


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

# Was können Vaskulitis register leisten? - CH Register - VASAS

PD Dr. Thomas Neumann  
 St. Gallen

AT-AVA-2300048  
DE-AVA-2300044





# Was können Vaskulitis-Register leisten?

## CH Register - VASAS

**PD Dr. med. Thomas Neumann**

Klinik für Rheumatologie und Immunologie

Kantonsspital St. Gallen



## Offenlegung

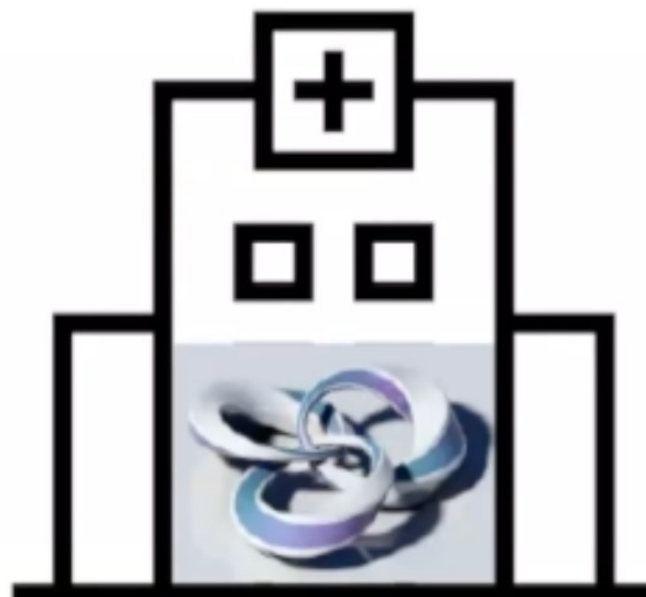
Vorträge/ Beratung: Roche Pharma (Switzerland) AG, GlaxoSmithKline AG, Celgene Switzerland,  
UCB-Pharma AG, AstraZeneca GmbH, Janssen-Cilag AG, Amgen S Switzerland AG, Vifor Pharma Switzerland,  
Boehringer Ingelheim (Switzerland), Novartis Pharma Schweiz AG

Reisekosten: Amgen Switzerland AG, UCB-Pharma AG, Roche Pharma (Switzerland) AG

Forschungsunterstützung: Vifor Pharma Switzerland, Pfizer Deutschland GmbH

# Register – Wissen als Behandlungsgrundlage

## Expertenzentren





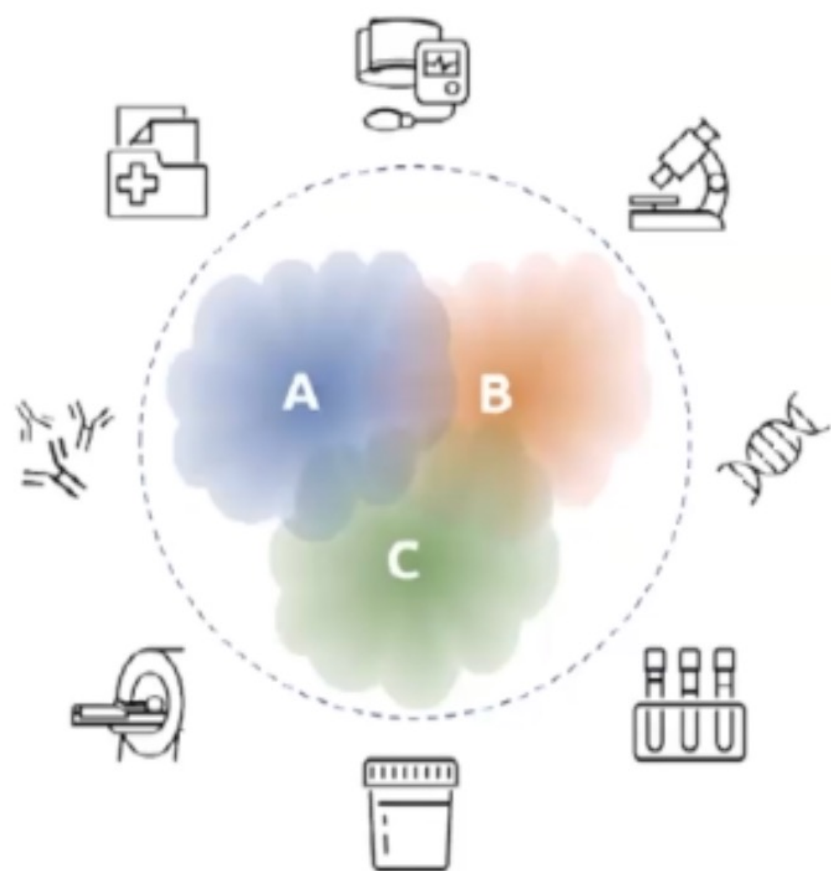
## Herausforderung „seltene Erkrankungen“



