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From the Editor

We continue to publish the posters presented at the INFARMED Pharmacovigilance Day, this time with safety data from the real world in pregnant and/or breastfeeding women in Portugal, as well as studies in the field of autoimmunity and atopy. Also in this issue: an adverse drug reactions clinic in central Portugal, and a review on the safety of drugs commonly used in familial amyloid polyneuropathy.

Adverse Drug Reactions (ADR) clinic at the Coimbra University Hospital Centre Pharmacology Unit

The Coimbra University Hospital Centre Pharmacology Unit integrates and develops a range of activities in clinical pharmacology, including pharmacovigilance. In January 2020, an Adverse Drug Reactions (ADR) clinic was given the go-ahead to support physicians of the various hospital specialties and to facilitate the ADR reporting process as well as the clinical follow-up of patients when appropriate. As far as the author is aware, this is the first such clinic to be formally established in Portugal.

This consultation addresses queries from various specialties concerning ADRs. An assessment is made of their clinical context, concomitant medication, potential drug interactions, comorbidities, chronological match between the ADR and the suspected drug, prior listing status of the suspected ADR, and severity criteria. A causal relationship is then established as definite, probable, possible, improbable, or non-classifiable, and a report is entered in the INFARMED's ADR portal (Portal RAM).

The reporting rate of suspected ADRs at hospital level has been traditionally low for several reasons, including lack of time, which is why a continuing focus on promoting and facilitating ADR reporting is necessary.

Patrícia Paiva

INDEX CARD

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DADOS DE SEGURANÇA DO MUNDO REAL EM MULHERES GRÁVIDAS E/OU A AMAMENTAR EM PORTUGAL: ESTUDO RETROSPETIVO

Ana-Marta Silva[1,2,3,4], Joana Marques[1,2,3,4], Jorge Polónia[1,3,5], Ricardo Cruz Correia[1,2,3,5], Inês Ribeiro[1,2,3,5]

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INTRODUÇÃO

As mulheres grávidas e/ou a amamentar raramente são incluídas em ensaios clínicos, pelo que o conhecimento sobre o perfil de segurança dos medicamentos neste grupo especial é escasso no momento da autorização de introdução no mercado. A avaliação dos potenciais riscos associados ao uso de medicamentos na gravidez ou durante a amamentação, geralmente, baseia-se na extrapolação de dados não clínicos e no conhecimento de reações adversas a medicamentos (RAM) embrionárias/fetais de outros medicamentos com propriedades farmacológicas semelhantes. No entanto, evidências de ausência de danos para uma substância não podem ser extrapoladas para outras substâncias da mesma classe e interpretadas como indicando a ausência de um risco potencial para essas outras substâncias.

OBJETIVO

Obter uma perspetiva nacional das notificações enviadas por profissionais de saúde e utentes ao Sistema Nacional de Farmacovigilância (SNF) envolvendo mulheres grávidas e/ou a amamentar, nos últimos 10 anos. Pretende-se caracterizar as principais variáveis das respetivas notificações, como a gravidade dos casos e principais grupos de medicamentos e de reações adversas.

METODOLOGIA

Tipo de Estudo
- Observacional
- Retrospetivo
- 2012 a 2021 (10 anos)

Amostra
- Notificações RAM
- Via direta (Utentes + PS)

Análise Macro
- Total de notificações
- Gravidade do caso
- Idade da mulher

Análise Medicamentos
- Grupo ATC*

Anatomical Therapeutic Chemical

Análise RAM
- Grupo sistémico SOC *
- Descrita / Não descrita**

* *System Organ Class*: nível hierárquico superior da codificação MedDRA
** *Fonte: Resumo das Características do Medicamento (RCM)*

Análise estatística: SPSS statistics 27.0

Nota: Cada ATC contribuiu para a contagem da seguinte forma: por cada medicamento diferente presente em cada caso foi contabilizada 1 ATC.

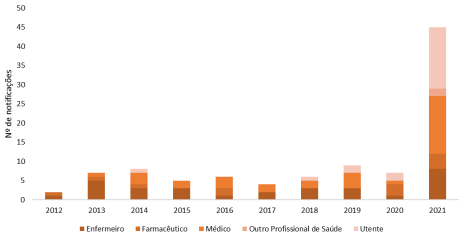
Nota: Se na mesma notificação existia mais do que uma reação adversa pertencente ao mesmo código MedDRA (SOC), apenas foi contabilizado o código uma vez.

