

Under the auspices of Slovak Medical Association
Organizer
Slovak Rheumatology Society

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Slovak Medical Association



BRATISLAVA

CECR

Central European Congress
of Rheumatology

1 – 3 December 2022
DoubleTree by Hilton Hotel
Bratislava, SLOVAKIA

eular

EUROPEAN ALLIANCE
OF ASSOCIATIONS
FOR RHEUMATOLOGY

EULAR endorsed course



Congress Venue

1 – 3 December 2022, DoubleTree by Hilton Hotel, Bratislava, Slovak Republic

Congress Scientific Committee

Branimir Anic (HRV)

Peter Balint (HUN)

Želmíra Macejová (SVK)

Žiga Rotar (SVN)

Judith Sautner (AUT)

Włodzimierz Samborski (POL)

Ladislav Šenolt (CZE)

President of the Congress

Želmíra Macejová

Congress Organising Committee

Chairman of the Organising Committee: Zdenko Killinger

Members of the Organising Committee: Emöke Šteňová

Martin Žlnay

Alena Tuchyňová

Congress Secretariat

Viera Džurná

Národný ústav reumatických chorôb (National Institute of Rheumatic Diseases)

Nábřežie I. Krasku 4

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Organising Secretariat

Progress CA s.r.o.

Krivá 18, 040 01 Košice, Slovak Republic

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Expert Programme Topics

- early rheumatoid arthritis
- gout
- imaging methods in rheumatology
- geronto-rheumatology
- medical research and rheumatology
- psoriatic arthritis
- vasculitis
- young rheumatologists section
- poster session

Expert Programme Information

1 December 2022 from 14:00

2 December 2022 from 9:00 to 17:00

3 December 2022 from 9.00 to 13:00

Congress Language

English (without simultaneous interpreting)

Congress Fee

	by 15 November 2022	after 15 November and on the spot
CECR Member	<input type="checkbox"/> 350,- EUR	<input type="checkbox"/> 400,- EUR
One-day registration fee	<input type="checkbox"/> 200,- EUR	<input type="checkbox"/> 250,- EUR
Student/doctoral candidate	<input type="checkbox"/> 100,- EUR	<input type="checkbox"/> 150,- EUR

Congress Fee Payment Method

Once you have registered to attend online via the **www.cecr2022.sk** website, you will be emailed an invoice in advance, against which please pay the required items. The congress fee together with other payments must be paid in full before the start of the congress by bank transfer, using the invoice number as the variable symbol.

Registration, signing up for active or passive participation

Online at: **www.cecr2022.sk** , **www.progress.eu.sk**

Post-Congress Activities

What	When	Where
Discussion Forum	1 December 2022 at 19:00	DoubleTree by Hilton Hotel
Dinner	2 December 2022 at 19:00	Radisson Blu Carlton Hotel

Entrance Fee of € 50 /person



Accommodation Assistance by Progress CA, s.r.o.

Online at www.cecr2022.sk

DoubleTree by Hilton ****

Trnavská cesta 27/A
831 11 Bratislava, Slovak Republic
www.doubletree3.hilton.com

Lindner Hotel Gallery Central****

Metodova 4
821 08 Bratislava, Slovak Republic
<https://www.lindner.de/sk/bratislava-hotel-gallery-central/vitajte.html>

City Hotel Bratislava ****

Seberíniho 9
821 03 Bratislava, Slovak Republic
www.hotelbratislava.sk

Hotel Set ***

Kalinčiakova 12085/29A
831 04 Bratislava, Slovak Republic
www.hotelset.sk

	<input type="checkbox"/> Single room	<input type="checkbox"/> Double room
<input type="checkbox"/> Hotel DoubleTree by Hilton ****	from 109,- EUR	from 127,- EUR
<input type="checkbox"/> Hotel Lindner ****	from 109,- EUR	from 127,- EUR
<input type="checkbox"/> City Hotel Bratislava ****	from 87,- EUR	from 103,- EUR
<input type="checkbox"/> Hotel Set ***	from 72,- EUR	from 85,- EUR

The prices are per room per night, including VAT and are for information only.

The exact room rate will be confirmed upon booking, depending on room type and occupancy. Each participant is obliged to book his/her accommodation in the selected hotel online at Progress CA s.r.o. by **15 August 2022** at the latest.

The number of places in individual hotels is limited, we recommend early booking of accommodation. After the deadline of **15 August 2022**, it will not be possible to guarantee free rooms.

Once you have registered to participate online via the website www.cecr2022.sk, an advance invoice will be emailed to you, upon which please pay the required items.

Group bookings cannot be made online as different conditions apply. If you need to register a group, please contact the Organising Secretariat at gabriela.sujanova@progress.eu.sk.