	Mitteleuropa	Inzidenzen/Jahr	Schweiz
Granulomatose mit Polyangiitis (GPA)	3,4-34/1.000.000		ca. 125
Mikroskopische Polyangiitis (MPA)	3,4-13/1.000.000		ca. 75
Eosinophile Granulomatose mit Polyangiitis (EGPA)	1,2/1.000.000		ca. 10



## Spezifische Ausprägungen und Verläufe

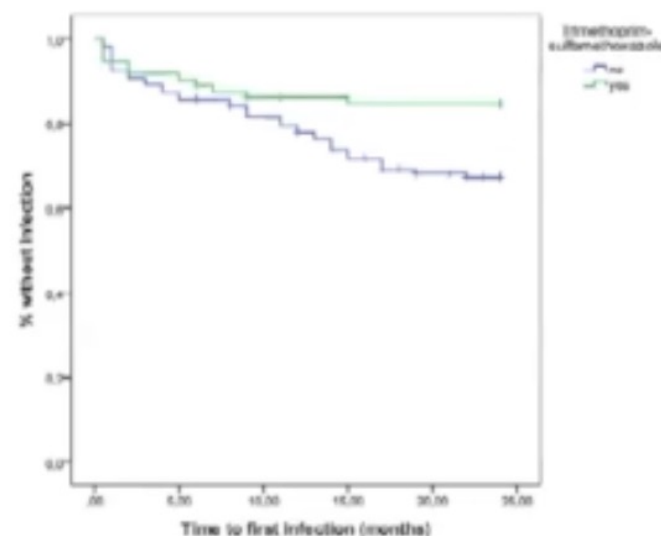
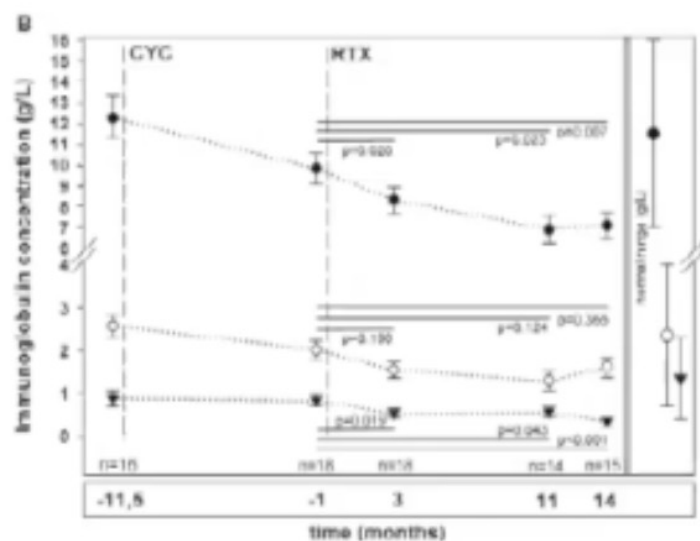
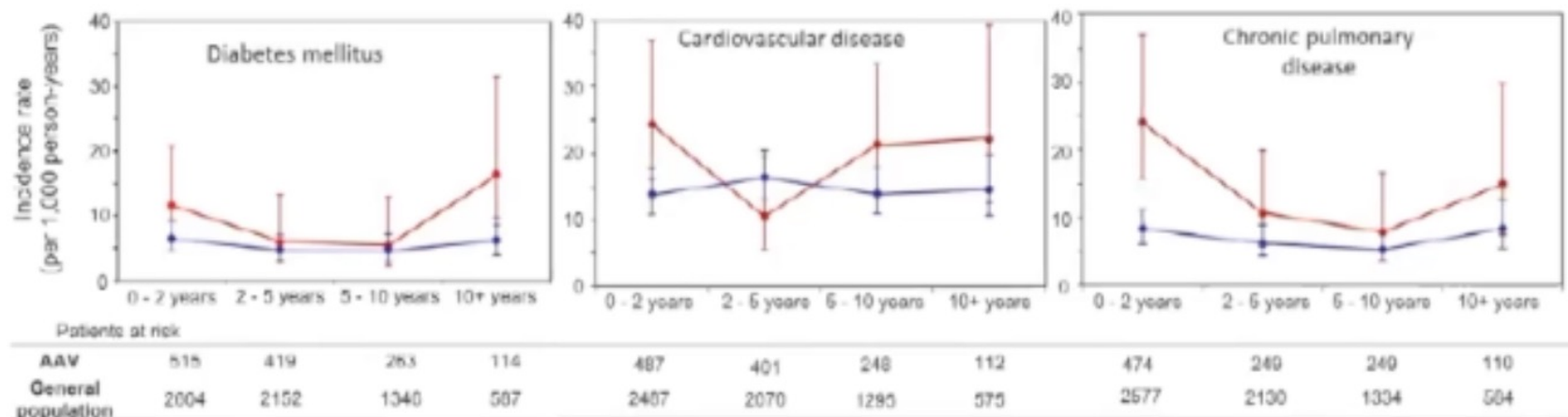


