

New safety checklist aims to prevent side effects in patients with arthritis

August 5 2024, by Line Rønn

5	age of the same of	Year of approval					Infections and	infestations				Neoplasms benign, malignant and	(incl cysts and	Nervous system disorders			Injury, poisoning and procedural complications		Cardiac disorders			Respiratory, thoracic and	mediastinal	Vascular disorders		Hepatobiliary				Gastrointestinal		Renal and urinary disorders	Blood and	lymphatic system disorders		nutrition disorders		Immune system disorders		Psychiatric	Skin and subcutaneous	Age vs event	Drug interactions	Investigations	Musculoskeletal	and connective tissue disorders
Mode of actic	Biotopic origina			EMA: active infections FDA: risk of infections, discontinue if develops	Tuberculosis	Herpes zoster		нерекия в	Hepatitis C	Progressive multifocal leukoencephalopathy (PHL)	Opportunistic		Demyelinating	disease	Seizure	Severe uncontrolled cardiac disease, arrythmias.	AMI	Cerebrovascular events	Major adverse cardiac events and all cause mortality	Heart failure	Cardiovascular risk	D. asthma		Thrombosis	Alcoholic hepatitis	Hepatotoxicity, transaminase	elevations		Crohns disease/UC	Obstruction, perforation often with diverticulitis	Underweight and diarrhoes nauses, vomiting	Impairment	Cytopenias	Caution when low ANC, ALC, PC, HB	Hypoglycemia	Elevated lipids	Lupus-like syndrom, autoantibodies	Autoimmune hepatitis	severely	Suicidal ideation and behaviour		General caution when	<u> </u>	Laboratory test		Bone fractures
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anti-CD20	Rituximab (MabThera/Rituxan)	1998	1997				I											П			П		П					\perp	П											П				П	\perp	
	Adalimumab (Humira)	2003	2002			Н	4	Ц	+	Ш		ш			_	Ш	\perp	Ш			Ш	+	Н	Ш		Ш	\perp	_	Н		Ш	1	4	Н.	1	1	ш		11	11	Н	ш		4	4	
1200	Infliximab (Remicade) Gollmumab	1999	1998	#		Н	-	Н	+	Ш	ш	ш		Н	_	Н	+	Н	\perp		Н	+	Н	Н		Н	ш	_	Н	_	Н-	Н-	ш	Н-	1	-	Н	-	++	1	+	ш	-	+	+	\perp
TNFI	(Simponi) Certolizumab pegol	2009	2009	-		Н	+	Н	+	\vdash	Н	Н	-	Н	+	H	+	Н	+		Н	_	\Box	+			Н		+	-	\vdash	-		\vdash	-	-		-	+	+	+	+	-	+	_	-
	(Cimzia) Etanercept (Enbrei)	2009	1998	1		\vdash	+	Н	+	H		Н	Н	Н	+	\vdash	+	H	+		Н	-		Н	+	H	+	+	+	+	\vdash	-	Н	-	-	-	Н		++	++	++	+	++	++	+	+
100	Anakinra (Kineret)	2002	2001	200			+	Н	_	\vdash		Н					+	+		Н	H			Н	_		+	+	+	+	H						H	H	++	++			++	+	+	-
IL-11	Canakinumab (Ilaris)	2009	2009		т	H	۰	Н	+		H	Ħ	+		+	H	+	H		\vdash	H			Н			Н	+	$^{++}$		\vdash		Н			+	+	Н	++	++	Н	Н	++	+	+	+
CTLA4-Ig	Abatacept (Orencia)	2007	2005			Н		Н			п	Н		Н	$^{+}$	Н	$^{+}$	Н		\vdash	Н	+		Н			$^{+}$	$^{+}$	Ħ		\vdash	\vdash			$^{+}$			11	$^{+}$	+	П		+	\mathbf{T}		\vdash
IL-12/23i	Ustekinumab (Stelara) FOCIIIZUMAD	2009	2009			П	Т	П				П	т		\top	П	\top						П	П		П	\Box	1	П															\top		
IL-6Ri	(Roactemra/Actemr	2009	2010																																									П		
10-010	Sarilumab (Kevzara)	2017	2017	1											\perp		\perp																					Ш		П	П			П	\perp	
	Tofacitinib (Xeljanz)	2017	2012					Ц	4			ш			\perp	Ш	\perp						Ц			ш		_	Ш					ш						Ш	ш		ш	4		
JAKI	Baricitinib (Olumiant)	2017	2018				1		1						_		1				П					Ц	\perp											1	Н	Н	н	П		4		
	Filgotinib (Jyseleca only EMA approved) Upadacitinib	2020				Н			+			Н			-		+				Н					Ш												ш	H	H	H	Н		Н	+	
	(Rinvoq)	2019	2019			Н		Н	+	-		Н	-	Н	+	Н	+	H		\vdash	Н	-	H		-	Н		-	+	_	Н	-		-	-	-	++	++	++	++	++	+	-	4	+	-
POE4I	Apremilast (Otezia) Secukinumab	2015	2014			H	+	Н	+	\vdash	₩	+	+	Н	+	H	+	H	+	\vdash	Н	+	H	Н	+	H	+++	-	H	-	H		-	-	-	-	++	++	++	-	-	++	-	₩	+	+
	(Cosentyx) Ixekizumab (Taltz)	2015	2015		Н		+	Н	+	\vdash	+	+	+	\forall	+	\vdash	+	+	+	\vdash	\vdash	+	\vdash	+	-		+				+		+	+	+		+	++	++	+	+	+	++	+	+	+
	Bimekizumab	2022	2016	•						100	+	$^{+}$									Н	-0		Н			Н		100			100					Н	Н	Н	Н	Н	Н		Н		
	Guselkumab	2017	2017			Н		П			H	H	_		T	Н	_		т		Н			П		М	71				Н			ш	т	ш	Н	ш	Ħ	т	т	Н	11	Ħ	1	F
IL-23i	(Tremfya) Risankizumab (Skyrizi)	2019	2019			H	†	\Box	\top		Ħ	\Box	†				†	\Box			Н	\top	\Box	\forall			\top		+		\vdash			\Box			†			+		+		+	1	