Credits

The event is included in the ARS CME Continuing Medical Education. Registered participants will receive confirmation of attendance on the last day of the congress.

Orientation map



More informations

www.cecr2022.sk

www.progress.eu.sk



Programme

Thursday, 1st December 2022

11:00-19:00 **Registration**

12:00-14:00 **Pre-Congress refreshments**

14:00-14:20 **OPENING CEREMONY**

Moderator: Martin Žlnay (SK), *Scientific Secretary of the Congress*

Guests: Želmíra Macejová (SK), *President of the Congress*

Annamaria Iagnocco (IT), *EULAR President*

Daniel Aletaha (AT), *EULAR President-Elect*

Zoltán Szekanecz (HU), *EULAR Scientific Societies Vice President
Presidents of the Scientific Rheumatology Societies*

Welcome address

CECR Awards Ceremony

14:20-15:00 **INVITED PLENARY LECTURES**

THE FUTURE OF RHEUMATOLOGY AND WHAT EULAR CAN DO FOR US? (15 min.)

Daniel Aletaha, *Austria*

THE NATIONAL RHEUMATOLOGY SOCIETIES AND EULAR (20 min.)

Zoltán Szekanecz, *Hungary*

15:00-16:30 **IMAGING**

Host country Hungary

Moderators: Péter Bálint, Zoltán Szekanecz

ULTRASONOGRAPHY IN SPA (12')

Péter Bálint, *Hungary*

IMAGING OF MICROCIRCULATION (12')

Gábor Kumánovics, *Hungary*

LUNG INVOLVEMENT (12')

Gabriella Szűcs, *Hungary*

FUSION TECHNIQUES (12')

László Kovács, *Hungary*

ULTRASONOGRAPHY IN RA (12')

Dóra Niedermayer, *Hungary*

PET-CT IN RHEUMATOLOGY (12')

Emőke Šteňová, *Slovakia*



MRI IN SPA (12')

Martin Žlnay, Slovakia

Discussion (5')

16:30-16:50 Break

16:50-17:50 GERONTO-RHEUMATOLOGY (RHEUMATOLOGIC PROBLEMS IN ELDERLY POPULATION)

Host country Croatia

Moderators: Simeon Grazio, Branimir Anić

PHARMACOTHERAPY OF INFLAMMATORY RHEUMATIC DISEASES IN THE ELDERLY (20')

Mislav Radić, Croatia

SARCOPENIA IN PATIENTS WITH RHEUMATOID ARTHRITIS (20')

Nadica Laktašić Žerjavić, Croatia

PARANEOPLASTIC SYNDROMES IN RHEUMATOLOGY (20')

Jasminka Milas-Ahić, Željka Kardum, Croatia

18:00-19:00 INDUSTRY SPONSORED SYMPOSIUM

The FILgood way of growth: Focusing on patients experience during Jyseleca treatment

Symposium sponsored by Swedish Orphan Biovitrium (60 min.)

Moderator: Zoltán Szekaneecz, (HU)

1. Piotr Trzonkowski (PL): At the Root of Rheumatoid Arthritis

2. Želmíra Macejová (SK): The Trunk of Rheumatoid Arthritis

3. Ladislav Šenolt (CZ): Leaves of Treatment

Discussion

20:00-22:30 Welcome reception in Hotel DoubleTree by Hilton



Friday, 2nd December 2022

08:00-18:00 Registration

08:30-09:50 PSORIATIC ARTHRITIS

Host country Poland

Moderators: Włodzimierz Samborski, Eugeniusz Kucharz

PSORIATIC ARTHRITIS: INFLAMMATION, IMMUNITY AND INTERNAL ORGAN INVOLVEMENT (20')

Eugeniusz Kucharz, Poland

ULTRASOUND ASSESSMENT OF CHANGES IN NAIL APPARATUS IN PSORIASIS AND PSORIATIC ARTHRITIS (20')

Magdalena Krajewska-Włodarczyk, Poland

BONE REMODELING IN PSORIATIC ARTHRITIS (20')

Mariusz Korkosz, Poland

DEPRESSIVE DISORDERS IN PSORIATIC ARTHRITIS (20')

Dorota Sikorska, Poland

09:50-10:10 Break

10:10-11:10 INDUSTRY SPONSORED SYMPOSIUM

Opportunity to Maximize Standard of Care in Rheumatology

Symposium sponsored by AbbVie (60 min.)