RESULTADOS

Análise Macro

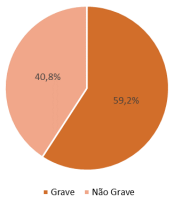
Ao longo de 10 anos, o SNF recolheu **244 notificações de exposição na mulher grávida e/ou a amamentar** (por via direta), sendo que **98 casos (40,2%) tinham RAM associada**.

Gráfico 1: Nº de Notificações/Ano: Distribição por grupo de notificador



Neste período, verificou-se uma **percentagem de notificações graves foi superior** às notificações não graves, 59,2% e 40,8% respetivamente.

Gráfico 2: Distribuição por Gravidade



Relativamente aos **critérios de gravidade** constatamos que o critério "**clinicamente relevante**" foi o mais frequente notificado (**67,3%**), seguido de "**risco de vida**" (**12,1%**), **hospitalização**" (**10,3%**) e "**incapacidade**" (**10,3%**).

Dados Demográficos da Mulher

A **mediana** das idades da mulher grávida e/ou a amamentar é **33 anos** [$IQR_{25\%-75\%}$ = 29 - 37 anos].

Análise dos Medicamentos

A tabela seguinte apresenta os **5 ATC mais frequentemente** envolvidos nas reações adversas notificadas.

ATC	n	%
J07 VACCINES	73	65%
COVID-19 vaccines	38	52,1%
tetanus toxoid, combinations with diphtheria toxoid	12	16,4%
Measles vaccines	9	12,3%
BACTERIAL VACCINES	7	9,6%
Others vacines	7	9,6%
J01 ANTIBACTERIALS FOR SYSTEMIC USE	7	6%
J05 ANTIVIRALS FOR SYSTEMIC USE	6	5%
G02 OTHER GYNECOLOGICALS	4	4%
B03 ANTIANEMIC PREPARATIONS	3	3%

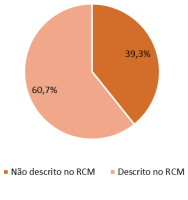
Análise das RAM

A tabela apresenta o **top 10 das SOC** mais notificadas:

SOC	n	%
General disorders and administration site conditions	53	25%
Pregnancy, puerperium and perinatal conditions	31	14%
Injury, poisoning and procedural complications	24	11%
Nervous system disorders	22	10%
Gastrointestinal disorders	15	7%
Skin and subcutaneous tissue disorders	15	7%
Musculoskeletal and connective tissue disorders	10	5%
Cardiac disorders	9	4%
Respiratory, thoracic and mediastinal disorders	8	4%
Investigations	6	3%

Relativamente ao conhecimento prévio da RAM no RCM, verificou-se que foram notificadas maioritariamente RAM descritas (60,7%), apesar de se ter verificado 39,3% de RAM não descritas.

Gráfico 3: Conhecimento prévio da RAM no RCM



DISCUSSÃO / CONCLUSÃO

Verificou-se um aumento de notificações de exposição na grávida e/ou na mulher a amamentar em 2021, o que era expectável, dado o número de notificações ter aumentado no geral. Os casos mais frequentemente notificados ao SNF são os casos de exposição durante a gravidez às vacinas, nomeadamente às vacinas contra a COVID-19. Esta situação demonstra que existe uma preocupação crescente com a monitorização de medicamentos novos em grupos especiais, como é o caso da mulher grávida e/ou a amamentar e os Sistemas de Farmacovigilância são estruturas robustas que podem e devem ser utilizadas para recolher este tipo de informação, aumentando assim o conhecimento acerca do perfil de segurança dos medicamentos comercializados.

REFERÊNCIAS

1. Introductory cover note, last updated with release of Addendum III of Module XVI on pregnancy prevention programmes for public consultation. Guidelines on good pharmacovigilance practices (GVP). European Medicines Agency (EMA).

Fonte: Sistema Nacional de Farmacovigilância – Portal RAM – INFARMED, I.P.

