organ/life-threatening
Serum creatinine 3.4 mg/dl (>300 µmol/l)

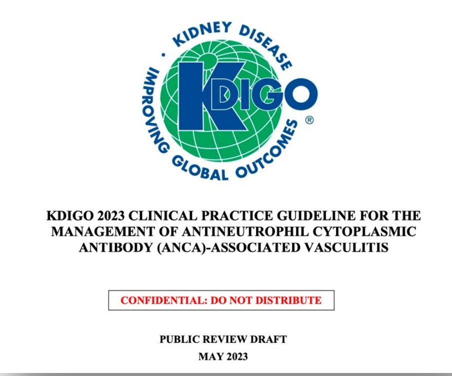
Consider mycophenolate mofetil

Cyclophosphamide + glucocorticoids

Rituximab + glucocorticoids

Consider plasmapheresis

Disease control 'on drug' remission

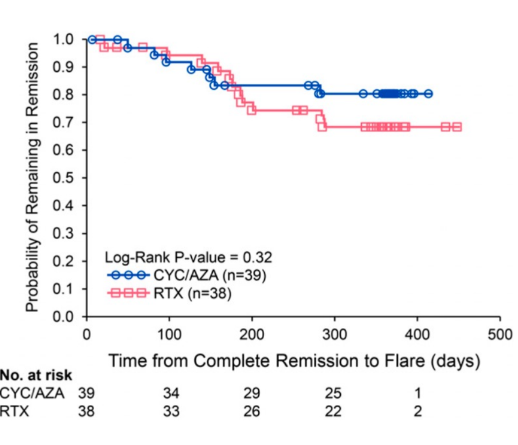


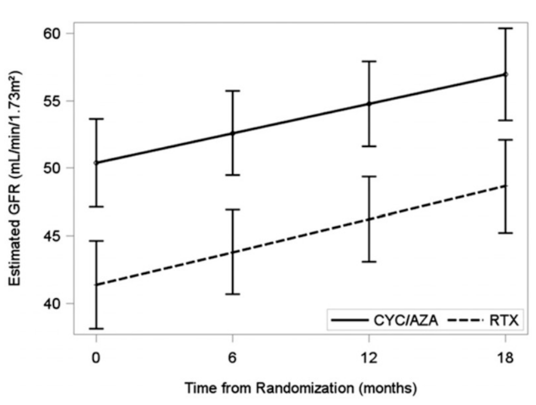
Therapie

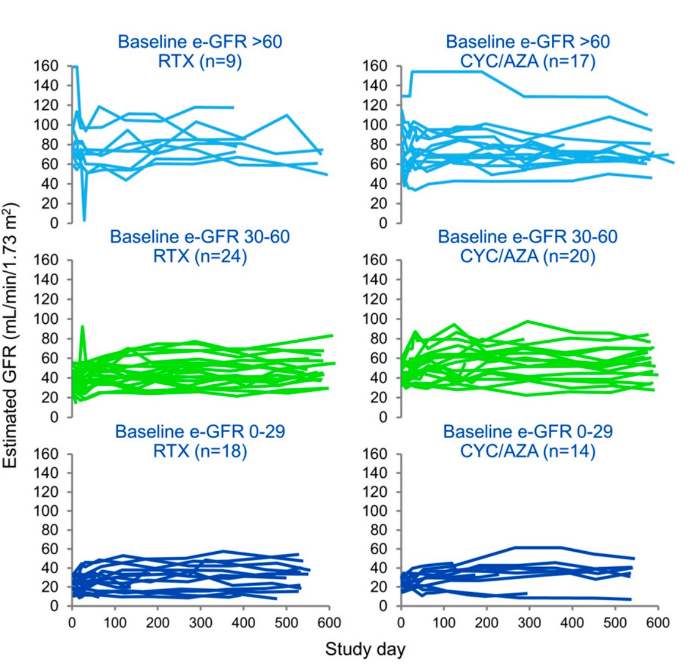
Practice Point 9.3.1.2: In patients presenting with markedly reduced or rapidly declining glomerular filtration rate (GFR) (serum creatinine [SCr] >4 mg/dl [>354 µmol/l]), there are limited data to support rituximab and glucocorticoids. Cyclophosphamide and glucocorticoids are preferred for induction therapy. The combination of rituximab and cyclophosphamide can also be considered in this setting.