Chairs: Želmíra Macejová (SK), Branimir Anić (HR)

1. Daniel Aletaha (AT): Treating rheumatic diseases to target – story of success
2. Karel Pavelka (CZ): Improving patient outcomes in RA – a subgroup analysis of SELECT – COMPARE study in Central and Eastern European patients
3. Želmíra Macejová (SK): Evidence supporting JAK inhibitors in SpA – focus on upadacitinib
4. Zoltán Szekanez (HU): Safety of JAK inhibitors – long-term data and integrated analyses
5. Closing remarks by Branimir Anić (HR)

11:10-11:30 Break



11:30-12:30 HEALTH CARE RESEARCH - INITIATIVES AND CONCEPTS FOR FUTURE IMPROVEMENTS

Host country Austria

Moderators: Daniel Aletaha, Judith Sautner

HOW MANY RHEUMATOLOGISTS DO WE NEED IN AUSTRIA? DEMANDS AND REAL LIFE (20')

Rudolf Puchner, Austria

HOW TO REACH EXCELLENCE - CONCEPTS FOR INNOVATIVE TEACHING PRACTICE (20')

Christian Dejaco, Austria

IMPACT OF A LITTLE DIFFERENCE - GENDER GAP, LEAKY PIPELINE, FAIR, FEMALE MENTORING ETC. IN RHEUMATOLOGY (20')

Christina Duftner, Judith Sautner, Austria

12:30-14:00 Lunch

The joint lunch of the Scientific Societies Presidents

13:00-14:00 Poster viewing

14:00-14:30 INDUSTRY SPONSORED SYMPOSIUM

How can RWE facilitate our treatment decisions?

Symposium sponsored by Eli Lilly Slovakia s.r.o. (30 min.)

Chair: Martin Žlnay (SK)

1. Želmíra Macejová (SK): Can we achieve optimal RA treatment results with JAKs in real world practice?

2. Karel Pavelka (CZ): IL-17 inhibitors in the treatment of psoriatic arthritis – RWE data from the Czech registry

14:30-15:40 VASCULITIS

Host country Slovenia

Moderators: Žiga Rotar, Alojzija Hočevar

COVID-19 IN PATIENTS WITH ANCA ASSOCIATED VASCULITIS (20')

Alojzija Hočevar, Slovenia

INTERFERON SIGNATURE OBSERVED IN ADULT IGA VASCULITIS (20')

Matija Bajželj, Slovenia

LEFLUNOMIDE IN A GCA THERAPEUTIC SCHEME - OUR EXPERIENCE (20')

Alojzija Hočevar, Slovenia



SUBGLOTTIC STENOSIS IN GRANULOMATOSIS WITH POLYANGIITIS (10')
Jan Tomš, Petr Bradna, Tomáš Soukup, Czech Republic

15:40-16:00 Break

16:00-16:40 INDUSTRY SPONSORED SYMPOSIUM

Taming the enthesiTiger

Symposium sponsored by UCB (40 min.)

Chair: Želmíra Macejová (SK)

1. Intro by Chair
2. Márton Pálkás (HU): Enthesitis in rheumatic diseases, with a case report and differential diagnosis
3. Kristína Bubová (CZ): Ultrasound as an underappreciated tool in the diagnosis of rheumatic diseases
4. Martin Žlnay (SK): Enthesitis treatment options – how far have we walked so far?
5. Closing remarks by Chair

16:50-17:50 INDUSTRY SPONSORED SYMPOSIUM

Role of IL-23 inhibition in psoriatic disease

Symposium sponsored by Janssen (60 min.)

Chair: Zoltán Szekanecz (HU)

1. Zoltán Szekanecz (HU): Perspective from a Rheumatologist
2. Martina Part (SK): Perspective from a Dermatologist

19:30-22:30 Gala Dinner in Radisson Blue Carlton Hotel, Bratislava



Saturday, 3rd December 2022

08:00-12:00 Registration

08:30-10:00 GOUT

Host country Czech Republic

Moderators: Ladislav Šenolt, Karel Pavelka

THE ROLE OF IMAGING TECHNIQUES IN THE MANAGEMENT OF GOUT (20')

Petra Hánová, Jindřiška Gaterová, Czech Republic

COMORBIDITIES IN GOUT AND HYPERURICEMIA (20')

Lenka Hasiková, Czech Republic

GOUT THERAPY (20')

Karel Pavelka, Czech Republic

GENETICS OF HYPERURICEMIA AND GOUT (15')

Blanka Stiburková, Czech Republic

APPROACH TO A PATIENT WITH REFRACTORY GOUT (15')

Jakub Závada, Slovakia

10:00-10:20 Break

10:20-11:00 INDUSTRY SPONSORED SYMPOSIUM

Secukinumab (anti-IL-17A) as Masterpiece in Rational Management of SpA

Symposium sponsored by Novartis (40 min.)