Overview of contraindications and warnings from EMA SmPC and FDA PI for biologic and targeted synthetic disease modifying antirheumatic drugs based on MedDRA system organ class (SOC) and Term Selection Points and year of first approval by EMA and FDA. Credit: *Drug Safety* (2024). DOI: 10.1007/s40264-024-01461-1

Inappropriate prescription of an antirheumatic drug for an unsuitable patient can lead to severe side effects such as intestinal perforations, blood clots, heart failure, or liver damage.

To address this issue, researchers from the Department of Biomedicine



at Aarhus University and the Rheumatology Department at the University Clinic for Innovative Patient Pathways in Silkeborg have developed a comprehensive safety <u>checklist</u> for the newer medications used in treating rheumatic diseases.

"With the increasing number of medications on the market, it becomes more challenging for health care professionals to make prescriptions without risking serious side effects," explains Associate Professor Tue Wenzel Kragstrup, one of the researchers behind the study and article recently <u>published</u> in the journal *Drug Safety*.

The article presents the checklist designed to help prevent patients from receiving medications they cannot tolerate.

"With over 20 antirheumatic drugs, each with up to 10 specific contraindications or precautions, there is an urgent need for advanced support tools to assist doctors and pharmacists in navigating the medical landscape," adds Tue Kragstrup.

The checklist enables doctors to quickly determine if a patient has comorbidities that limit the use of certain medications.

The principles can be applied across other disease areas

This checklist is the first of its kind, created by analyzing all available patient information leaflets and international treatment guidelines in Europe and the U.S. It is based on data from both the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) in the U.S..

Primarily intended for doctors prescribing medications to patients with



rheumatic diseases, the study is also relevant to other doctors and patients as it highlights the risks associated with <u>medical treatments</u> and the need for tools to improve prescription safety in general. Dr. Lykke Skaarup, one of the researchers behind the data extraction in the study, explains.

"The principles behind the checklist can be applied across other disease areas because we have documented a method to systematically identify contraindications and precautions for a group of medications," she says.

For example, similar checklists could be created for antihypertensive drugs, migraine medications, or cholesterol-lowering drugs using the same approach.

The study has made a wide range of medication information clear, accessible, and user-friendly, enabling doctors to make more informed decisions. Consequently, they can reduce the risk of side effects and enhance patient safety for those treated for inflammatory rheumatic diseases, both now and in the future.

Tue Wenzel Kragstrup notes that the results align with previous studies highlighting the need for better medication safety.

"We hope our work can contribute to safer and more effective treatment of <u>rheumatic diseases</u>," he says.

The checklist will, of course, need to be continuously updated with new research and the latest reported side effects. The researchers are already working on implementing AI-driven support tools to handle much of this task.

More information: Lykke Skaarup et al, A Systematic Overview of Contraindications and Special Warnings for Biologic and Targeted



Synthetic Disease Modifying Antirheumatic Drugs: Establishing a Framework to Create a "Safety Checklist", *Drug Safety* (2024). DOI: 10.1007/s40264-024-01461-1

Provided by Aarhus University

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