Characterization of Spontaneous Reports containing Immune-Mediated and Autoimmune Disorders received by the Pharmacovigilance Unit of Coimbra

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1. Pharmacovigilance Unit of Coimbra (UFC), Association for Innovation and Biomedical Research on Light and Image (AIBILI), Coimbra, Portugal.; 2. DruSER.Net – Drug Safety and Effectiveness Research Network, Coimbra, Portugal; 3. Coimbra Hospital and University Centre (CHUC), Coimbra, Portugal.

www.aibili.pt

Introduction

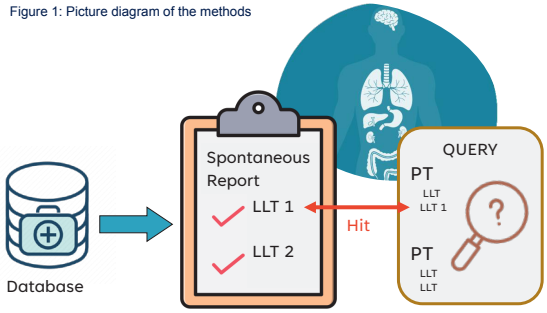
Immune-related adverse reactions are commonly associated with immunotherapy, particularly with immune checkpoint inhibitors. However, there is a growing concern regarding this type of reactions associated with other medications.

Aim

This study aims to characterize Spontaneous Reports (SR) containing at least one Adverse Drug Reaction (ADR) pertaining to the Immune-Mediated and Autoimmune Disorders Standardised Medical Dictionary for Regulatory Activities (MedDRA®) Query (SMQ) during a 12-year period (2010-2022) by the Pharmacovigilance Unit of Coimbra (UFC).

Methods

Figure 1: Picture diagram of the methods



SRs were identified through a search on the National Pharmacovigilance System's database using SMQ: Immune-Mediated and Autoimmune Disorders. The cases were characterized according to their MedDRA® preferred term, reported in the adverse reaction section, patient demographics, seriousness, and suspected drug Anatomical Therapeutic Chemical (ATC) Classification System code.

Results

The UFC received 6616 SRs during the selected period, from which 193 (2.92%) contained terms included in the SMQ. These adverse reactions were most frequently reported for female patients (n=108; 55.96%). The average age was 49.8 ± 22.2 years old. Over half (n=109; 54.77%) of the SRs received related to ATC J "Antiinfectives for Systemic Use", followed by ATC L "Antineoplastic and Immunomodulating Agents" (n=30; 15.08%) and ATC M "Musculo-Skeletal System" (n=19; 9.55%) medicines. Only 13 SRs, (7%) were assessed as non-serious. One hundred and fifty-six preferred terms were identified within the Broad Scope, while 48 preferred terms were identified within the Narrow Scope.

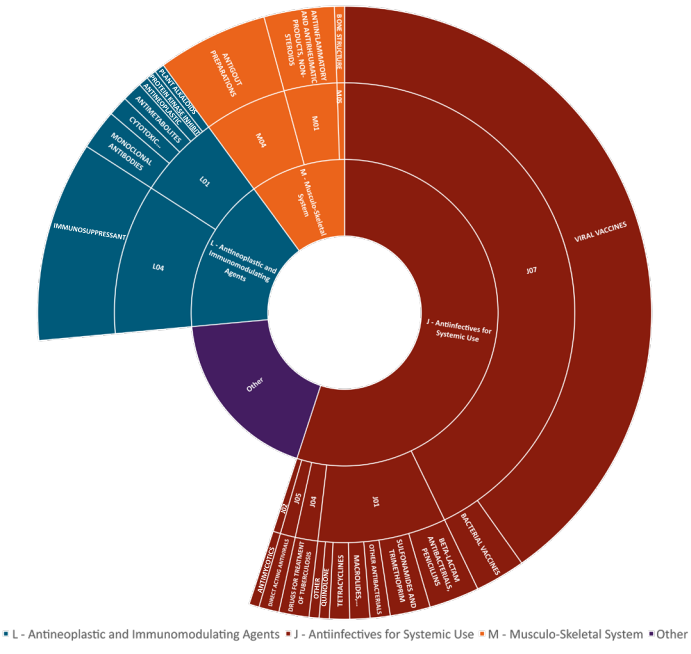


Figure 2: Most frequently reported medicines associated with Immune-Mediated and Autoimmune Disorders (Anatomical Therapeutic Chemical Classification System - The fourth level of the code indicates the chemical/therapeutic/pharmacological subgroup and consists of one letter.)

Within the Broad Scope, the most frequently reported reactions were "**Stevens-Johnson syndrome**" (n=24; 15.83%), "**Myocarditis**" (n=17; 10.90%) and "**Hepatitis**" (n=10; 6.41%). Within the Narrow Scope, the most frequently reported reactions were "**Guillain-Barre syndrome**" (n=11; 22.92%); "**Vasculitis**" (n=9; 18.75%) and "**Psoriasis**" (n=7; 14.58%).