Chair: Želmíra Macejová (SK)

1. Michaela Záríková (SK): The rational treatment decision in axSpA patients with persistently high disease activity

2. Vanda Mlynáriková (SK): AS domains throughout the time with secukinumab

11:00-12:30 EARLY RHEUMATOID ARTHRITIS

Host country Slovakia

Moderators: Želmíra Macejová, Zdenko Killinger

NEUTROPHILS IN RHEUMATOID ARTHRITIS – NOT SO NEUTRAL IN THE END (20')

Peter Celec, Slovakia

EARLY RHEUMATOID ARTHRITIS - ARE WE THE PILOTS? (20')

Emöke Šteňová, Slovakia



IMAGING IN ERA (20')

Martin Žlnay, *Slovakia*

A NEW PRO-INFLAMMATORY CYTOKINE IL-40 IS PRODUCED BY ACTIVATED NEUTROPHILS AND PLAYS A ROLE IN THE EARLY STAGES OF THE DEVELOPMENT OF RHEUMATOID ARTHRITIS (10')

Adéla Navrátilová, Viktor Bečvář, Hana Hulejová, Michal Tomčík, Heřman Mann, Olga Růžičková, Olga Šlégllová, Jakub Závada, Karel Pavelka, Jiří Vencovský, Ladislav Šenolt, Lucie Andrés Cerezo, *Czech Republic*

SCREENING OF SYMPTOMS IN THE AT-RISK OF RHEUMATOID ARTHRITIS CZECH COHORT USING SYMPTOMS IN PERSONS AT RISK OF RHEUMATOID ARTHRITIS (SPARRA) QUESTIONNAIRE (10')

Mária Filková, Nora Petrovská, Klára Prajzlerová, Petra Hánová, Jiří Vencovský, Ladislav Šenolt, *Czech Republic*

DYSREGULATION OF $\gamma\delta$ -T CELLS IN INDIVIDUALS AT RISK OF DEVELOPING RHEUMATOID ARTHRITIS (10')

Klára Prajzlerová, Olga Kryštůfková, Nora Petrovská, Petra Hánová, Hana Hulejová, Jiří Vencovský, Ladislav Šenolt, Mária Filková, *Czech Republic*

12:30-12:45 Final remarks and closing of the congress

12:45-14:00 Lunch

**POSTER SECTION:**

1. DECREASED FREQUENCY OF MARGINAL-ZONE B CELLS IN PERIPHERAL BLOOD OF SLE PATIENTS IN REMISSION OR LOW DISEASE ACTIVITY IN FIVE-YEAR FOLLOW-UP COHORT STUDY
Zbyněk Hrnčíř, Doris Vokurková, Marcela Drahošová
University Hospital Hradec Králové, Czech Republic
2. miRNome PROFILE IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS
Aneta Pekáčová, Jiří Baloun, Kristína Bubová, Monika Gregová, Šárka Forejtová, Jana Hořínková, Markéta Hušáková, Michal Tomčík, Jindřiška Gatterová, Jiří Vencovský, Karel Pavelka, Ladislav Šenolt
Institute of Rheumatology, Prague, First Faculty of Medicine, Charles University, Prague, Czech Republic
3. SCREENING FOR SUSPECTED SJÖGREN'S DISEASE
Katja Perdan Pirkmajer, Alojzija Hočevar
University Medical Centre Ljubljana, Slovenia
4. DISTRIBUTION OF FIBROBLASTS AND FIBROCYTES IN THE JOINT CAPSULE DURING THE POSTNATAL PERIOD IN NORM AND AFTER ANTENATAL ANTIGENIC STIMULATION
Andrii Fedotchenko
Regio Clinic Elmshorn. Elmshorn, Germany
5. FACTORS ASSOCIATED WITH DISEASE ACTIVITY IN RA PATIENTS TREATED WITH BIOLOGICS
Alexandra Husivargová, Vladimíra Timková, Želmíra Macejová, Zuzana Kotrádyová, Dagmar Breznoščáková, Robbert Sanderman, Iveta Nagyová
Department of Social and Behavioural Medicine, Faculty of Medicine, PJ Safarik University in Kosice, Slovakia
6. FACTORS INFLUENCING PHYSICAL ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS
Vladimíra Timková, Alexandra Husivargová, Želmíra Macejová, Zuzana Kotrádyová, Dagmar Breznoščáková, Robbert Sanderman, Iveta Nagyová
Department of Social and Behavioural Medicine, Faculty of Medicine, PJ Safarik University in Kosice, Slovakia
7. MAY AN 8-WEEK TAILORED PHYSIOTHERAPY HAVE A POSITIVE IMPACT ON SEXUAL FUNCTION IN WOMEN WITH SYSTEMIC SCLEROSIS AND IDIOPATHIC INFLAMMATORY MYOPATHIES? A PILOT STUDY
Barbora Heřmanková ^{1,2}, Maja Špiritovič ^{1,2}, Sabína Oreská ^{1,3}, Hana Štorkánová ^{1,3}, Karel Pavelka ^{1,3}, Ladislav Šenolt ^{1,3}, Jiří Vencovský ^{1,3}, Radim Bečvář ^{1,3}, Michal Tomčík ^{1,3}
¹Institute of Rheumatology, ²Department of Rheumatology, ³1st Faculty of Medicine,