Rituximab Versus Cyclophosphamide for ANCA-Associated Vasculitis with Renal Involvement

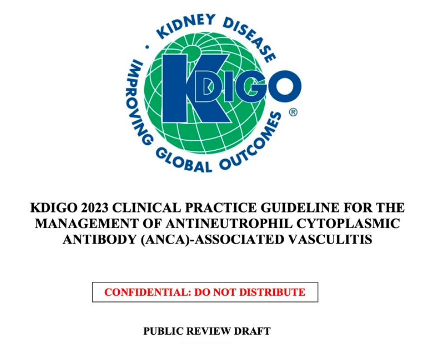
Post-hoc Analyse der RAVE Studie







Geetha et al., J Am Soc Nephrol. 2015 Apr;26(4):976-85.



Therapie

Practice Point 9.3.1.7: Avacopan may be used as an alternative to glucocorticoids. Patients with an increased risk of glucocorticoids toxicity are likely to have the most benefit from avacopan. Patients with lower GFR may benefit from greater GFR recovery.

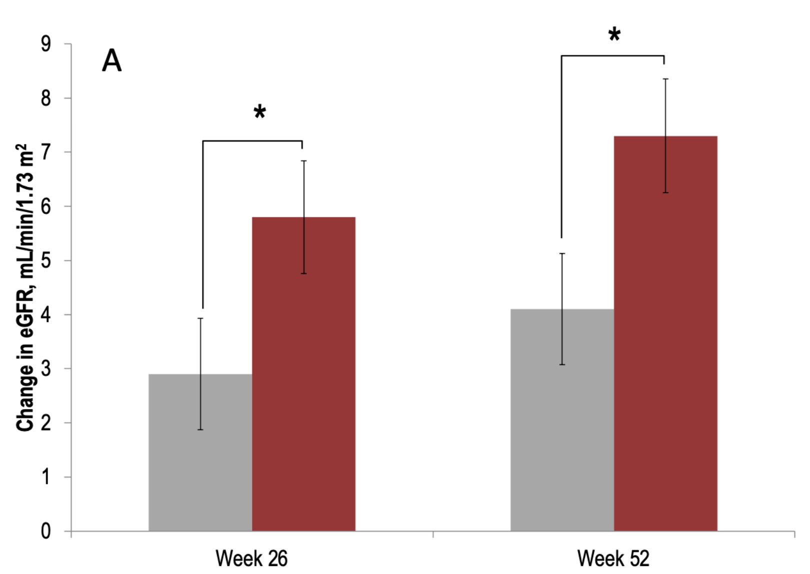
Practice Point 9.3.1.8: Recommendations for immunosuppressive dosing are given in Figure 10.