Conclusions

The release of the MedDRA® SMQ for medication errors has been an important milestone to improve the detection and retrieval of immune-mediated/autoimmune disorders in pharmacovigilance databases. This characterization shows that most SRs associated with immune-mediated/autoimmune disorders are serious and remain to be further explored.

Funding

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SISTEMA NACIONAL Farmacovigilância Infarmed

30º Aniversário do INFARMED, I.P.

THE SAFETY OF SYSTEMIC JANUS KINASE INHIBITORS IN ATOPIC DERMATITIS: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS

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** The authors have no relationships to disclose.*

Introduction and objective

Janus kinase (JAK) inhibitors have been developed to treat moderate to severe atopic dermatitis, but there is little evidence comparing the safety profile of these drugs.

This systematic review and network meta-analysis aims to compare the relative safety of the different systemic JAK inhibitors in atopic dermatitis.

Method

Medline, EMBASE and clinicaltrials.gov were searched to identify phase 2/3, clinical trials (RCTs) designed to evaluate the efficacy and safety of systemic JAK inhibitors in atopic dermatitis. Outcomes were the risk of any adverse event (AE), serious AEs, AEs leading to treatment discontinuation, any infection, serious infections, herpes zoster infection and any cardiac or vascular event.

Results

Eighteen RCTs were included.

Compared with placebo, baricitinib (Odds Ratio [OR] 1.25, 95% credible interval [CrI] 1,03 – 1.55), abrocitinib (OR 1.54, 95% CrI 1,25 – 1.90), and upadacitinib (OR 1.46, 95% CrI 1,19 – 1.81) increase the risk of any adverse event.

Abrocitinib (OR 1.62, 95% CrI 1.17 – 2.72), upadacitinib (OR 1.67, 95% CrI 1.19 – 2.43), and dupilumab (OR 1.69, 95% CrI 1.02 – 2.79) increase the risk of infections when compared with placebo (Figure 1).

Dupilumab has a reduced risk of herpes zoster infection when compared with upadacitinib (OR 0.23; 95% CrI 0.08 – 0.81) (Figure 2).

No further statistically significant risk differences between treatments were identified.

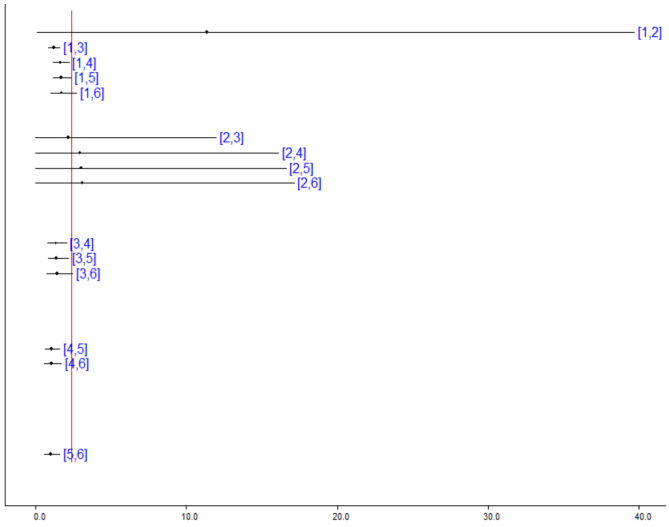

Figure 1. Risk of any infection.
1, Placebo; 2, Gusacitinib; 3, Baricitinib; 4, Abrocitinib; 5, Upadacitinib; 6, Dupilumab

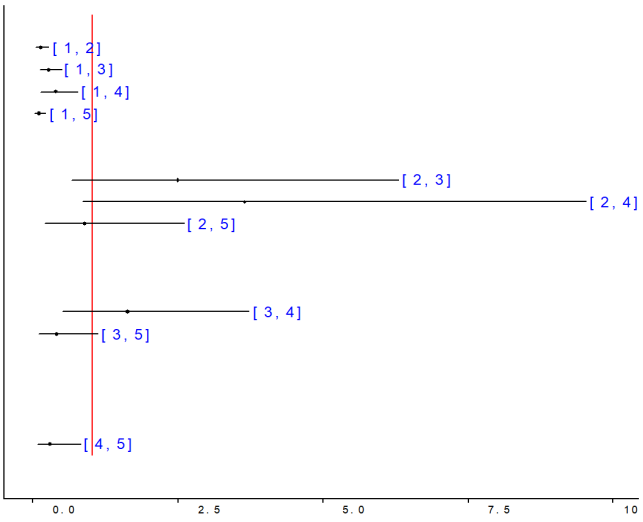

Figure 2. Risk of herpes zoster.
1, Placebo; 2, Baricitinib; 3, Abrocitinib; 4, Upadacitinib; 5, Dupilumab