³Department of Physiotherapy, Faculty of Physical Education and Sport, ⁴3rd Department of Internal Medicine, General University Hospital, Charles University, Prague, Czech Republic

8. ALTERATIONS OF NUTRITIONAL STATUS OF SCLERODERMA PATIENTS AND ASSOCIATIONS WITH DISEASE-SPECIFIC FEATURES

Sabina Oreská ^{1,2}, Hana Štorkánová ^{1,2}, Maja Špiritović ^{1,3}, Barbora Heřmanková ^{1,3}, Michal Vráblik ⁴, Karel Pavelka ^{1,2}, Jiří Vencovský ^{1,2}, Ladislav Šenolt ^{1,2}, Radim Bečvář ^{1,2}, Michal Tomčík ^{1,2}

¹Institute of Rheumatology, ²Department of Rheumatology, ^{1st Faculty of Medicine}, ³Department of Physiotherapy, Faculty of Physical Education and Sport, ⁴3rd Department of Internal Medicine, General University Hospital, Charles University, Prague, Czech Republic

9. NUTRITIONAL STATUS IN PATIENTS WITH IDIOPATHIC INFLAMMATORY MYOPATHIES AND THE ASSOCIATION WITH DISEASE-RELATED FEATURES

Sabina Oreská ^{1,2}, Hana Štorkánová ^{1,2}, Maja Špiritović ^{1,3}, Barbora Heřmanková ^{1,3}, Michal Vráblik ⁴, Karel Pavelka ^{1,2}, Ladislav Šenolt ^{1,2}, Heřman Mann ^{1,2}, Jiří Vencovský ^{1,2}, Michal Tomčík ^{1,2}

¹Institute of Rheumatology, ²Department of Rheumatology, ^{1st Faculty of Medicine}, ³Department of Physiotherapy, Faculty of Physical Education and Sport, ⁴3rd Department of Internal Medicine, General University Hospital, Charles University, Prague, Czech Republic

10. LIPID PROFILE IN SCLERODERMA PATIENTS COMPARED TO HEALTHY CONTROLS AND THE ASSOCIATIONS WITH DISEASE-SPECIFIC FEATURES

Sabina Oreská ^{1,2}, Hana Štorkánová ^{1,2}, Maja Špiritović ^{1,3}, Barbora Heřmanková ^{1,3}, Michal Vráblik ⁴, Karel Pavelka ^{1,2}, Jiří Vencovský ^{1,2}, Ladislav Šenolt ^{1,2}, Radim Bečvář ^{1,2}, Michal Tomčík ^{1,2}

¹Institute of Rheumatology, ²Department of Rheumatology, ^{1st Faculty of Medicine}, ³Department of Physiotherapy, Faculty of Physical Education and Sport, ⁴3rd Department of Internal Medicine, General University Hospital, Charles University, Prague, Czech Republic

11. COMPARISON OF LIPID PROFILE IN PATIENTS WITH IDIOPATHIC INFLAMMATORY MYOPATHIES AND HEALTHY POPULATION AND ITS ASSOCIATION WITH DISEASE-RELATED FEATURES

Sabina Oreská ^{1,2}, Hana Štorkánová ^{1,2}, Maja Špiritović ^{1,3}, Barbora Heřmanková ^{1,3}, Michal Vráblik ⁴, Karel Pavelka ^{1,2}, Ladislav Šenolt ^{1,2}, Heřman Mann ^{1,2}, Jiří Vencovský ^{1,2}, Michal Tomčík ^{1,2}

¹Institute of Rheumatology, ²Department of Rheumatology, ^{1st Faculty of Medicine}, ³Department of Physiotherapy, Faculty of Physical Education and Sport, ⁴3rd Department of Internal Medicine, General University Hospital, Charles University, Prague, Czech Republic