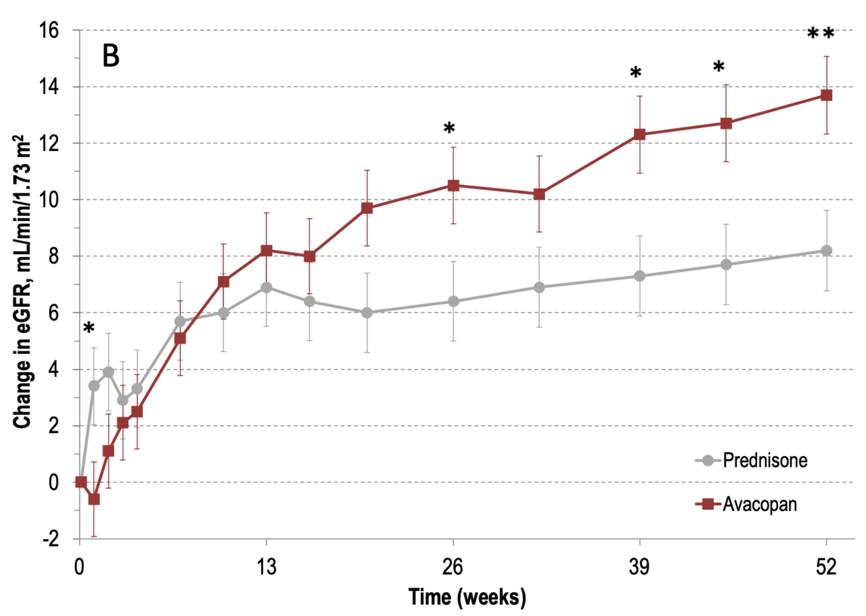
Oral cyclophosphamide	Intravenous cyclophosphamide	Rituximab	Rituximab and i.v. cyclophosphamide	MMF	Avacopan
2 mg/kg/d for 3 months, continue for ongoing activity to a maximum of 6 months	15 mg/kg at weeks 0, 2, 4, 7, 10, 13 (16, 19, 21, 24 if required)	375 mg/m²/week × 4 weeks OR 1 g at weeks 0 and 2	Rituximab 375 mg/m²/week × 4 weeks, with i.v. cyclophosphamide 15 mg/kg at weeks 0 and 2 OR Rituximab 1 g at 0 and 2 weeks with cyclophosphamide 500 mg/2 weeks × 6	2000 mg/d (divided doses), may be increased to 3000 mg/d for poor treatment response	30 mg twice daily as alternative to glucocorticoids, in combination with rituximab or cyclophosphamide induction
Reduction for age: • 60 yr, 1.5 mg/kg/d • 70 yr, 1.0 mg/kg/d Reduce by 0.5 mg/kg/day for GFR <30 ml/min/1.73 m²	Reduction for age: • 60 yr 12.5 mg/kg • 70 yr, 10 mg/kg Reduce by 2.5 mg/kg for GFR <30 ml/min/1.73 m²				

Figure 10. Immunosuppressive drug dosing for AAV. AAV, ANCA-associated vasculitis; GFR, glomerular filtration rate; i.v., intravenous; MMF, mycophenolate mofetil

Avacopan for the Treatment of ANCA-Associated Vasculitis

David R.W. Jayne, M.D., Peter A. Merkel, M.D., M.P.H., Thomas J. Schall, Ph.D., and Pirow Bekker, M.D, Ph.D.,
for the ADVOCATE Study Group*

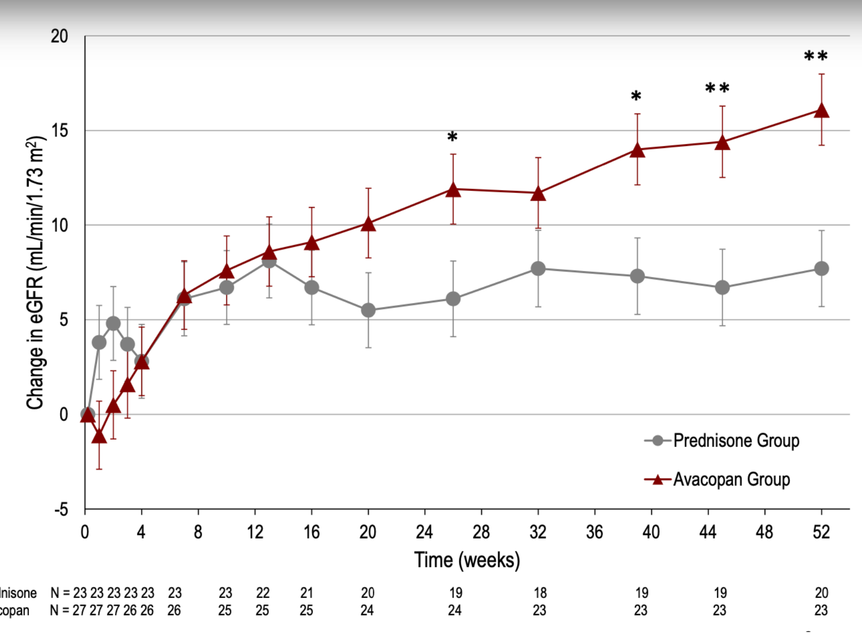




Jayne et al., N Engl J Med. 2021 Feb 18;384(7):599-609.