Conclusions

The results suggest systemic JAK inhibitors for atopic dermatitis have a similar safety profile. However, as current data present limitations, postmarketing safety evidence will be crucial to draw definitive conclusions regarding the safety of JAK inhibitors.

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Infarmed Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

SISTEMA NACIONAL Farmacovigilância Infarmed

30º Aniversário do INFARMED, I.P.

TOPICAL JANUS KINASE INHIBITORS IN ATOPIC DERMATITIS: A SAFETY NETWORK META-ANALYSIS

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1. Laboratory of Social Pharmacy and Public Health, Faculty of Pharmacy, University of Coimbra, Portugal;
** The authors have no relationships to disclose.*

Introduction and objective

Topical janus kinase (JAK) inhibitors are being developed for the treatment of mild to moderate atopic dermatitis. However, comparative evidence on their safety profiles is still limited.

This systematic review and network meta-analysis aims to compare the relative safety of topic JAK inhibitors in patients with atopic dermatitis.

Results

Ten RCTs were included in this network meta-analysis.

Tofacitinib was associated with a reduced risk of any AE when compared with ruxolitinib (OR 0.18, 95% CrI 0.03 – 0.92) (Figure 1).

The analyses for the remaining outcomes did not identify other statistically significant risk differences between the topical JAK inhibitors (Figure 2: serious adverse events).

Method

Phase 2 and 3 clinical trials (RCTs) evaluating the efficacy and safety of topical JAK inhibitors in atopic dermatitis were searched on Medline, EMBASE and clinicaltrials.gov. The following outcomes were considered: any adverse event (AE), serious AEs, AEs leading to treatment discontinuation, any infection, any application site reaction.

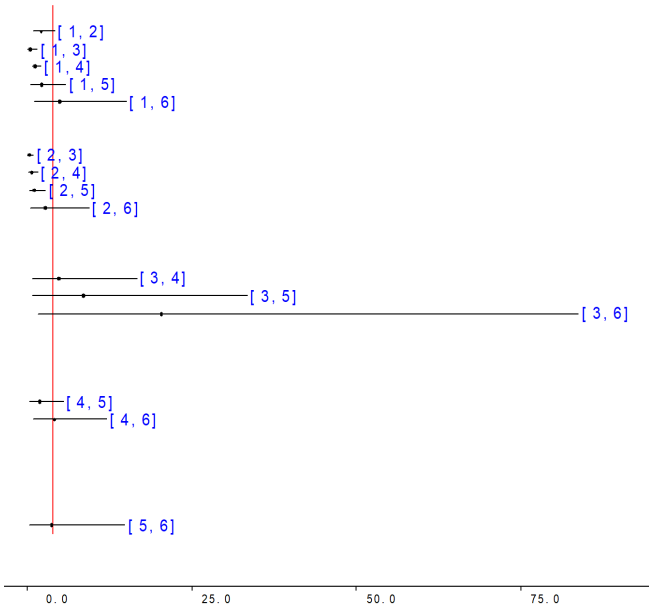

Figure 1. Risk of any adverse event.
1, Placebo; 2, Ruxolitinib; 3, Tofacitinib; 4, Delgocitinib; 5, TAC; 6, Tacrolimus

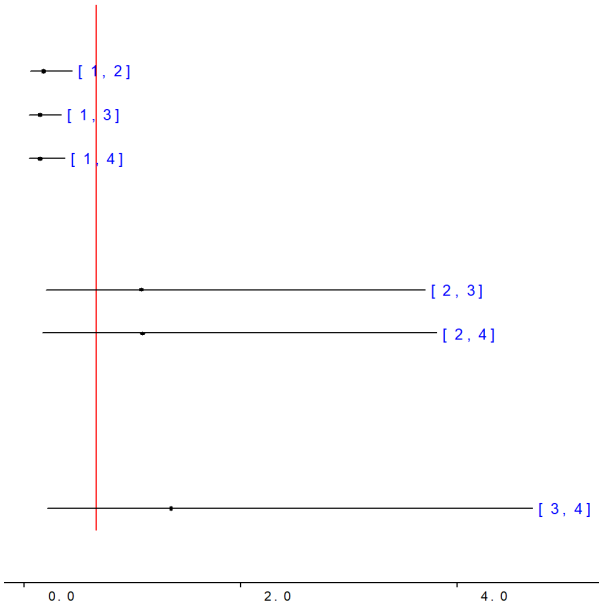

Figure 2. Risk serious adverse events.
1, Placebo; 2, Ruxolitinib, 3, Delgocitinib, 4, TAC.