12. IMPACT OF SARS-CoV-2 EPIDEMIC ON THE QUALITY OF LIFE OF PATIENTS WITH INFLAMMATORY RHEUMATIC DISEASES

Domen Lah, Artur Pahor, Iztok Holc

Department of Rheumatology, Division of Internal Medicine, UMC Maribor, Slovenia



13. LONG-TERM SAFETY AND EFFICACY OF UPADACITINIB OR ADALIMUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS: RESULTS AT 3 YEARS FROM THE SELECT-COMPARE STUDY
Mária Keľová, Kamila Franková
Medical Department AbbVie

14. THE GUT MICROBIOME AND AUTOIMMUNE ARTHRITIS: A REVIEW
Mundher A.S. Aljubouri, Želmíra Macejová, Zuzana Kotrádyová
I. Department of Internal Medicine, MF UPJŠ a UNLP, Košice, Slovakia

15. CIRCULATING MIRNA CHARACTERIZING PATIENTS WITH DIFFICULT-TO-TREAT RHEUMATOID ARTHRITIS
Jiří Baloun, Aneta Pekáčová, Heřman Mann, Jiří Vencovský, Karel Pavelka, Ladislav Šenolt
Institute of Rheumatology, Prague, Czech Republic

16. CLINICAL MANIFESTATIONS OF HLA B51(5) POSITIVE PATIENTS IN UNIVERSITY HOSPITAL OF SPLIT
Dijana Perković, Petra Šimac, Martina Madunić, Mislav Radić, Daniela Marasović Krstulović, Esma Čečuk-Jeličić
University Hospital of Split, Croatia

17. HLA B35 ASSOCIATION WITH FIBROMYALGIA
Dijana Perković, Kristina Bakota, Katarina Borić, Petra Šimac, Mislav Radić, Daniela Marasović Krstulović, Ivona Božizić
University Hospital of Split, Croatia

18. EXPERIENCE WITH BELIMUMAB IN MANAGEMENT OF ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS
M. Záríková ^{1,2}, Ž. Macejová ¹
¹1st Department of Internal Medicine, LF UPJŠ and UNLP, Košice, ²Artromac n.o., Košice, Slovakia



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1. <https://www.ema.europa.eu/en/medicines/human/EPAR/remsima>. 2. Byun HG, et al. Appl Health Econ Health Policy. 2021;19(5):735-745. 3. European Commission Grants Marketing Authorisation For World's First Subcutaneous Formulation Of Infliximab Reimsima SC For An Additional Five Indications Including For Use In Inflammatory Bowel Disease And Ankylosing Spondylitis. <https://www.biosimilardevelopment.com/doc/european-commission-grants-marketing-authorisation-for-world-s-first-subcutaneous-0001>; 2021. [Accessed Dec 2021]. 4. Data on File. Celltrion Healthcare. 2021. 5. Schreiber S et al. Gastroenterology. 2021;160(7):2340-2353. 6. Solitano V, et al. Gastroenterology. 2021;160(7):2444-2447. 7. Overton PM, et al. Patient Prefer Adherence. 2021;15:811-834. 8. Westhovens R, et al. Rheumatology (Oxford). 2021;60(5):2277-2287. 9. Combe B, et al. Arthritis Res Ther. 2021;23(11):119. 10. Caporali R, et al. Expert Rev Clin Immunol. 2021;17(11):85-99. 11. Smith PJ, et al. J Crohns Colitis. 2021;15(Suppl_1):S480-S481. 12. Schreiber S, et al. Switching from intravenous to subcutaneous infliximab in patients with active inflammatory bowel disease: Post-hoc analysis of pre-/post-switch outcomes from a multicentre, randomized controlled pivotal trial. Poster (P0472). Prezentované na UEG Week Virtual 2021.

Základné informácie o lieku:

Reimsima 120 mg injekčný roztok v naplnenej injekčnej striekačke, Reimsima 120 mg injekčný roztok v naplnenom pere