Renal Recovery for Patients with ANCA-Associated Vasculitis and Low eGFR in the ADVOCATE Trial of Avacopan

Frank B. Cortazar[1], John L. Niles[2], David R.W. Jayne[3], Peter A. Merkel[4], Annette Bruchfeld[5,6], Huibin Yue[6], Thomas J. Schall[6], Pirow Bekker[6] and on behalf of the ADVOCATE Study Group[7]

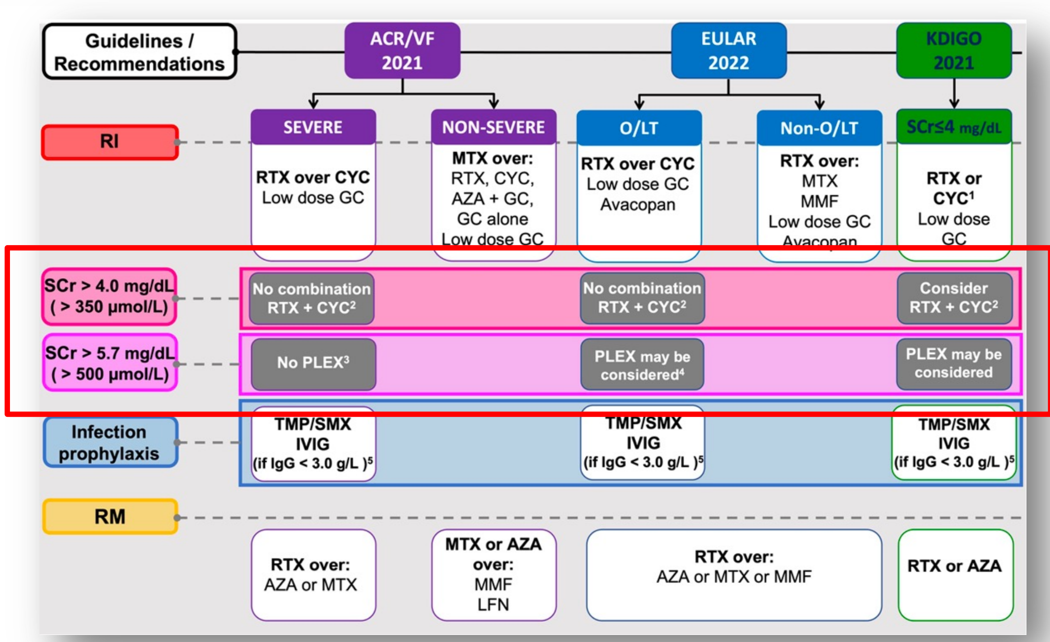


Patienten mit eGFR <15 ml/min pro 1.73 m^2 ausgeschlossen

n=50 Patienten mit einer eGFR <20 ml/min pro 1.73 m^2

Cortazar et al., Kidney Int Rep. 2023 Feb 3;8(4):860-870.

Management of anti-neutrophil cytoplasmic antibody associated vasculitis with glomerulonephritis as proposed by the ACR 2021, EULAR 2022 and KDIGO 2021 Guidelines/Recommendations



Moura et al., Nephrol Dial Transplant. 2023 May 10:gfad090.

Challenges of defining renal response in ANCA-associated vasculitis: call to action?