Conclusions

This network meta-analysis of RCTs suggest that topical JAK inhibitors used in patients with atopic dermatitis have comparable safety profiles. Nonetheless, these results should be interpreted with caution because the available data are scarce. Post-marketing pharmacovigilance activities will be essential to confirm the findings from this study.

1 2 9 0 FACULDADE DE FARMÁCIA UNIVERSIDADE D COIMBRA

Infarmed Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

Familial amyloid polyneuropathy: safety aspects of the pharmacotherapeutic options

Familial amyloid polyneuropathy (FAP), commonly known as para-amyloidosis, was first described in the Portuguese population, in the Póvoa do Varzim region, by the Professor of neurology Dr Corino de Andrade. The condition results from the deposition in tissues, especially nerves, of a highly insoluble fibrillar substance called amyloid. Amyloid fibers are made up of subunits of a blood protein that transports thyroid hormones and vitamin A. The onset of the disease is between the ages of 25 and 35 years (though it may occur after the age of 50), initially involving the lower limbs and affecting sensitivity to stimuli (e.g., temperature sensitivity), as well as motor ability; it is eventually fatal, with a mean evolution of 10 years.

Since the liver is the primary source of amyloid substance, liver transplantation is a well-established therapeutic option to halt disease progression and increase quality of life, if performed early. However, liver transplantation has limitations in that it is an invasive treatment with significant perioperative mortality and with associated adverse effects resulting from prolonged immunosuppression.

In 2011, the European Medicines Agency (EMA) approved the marketing of a specific drug (tafamidis) for the treatment of para-amyloidosis in adult patients. It has been demonstrated that this drug stymies the progression of the disease and increases patients' life quality and expectancy. More recently, two new drugs have been approved, inotersen and patisiran, which were developed to act in the shortest interval possible. Selected safety aspects of these three drugs are discussed below.

Vyndaqel® (tafamidis)

An orphan drug used to delay nerve damage caused by transthyretin. Tafamidis is a stabilizer of transthyretin; by binding to it, it prevents the protein from breaking down, thus stopping the formation of amyloid and delaying the progression of nervous disease.

The **most common side effects** of tafamidis (in more than 1 in 10 treated patients) are urinary tract infection, vaginal infection, upper abdominal pain and diarrhoea. Tafamidis is associated with a risk of serious **birth defects** and other developmental abnormalities in neonates. It is therefore not recommended during pregnancy or in women of childbearing potential not using effective contraception. Data on pregnancy in humans are limited and developmental toxicity studies in animals have revealed abnormalities.

One of the ways to minimize risks is to provide healthcare professionals with a **guide** to highlight the importance of:

- strongly advising women to avoid becoming pregnant or breast-feeding while receiving Vyndaqel®;
- reporting ADRs;
- reporting any pregnancy in female patients who are taking the drug;
- promoting enrollment in the **THAOS** (Transthyretin Amyloidosis Outcomes Survey), a multicentric global disease registry that aims to collect longitudinal data from patients with hereditary or wild-type transthyretin amyloidosis (ATTR) and asymptomatic carriers of TTR variants, and to confirm the diagnosis in order to avoid administration of Vyndaqel ® to non-eligible patients.

Tegsedi® (inotersen)

An orphan drug used for the treatment of hereditary transthyretin-mediated amyloidosis (ATTR) in adult patients with stage 1 or stage 2 polyneuropathy (stage 1: patient can walk without assistance; stage 2: patient can still walk but needs help).