### Klinische Studien





# Longitudinale Beobachtung von Ereignissen





# Beobachtung neuer Therapien



## Postmarketing Daten

- Potentielle Nebenwirkungen und Interaktionen
- Effekte, die nach dem Endpunkt der klinischen Prüfung auftreten





# Aufbau, Durchführung, Auswertung

- Herausforderung: Vermeidung von Bias
- Balance zwischen dem Möglichen und dem Machbaren

## „Warum“ – Aufgabe und Ziel

- Verbesserung der Behandlung, Monitoring von Therapien, Kosteneffektivität, PROMs
- Feedback-loops

## „Wer“ – Beteiligte und Finanzierung

- Kliniker, Patienten, Wissenschaftler, staatliche Institutionen, Krankenversicherer, Industrie
- Potentielle Interessenskonflikte, Daten: Eigentum, Zugang, Austausch

## „Was“ – Typ und Inhalt

- Krankheitsbasiert: Charakteristika, Verläufe, (nicht)-Therapie, PROMs, Qualitätsindikatoren, Proben
- Abwägung: Zuverlässigkeit, Gültigkeit, Spezifität der Daten versus Durchführbarkeit

## „Wie“ – Identifizierung und Patienteneinschluss, Datenmanagement, Pharmakovigilanz

- Potentieller „selection bias“, CRF Praktikabilität, Monitoring, Privatsphäre der Patienten
- Sicherheitsmeldungen: EMA „noninterventional postauthorization studies with primary data collection“
- Datenauswertung und Publikation



# ANCA-Vaskulitis Register in Europa

Variables	France	UK and Ireland	Poland	Czech Republic	Germany/Austria/ Swiss	Ireland	Sweden	Portugal	The Netherlands
Name of registry	FVSG Registry	UKIVAS	POLVAS	Czech Registry of AAV	GEVAS	RKD registry	Skåne registry	Reuma.pt/ vasculitis	ARCH AAV
FAIRVASC registry	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No	No
Start date	1981	2010	2015	2009	2019	2012	1997	2014	2018
Type of vasculitis	All	All	All	AAV	All	All	AAV	All	AAV
Patients (n)	4350	7500	1262	1050	260	839	325	1123	230
Centers (n)	101	51	13	16	15	7	2	15	15
Medical specialties	Various	Various	Various	Various	Various	Various	Various	Mainly rheum	Various
Biosampling	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No

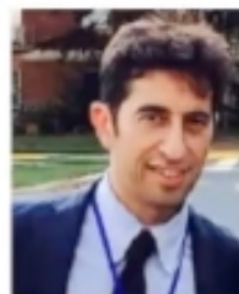
# ANCA-Vaskulitis Register in Europa



*FAIRVASC – building registry interoperability to inform clinical care*



Mark Little (Dublin)