Balazs Odler[1,2], Annette Bruchfeld[3,4], Jennifer Scott[5], Duvuru Geetha[6], Mark A. Little[5], David R.W. Jayne[2] and Andreas Kronbichler[2]

- Keine standardisierte Definition des "*renal response*"
  - S-Crea, eGFR, 3 oder 12 Monate, ...
- Hämaturie, Proteinurie, BVAs: Limitationen (Korrelation mit Aktivität in der Niere?)
- ANCA (Korrelation mit Aktivität in der Niere?)
- Neue Biomarker: sCD163, MCP-1: Vielversprechend. Validierung? Therapieansprechen
- Nierenbiopsie: Serielle (Protokoll) biopsien?

Odler et al., Clinical Kidney Journal, 2023

AAV aus der Sicht des Nephrologen

Michael Rudnicki

Medizinische Universität Innsbruck
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Nephrologie und Hypertensiologie

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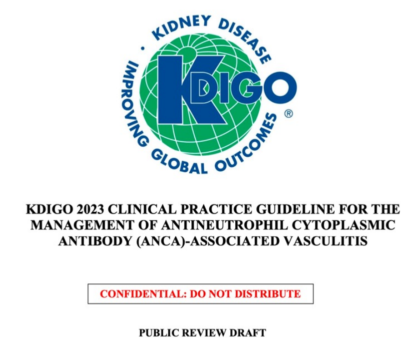
Challenges of defining renal response in ANCA-associated vasculitis: call to action?

Balazs Odler[1,2], Annette Bruchfeld[3,4], Jennifer Scott[5], Duvuru Geetha[6], Mark A. Little[5], David R.W. Jayne[2] and Andreas Kronbichler[2]

Table 2: Summary of different risk scores used to predict outcomes of patients with ANCA glomerulonephritis.

Risk groups	Score		
	Berden [73]	Brix[a] [74]	MCCS[b,c] [75]
	Focal (≥50% normal glomeruli) eGFR at presentation: 50 ± 29 ml/min/1.73 m^2 eGFR at 1 year: 61 ± 24 ml/min/1.73 m^2	Low risk (0), kidney survival at 3 years: 100%	Minimal (0–1) eGFR at baseline: 48.3 ml/min/1.73 m^2Renal recovery: 83.8%
	Crescentic (≥50% cellular crescents) eGFR at presentation: 18 ± 16 ml/min/1.73 m^2eGFR at 1 year: 37 ± 21 ml/min/1.73 m^2	Intermediate risk (2–7), kidney survival at 3 years: 96%	Mild (2–4) eGFR at baseline: 29.2 ml/min/1.73 m^2Renal recovery: 68.5%
	Mixed (<50% normal, cellular crescents, globally sclerotic, each) eGFR at presentation: 27 ± 19 ml/min/1.73 m^2eGFR at 1 year: 38 ± 21 ml/min/1.73 m^2	High risk (8–11), kidney survival at 3 years: 77%	Moderate (5–7) eGFR at baseline: 23.7 ml/min/1.73 m^2Renal recovery: 52.4%
	Sclerotic (≥50% globally sclerotic glomeruli) eGFR at presentation: 19 ± 12 ml/min/1.73 m^2eGFR at 1 year: 20 ± 16 ml/min/1.73 m^2		Severe (≥8) eGFR at baseline: 18.5 ml/min/1.73 m^2Renal recovery: 39.3%

Odler et al., Clinical Kidney Journal, 2023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PUBLIC REVIEW DRAFT