The **most common side effects** of inotersen (which may affect more than 1 in 10 patients) are: injection site reactions, nausea/vomiting, headache, fever, peripheral oedema (swelling especially of ankles and feet), chills, anaemia,

and low blood platelet counts (which can lead to bleeding and bruising). Tegsedi® should not be used by patients with low platelet counts (less than $100x10^9$/L) nor by patients with severe renal or hepatic disease.
Tegsedi® carries a risk of occurrence of thrombocytopenia and glomerulonephritis, of ocular toxicity due to vitamin A deficiency, and of liver transplant rejection.
To minimize those risks, an **alert card** has been issued for patients with safety information including on how to manage side effects. Recommendations and precautions have also been developed for healthcare professionals and patients and included in the SmPC and PL.
Patients treated with this medicine should have their platelet count monitored at least **every 2 weeks**. The platelet count and kidney function should still be monitored **for 8 weeks after discontinuation** of treatment.
Patients with a previous **liver transplant** should be monitored during treatment for possible signs and symptoms of rejection. In these patients, liver function tests should be obtained with monthly periodicity.
In case of confirmed **glomerulonephritis**, treatment with inotersen should be permanently discontinued and early initiation of immunosuppressive treatment considered. If the patient develops symptoms suggestive of **vitamin A deficiency**, ophthalmological referral is recommended.

Onpattro® (patisiran)

An orphan drug whose indications overlap those of inotersen.
The **most common side effects** of patisiran (affecting more than 1 in 10 patients) are peripheral oedema and infusion-related reactions, including pain, nausea, headache, tiredness, dizziness, cough and respiratory symptoms, flushing, facial oedema, tachycardia, high or low blood pressure.
The attending physician should assess the patient to determine whether it is appropriate for them to receive Onpattro® **infusion at home**. To reduce the risk of infusion-related reactions, patients should be on corticosteroids, paracetamol and H1/H2 blockers prior to infusion. They should also take vitamin A supplements during treatment. Some patients who sustain infusion-related reactions may benefit from a slower infusion rate, or from additional or higher doses of one or more of the above pre-meds. Educational materials have been produced for health professionals and patients with information on how to administer the drug safely in the home and how to manage potential side effects.

Cristina Mousinho

Selected links (references):

https://hff.min-saude.pt/paramiloidose-causas-sintomas-e-tratamentos/

https://www.ema.europa.eu/en/medicines/human/EPAR/onpattro

https://www.ema.europa.eu/en/medicines/human/EPAR/vyndaqel

https://www.ema.europa.eu/en/medicines/human/EPAR/tegsedi

https://pubmed.ncbi.nlm.nih.gov/23193944/

http://www.paramiloidose.com/

Communications to Healthcare Professionals published on the Infomed product information webpage

Click on the links

INN Medicinal product	Target	Materials Online publication date
Crizanlizumab *Adakveo*	**Physicians:** haematologists	Phase III study (CSEG101A2301) shows no superiority of crizanlizumab over placebo 14-02-2023
Onasemnogene abeparvovec *Zolgensma*	**Physicians:** neuropaediatricians at national hospitals with an SMA (Spinal Muscular Atrophy) clinic in the setting of a neuromuscular diseases unit	Fatal cases of acute liver failure 16-02-2023

Compiled by Patrícia Catalão

Educational Materials published on the Infomed product information webpage

Click on the links

INN Medicinal product	Target	Materials Online publication date
Ranibizumab *Ximluci*	**Patients**	Treatment guide Treatment audioguide 20-02-2023
Teriflunomidae *Aubagio*	**Physicians:** neurologists **Patients**	Guide Card 21-02-2023

Compiled by Patrícia Catalão

Pharmacovigilance: Engaging the Citizen

May 30th

Centro de Cultura e Congressos da Secção Regional do Norte da Ordem dos Médicos, Porto

As part of its 30th anniversary celebrations, Infarmed is organizing a pharmacovigilance event on 30 May 2023, at the Center for Culture and Congresses of the General Medical Council Northern Regional Section, in Porto, Portugal, with the theme *Pharmacovigilance: Engaging the Citizen*.
The event will include a poster exhibition. Posters will be selected from works in pharmacovigilance submitted to Infarmed until 14 May 2023. Abstracts can be submitted through this link in accordance with the event's regulations.
The programme cab be accessed here. Registration will be open here until 25 May 2023.

This event will be centered around the role of citizens in pharmacovigilance. The benefits of engaging citizens with the medicines safety monitoring system will be explored with a view to safeguarding public health.

What do they mean?

ADR	Adverse Drug Reaction
EMA	European Medicines Agency
MA	Marketing Authorization
PL	Patient Information Leaflet
PRAC	Pharmacovigilance Risk Assessment Committee (EMA)
SmPC	Summary of Product Characteristics