Zloženie: Jedna naplnená jednodávková injekčná striekačka/naplnené jednodávkové pero s objemom 1ml obsahuje 120 mg infliximabu. **Indikácie:** Reumatoidná artritída, Crohnova choroba, ulcerózna kolitída, ankylozujúca spondylitída, psoriatická artritída, psoriáza. **Dávkovanie a spôsob podania:** Doporučené dávkovanie pri udržiavacej liečbe je 120 mg s.c. každý 2. týždeň. Udržiavaciu liečbu je potrebné začať 4 týždne po poslednom podaní 2 intravenózných infúzií infliximabu 5 mg/kg (3 mg/kg pri liečbe reumatoidnej artritídy) podaných v rozmedzí 2 týždňov. Pri reumatoidnej artritíde je možné liečbu začať úvodnou dávkou 120 mg s.c. nasledovanou ďalšou dávkou 120 mg s.c. v 1., 2., 3. a 4. týždni po podaní prvej injekcie, a potom pokračovať v obvyklom dávkovaní. Pri prechode z udržiavacej liečby infliximabom i.v. na s.c. formu, sa infliximab s.c. môže podať 8 týždňov po poslednom podaní infliximabu i.v.. Dávkovanie u zvláštnych skupín pacientov viď. platné SPC. **Kontraindikácie:** Hypersenzitívnosť na liečivú látku, na iné myšie proteíny alebo na ktorúkoľvek pomocnú látku, aktívna tuberkulóza alebo iné závažné infekcie, ako je sepsa, abscesy a oportúnne infekcie, stredne závažné alebo závažné srdcové zlyhanie (NYHA trieda III/IV). **Zvláštne upozornenia a opatrenia pri použití:** V záujme lepšej sledovateľnosti biologických liekov je potrebné dôsledne zaznamenať názov a číslo šarže podávaného lieku. Užívanie infliximabu bolo spojené s akútnymi reakciami súvisiacimi s injekciou, vrátane anafylaktického šoku, a oneskorenými hypersenzitívnymi reakciami. Pacienti užívajúci TNF-antagonisty sú viacej náchylní na závažné infekcie, vrátane sepsy, pneumónie, oportúnnych infekcií (invazívne mykotické, vírusové), tuberkulózy, kandidózy, pneumocystózy a ďalších. U pacientov, ktorí sú chronickými nositeľmi vírusu, môže dôjsť k reaktivácii hepatitídy B. Infliximab môže zriedkavo spôsobiť demyelinizačné ochorenie CNS, poruchy pečene a žilových ciest, imunosupresiu, malígne ochorenia, tiež bolo spozorované zhoršenie srdcového zlyhávania a s tým súvisiacej zvýšenej mortality. **Interakcie:** Liek sa neodporúča kombinovať s inou biologickou liečbou používanou na liečbu rovnakých ochorení, vrátane anakinry a abataceptu. Súčasnne s liekom sa neodporúča aplikovať živé vakcíny. **Nežiaduce účinky:** Najčastejšie infekcie horných dýchacích ciest, sinusitída, vírusové infekcie (napr. chrípkové ochorenia, infekcie vírusom herpes simplex), bolesť hlavy, bolesť brucha, nauzea, reakcie spojené s injekciou, bolesť v mieste aplikácie a ďalšie, viď. platné SPC. **Zvláštne opatrenia pre uskladnenie:** Uskladnite v chladničke (2 °C - 8 °C). Chráňte pred mrazom. Uskladnite v pôvodnom obale, aby bol liek chránený pred svetlom. Liek je možné uskladniť pri teplotách maximálne až 25 °C po dobu až 28 dní. **Balenie:** 1 ml x 1 naplnená injekčná striekačka alebo 1 naplnené pero. **Držiteľ rozhodnutia o registrácii:** Celltrion Healthcare Hungary Kft., 1062 Budapešť, Váci út 1-3. WestEnd Office Building B torony, Maďarsko. **Registračné čísla:** EU/1/13/853/010 a EU/1/13/853/013. **Dátum poslednej revízie textu:** 6. 4. 2022. **Spôsob výdaja:** Viazaný na lekársky predpis. **Spôsob úhrady:** Hradený z verejného zdravotného poistenia. **Skôr, ako liek predpíšete, zoznámte sa, prosím, s úplnou informáciou o lieku (SPC).**

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STRENGTH of BALANCE

Efficacious RA therapy
with proven safety profile^{1,2}

 **Jyseleca**[▼]
filgotinib
100 mg and 200 mg tablets

JYSELECA is a once-daily,
oral JAK1 preferential
inhibitor combining
lasting efficacy with
a favourable safety profile.^{1,2}

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References: 1. Jyseleca (filgotinib) Summary of Product Characteristics; EMA; October 2022 2. Winthrop KL, Tanaka Y, Takeuchi T, et al. Integrated safety analysis of filgotinib in patients with moderately to severely active rheumatoid arthritis receiving treatment over a median of 1.6 years. *Ann Rheum Dis.* 2022;81(2):184-192. doi:10.1136/annrheumdis-2021-221051

RA - rheumatoid arthritis; JAK - Janus Kinase

PRESCRIBING INFORMATION

Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.

JYSELECA[▼]/filgotinib 100 mg or 200 mg film-coated tablets.