MAY 2023

≥ 50% globally sclerotic glomeruli → Yes → Sclerotic class

No ↓

≥ 50% normal glomeruli → Yes → Focal class

No ↓

≥ 50% cellular crescents → Yes → Crescentic class

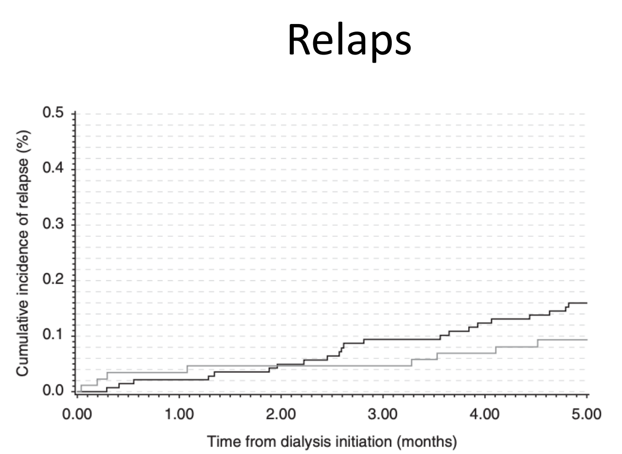
No → Mixed class

Disease Activity and Adverse Events in Patients with ANCA-Associated Vasculitides Undergoing Long-Term Dialysis

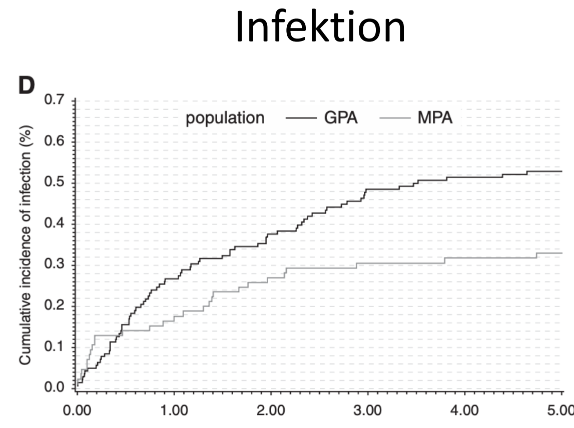
- n=229 Patienten (62% GPA, 38% MPA)
- Grund der Dialysepflichtigkeit:
  - Erstmanifestation der AAV 38%
  - Relaps der AAV 22%
  - Progression der CKD 40%

Disease Activity and Adverse Events in Patients with ANCA-Associated Vasculitides Undergoing Long-Term Dialysis

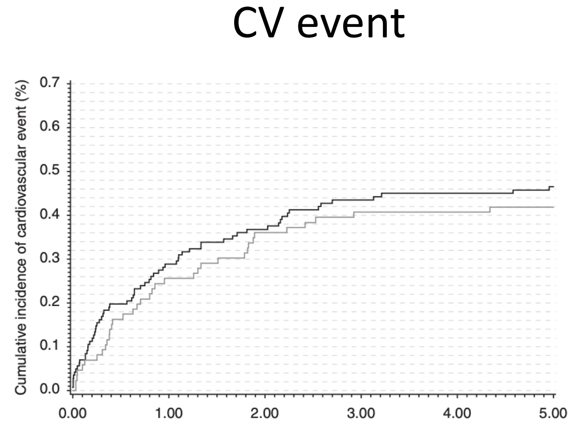
Relaps



Infektion



CV event



Kauffmann et al., Clin J Am Soc Nephrol. 2021 Nov;16(11):1665-1675.

Original Investigation | Rheumatology

Evaluation of Rituximab for Induction and Maintenance Therapy in Patients 75 Years and Older With Antineutrophil Cytoplasmic Antibody–Associated Vasculitis

Sara Thietart, MD; Alexandre Karras, MD, PhD; Jean-François Augusto, MD, PhD; Carole Philipponnet, MD; Pierre-Louis Carron, MD; Xavier Delbrel, MD; Rafik Mesbah, MD; Gilles Blaison, MD; Pierre Duffau, MD, PhD; Khalil El Karoui, MD; Perrine Smets, MD; Jonathan London, MD; Luc Mouthon, MD, PhD; Loïc Guillevin, MD; Benjamin Terrier, MD, PhD; Xavier Puéchal, MD, PhD; for the French Vasculitis Study Group

- Inzidenz einer schweren Infektion
  - RTX Induktion: 46.6/100 Patientenjahre (20% der Patienten)
  - RTX Erhaltung: 8.4/100 Patientenjahre (14% der Patienten)

Thietart et al., JAMA Netw Open. 2022 Jul 1;5(7):e2220925.