Augusto Vaglio (Florence)



The European Reference Network that aims at improving the care of patients with Rare Immunological Disorders



European Union's Horizon 2020 research and innovation programme



# Swiss AAV (GPA, MPA, EGPA) Registry



## Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

### Legend for status icons:

- Incomplete
- Unverified
- Complete
- Many statuses (mixed)
- Incomplete (no data saved)
- Partial Survey Response
- Completed Survey Response
- Many statuses (all saved)

Dashboard displayed: (Default dashboard) [Create custom dashboard](#)

Displaying Data Access Group: ... ALL ...

Displaying record: Page 1 of 1: "1" through "1 E.1" of 4 records ALL (0) records per page

[+ Add new record](#)

Displaying: [Instrument status only](#) | [Link status only](#) | [All status types](#)

Record ID	Demographics (Status)	General (Status)	Clinical History (Status)	Annual Or Encounter (Status)	Disease Activity (Status)	BVA2 (Status)	Y2I (Status)	AAV-P20 (Status)	CSAQ (Status)	QvL (Status)	Biopsy (Status)	Imaging (Status)	Congestive (Status)	Dialysis (Status)	Dissemin (Status)	Death (Status)
1 (Male, 100)	<span style="color: green;">●</span>	<span style="color: green;">●</span>	<span style="color: green;">●</span>	<span style="color: green;">●</span>	<span style="color: green;">●</span>	<span style="color: green;">●</span>	<span style="color: gray;">○</span>	<span style="color: red;">●</span>	<span style="color: gray;">○</span>	<span style="color: red;">●</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>
2 (M, 16)	<span style="color: green;">●</span>	<span style="color: green;">●</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>
14-1	<span style="color: green;">●</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>
15-1	<span style="color: green;">●</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>	<span style="color: gray;">○</span>

**Demographics (CRF)**

SEARCH BY ID:  [Go](#)

SEARCH BY INSTRUMENT:  [Go](#)

**Record ID**:

**Record's First Name**:

**Record's Last Name**:

**First Name**:

**Record's Date of Birth**:

**Age (years)**:

**Date of event**:

**Record's Full Address**:

**Record's Phone Number**:

**Gender**:

**Record's Date of Visit**:

**Activity**:

**Residence Status**:

**Location**:

**Event of Birth**:

**Date of entry in the study**:

**Appropriate regions**:

**Study Center**:

**Visit Status**:

**Event ID**:

Please confirm if you wish to allow the user with this account to interact with this instrument.





# Register – Design

Longitudinales Design

Querschnitts Design

	Visiten	Baseline (max. 6 Monate vor Studieneinschluss)	Follow-up (Induktion: 3 Monate, Remission: 1 Jahr)	Rezidiv	Abschluss Studienende /Tod
CRF					
Einschluss					
Baseline Eingabe					
Anamnese					
Klinische Parameter					
Laborparameter					
Bildgebung					
Histologie					
Lebensqualität (PROM)					
Komorbiditäten (Infektionen, weitere)					
Fataler Outcome Report					
Biosamples					
obligatorisch	optional				



# Register – Infrastruktur



CTU Basel

Datenmonitoring ?



zukünftige Erweiterungen





Kantonsspital  
St.Gallen



Peter Villiger  
Andrea Gloor  
Christoph Berger  
Christof Iking-Konert  
Laura Moi  
Thomas Hauser  
Sophie De Seigneux  
Lisa Christ  
Iliana Mebert

Marielle Rutquist (CTU Basel)



**VASAS**  
VASCULITIS  
Association  
Switzerland



European EGPA Study Group

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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, Orale 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

## Österreich

▼ 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® 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 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. 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](http://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](http://www.swissmedicinfo.ch). Stand der Information: September 2022. **Zulassungsinhaber:** Vifor Fresenius Medical Care Renal Pharma Ltd., St. Gallen. **Vertrieb:** Vifor Pharma Switzerland AG, CH-1752 Villars-sur-Glâne | CH-AVA-2300011