Indications: Jyseleca is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with lost response to, or were intolerant to either conventional therapy or a biologic agent. Jyseleca is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX). **Dosage:** Adults: 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole. **Ulcerative colitis:** In patients who do not show an adequate therapeutic benefit during the initial 10 weeks of treatment, 12 additional weeks of induction treatment with filgotinib 200 mg once daily may provide additional relief of symptoms (see SmPC). Patients who have not shown any therapeutic benefit after 22 weeks of treatment should discontinue filgotinib. **Laboratory Monitoring:** Refer to the SmPC for information regarding laboratory monitoring and dose initiation or interruption. **Elderly:** Ulcerative colitis No dose adjustment is recommended for patients with ulcerative colitis up to 75 years of age. Filgotinib is not recommended in patients aged 75 years and older as there is no data in this population. **Elderly:** Rheumatoid Arthritis A starting dose of 100 mg once daily is recommended for patients aged 75 years and older as clinical experience is limited. **Renal impairment:** No dose adjustment required in patients with estimated creatinine clearance (CrCl) \geq 60 mL/min. A dose of 100 mg of filgotinib once daily is recommended for patients with moderate or severe renal impairment (CrCl 15 to $<$ 60 mL/min). Not recommended in patients with CrCl $<$ 15 mL/min. **Hepatic impairment:** Mild/moderate hepatic impairment: No dose adjustment required. Severe hepatic impairment not recommended. **Children** ($<$ 18 years) Safety and efficacy not yet been established. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Active tuberculosis (TB) or active serious infections. **Pregnancy, Warnings/Precautions:** See SmPC for full information. **Immunosuppression:** Combination use, with immunosuppressants e.g. ciclosporin, tacrolimus, biologics or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded. **Infections:** Infections, including serious infections such as pneumonia and opportunistic infections e.g. tuberculosis (TB), oesophageal candidiasis, and cryptococcosis have been reported. Risk benefit should be applied prior to initiating in patients with infection risk factors (see SmPC). Patients should be closely monitored for the development of signs and symptoms of infections during and after filgotinib treatment. Treatment should be interrupted if the patient is not responding to antimicrobial therapy, until infection is controlled. There is a higher incidence of serious infections in the elderly aged 75 years and older, caution should be used when treating this population. **Tuberculosis:** Patients should be screened for TB before initiating filgotinib, and filgotinib should not be administered to patients with active TB. **Viral reactivation:** Cases of herpes virus reactivation (e.g. herpes zoster), were reported in clinical studies (see SmPC). If a patient develops herpes zoster, filgotinib treatment should be temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed. **Malignancy:** Immunomodulatory medicinal products may increase the risk of malignancies. Malignancies were observed in clinical studies (see SmPC). **Fertility:** In animal studies, decreased fertility, impaired spermatogenesis, and histopathological effects on male reproductive organs were observed (see SmPC). The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown. **Haematological abnormalities:** Do not start therapy, or temporarily stop, if Absolute Neutrophil Count (ANC) $<$ 1 \times 10⁹ cells/L, ALC $<$ 0.5 \times 10⁹ cells/L or haemoglobin $<$ 8 g/dL Temporarily stop therapy if these values are observed during routine patient management. **Vaccinations:** Use of live vaccines during, or immediately prior to, filgotinib treatment is not recommended. **Lipids:** Treatment with filgotinib was associated with dose dependent increases in lipid parameters, including total cholesterol, and high-density lipoprotein (HDL) levels, while low density lipoprotein (LDL) levels were slightly increased (see SmPC). **Cardiovascular risk:** Rheumatoid arthritis and ulcerative colitis patients have an increased risk for cardiovascular disorders. Patients should have risk factors (e.g., hypertension, hyperlipidaemia) managed as part of usual standard of care. **Venous thromboembolism:** Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors including filgotinib. Caution should be used in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery, and prolonged immobilisation. **Lactose content:** Contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take filgotinib. **Pregnancy/Lactation:** Filgotinib is contraindicated in pregnancy. Filgotinib should not be used during breast-feeding. Women of childbearing potential must use effective contraception during and for at least 1 week after cessation of treatment. **Driving/Using machinery:** No or negligible influence, however dizziness has been reported, during treatment with Jyseleca (SmPC for full information) **Side effects:** See SmPC for full information. **Common** (\geq 1/100 to $<$ 1/10): nausea, upper respiratory tract infection, urinary tract infection and dizziness. **Marketing authorisation number(s):** Jyseleca 100mg film-coated tablets EU/1/20/1480/001 EU/1/20/1480/002 Jyseleca 200mg film-coated tablets EU/1/20/1480/003 EU/1/20/1480/004

▼ This medicinal product is subject to additional monitoring.

Adverse events should be reported to Competent Authority or to Swedish Orphan Biovitrum AB by email: drugsafety@sobi.com

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Date of preparation: October 2022. PP-16665



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