EPIDEMIOLOGICAL SCIENCE

Risk factors for serious infections in ANCA-associated vasculitis

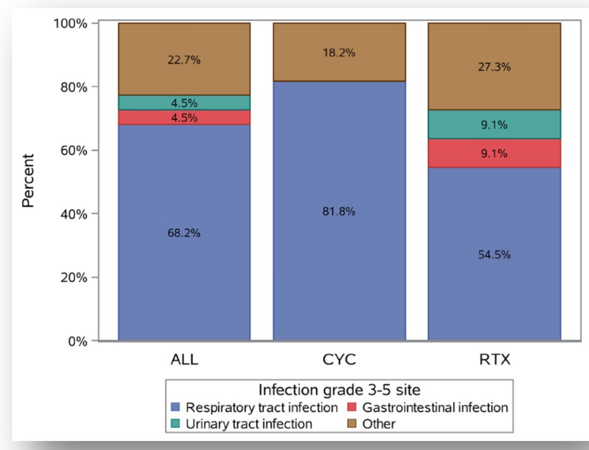
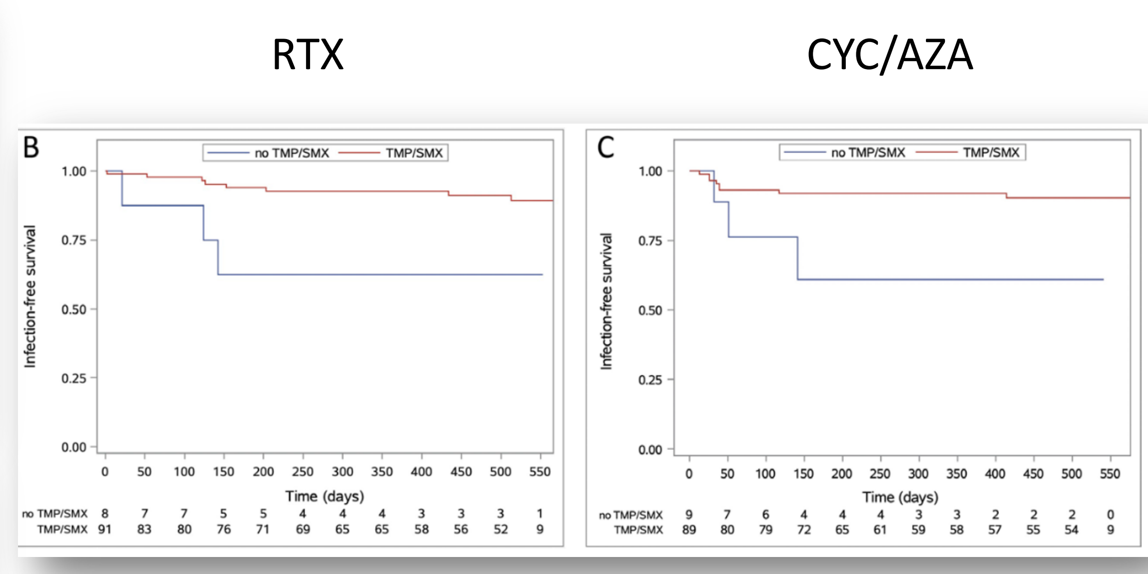


Table 2 Multivariable COX regression analysis of predictors of severe infections

Covariate	HR	95% CI	P value
Total CD19⁺ B cells	0.995	0.991 to 0.999	0.011
Serum IgM	1.005	1.002 to 1.009	0.006
Use of TMP/SMX	0.232	0.087 to 0.623	0.004

TMP/SMX, trimethoprim-sulfamethoxazole.



Odler et al., Ann Rheum Dis. 2023 May;82(5):681-687.

MR 2023

Zusammenfassung

- Renale Beteiligung bei AAV ist häufig, assoziiert mit erhöhter Mortalität und definiert die Induktions- und Erhaltungstherapie
- Pathologie: (crescentic) pauci-immune nekrotisierende Glomerulonephritis
- Induktionstherapie: RTX oder CYC nach den üblichen Richtlinien (bei RPGN: eher CYC als RTX)
- Avacopan bei eingeschränker Nierenfunktion (eGFR <30 ml/min pro $1.73 m^2$) dem Steroid überlegen
- PLEX überlegen bei RPGN und/oder S-Kreatinin 4-6 mg/dL (und/oder Hypoxämie bei pulmonalen Hämorrhagien oder bei Therapierefraktärität)
- Alter und Dialyse: Beachte Infektionsgefahr und Infektionsprophylaxe

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Die Fachpersonen können bei Vifor Pharma Switzerland AG eine vollständige Kopie des zitierten Prüfungsberichts anfordern.

Gekürzte Verschreibungsinformationen

Deutschland

▼ 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.

TAVNEOS®▼ 10 mg Hartkapseln: Wirkstoff: Avacopan. **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 Cyclophosphamid-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. **Nebenwirkungen:** Sehr häufig: Übelkeit, Kopfschmerzen, erniedrigte Leukozytenzahl, Infektion der oberen Atemwege, Diarrhö, Erbrechen, Nasopharyngitis, erhöhte Werte in Leberfunktionstests. Häufig: Pneumonie, Rhinitis, Harnwegsinfektion, Sinusitis, Bronchitis, Gastroenteritis, Infektion der unteren Atemwege, Zellulitis, Herpes zoster, Influenza, Orale Candidose, Oraler Herpes, Otitis media, Neutropenie, Schmerzen im Oberbauch, erhöhte Kreatinphosphokinase im Blut. Gelegentlich: Angioödem. **VERSCHREIBUNGSPFLICHTIG. Fachinformation beachten. Pharmazeutischer Unternehmer:** Vifor Fresenius Medical Care Renal Pharma France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, Frankreich. **Stand der Information:** Februar 2022

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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 indi- ziert 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: L04AJ05 Complement Inhibitors **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: Letzter Stand Fachinformation

Schweiz

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

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: September 2022. **Zulassungsinhaberin:** Vifor Fresenius Medical Care Renal Pharma Ltd., St. Gallen. **Vertrieb:** Vifor Pharma Switzerland AG, CH-1752 Villars-sur-Glâne | CH-AVA-2300011

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Die Fachpersonen können bei Vifor Pharma Switzerland AG eine vollständige Kopie des zitierten Prüfungsberichts anfordern.

Gekürzte Verschreibungsinformationen

Deutschland

▼ 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.

TAVNEOS®▼ 10 mg Hartkapseln: Wirkstoff: Avacopan. **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 Cyclophosphamid-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. **Nebenwirkungen:** Sehr häufig: Übelkeit, Kopfschmerzen, erniedrigte Leukozytenzahl, Infektion der oberen Atemwege, Diarrhö, Erbrechen, Nasopharyngitis, erhöhte Werte in Leberfunktionstests. Häufig: Pneumonie, Rhinitis, Harnwegsinfektion, Sinusitis, Bronchitis, Gastroenteritis, Infektion der unteren Atemwege, Zellulitis, Herpes zoster, Influenza, Orale Candidose, Oraler Herpes, Otitis media, Neutropenie, Schmerzen im Oberbauch, erhöhte Kreatinphosphokinase im Blut. Gelegentlich: Angioödem. **VERSCHREIBUNGSPFLICHTIG. Fachinformation beachten. Pharmazeutischer Unternehmer:** Vifor Fresenius Medical Care Renal Pharma France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, Frankreich. **Stand der Information:** Februar 2022

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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 indi- ziert 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: L04AJ05 Complement Inhibitors **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: Letzter Stand Fachinformation

Schweiz

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

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**:** September 2022. **Zulassungsinhaberin:** Vifor Fresenius Medical Care Renal Pharma Ltd., St. Gallen. **Vertrieb:** Vifor Pharma Switzerland AG, CH-1752 Villars-sur-Glâne | CH-AVA-2300011