## **Drugs used in vasculitis**

### 5<sup>th</sup> October 2019

**Dawn Davin** 

**Renal Clinical Pharmacist** 

Dawn.davin@tuh.ie







An Academic Partner of Trinity College Dublin



### What does it feel like to be a patient?







Remember: You add value & insight to healthcare & how it is provided PAMs PREMs PROMs







### **Concept of Perspective**















Tallaght<br/>University<br/>HospitalOspidéal<br/>Ollscoile<br/>ThamhlachtaAn Academic Partner of Trinity College Dublin



## Medicines used to treat Vasculitis



Immune system modifying drugs			
Rituximab			
Cyclophosphamide			
Azathioprine	Imuran <sup>®</sup>		
Methotrexate			
Mycophenolate	Cellcept®		
Immunoglobulin			
Steroids – Prednisolone	Deltacortril®		
Supportive Medicines			
Bone Protection	Kalcipos <sup>®</sup> Calcichew <sup>®</sup>	Alendronate, Alendronic Acid	
Calcium & Vitamin D	Ad-cal <sup>®</sup> Desunin <sup>®</sup>	Fosamax <sup>®</sup> , Fosavance <sup>®</sup>	
Stomach Protection (PPIs)	Esomeprazole, Omeprazole, Lansoprazole		
Blood Pressure Control	Bisoprolol, Amlodipine, Irbesartan		
Infection prevention	Septrin (Co-trimoxazole), Nystatin		
Other Medicines	Apixaban, Paracetamol, Serc, Simvastatin, Dymista, Duloxetine		

## How do the medicines work?



### Immunosuppression – what do you need to think of?

**Side-effects of individual medicines** 

Managing side-effects of medicines, e.g. bone protection if taking steroids

Infection risk & exposure to people with infections

**Skin protection** 

Wound healing

Sick day rules for some drugs, e.g. steroids

Vaccines

Effects on fertility/pregnancy & breast-feeding issues



## They do what?

Drug	How does it work?
Cyclophosphamide	DNA of immune cells is affected (alkylating agent)
Rituximab	Monoclonal antibody – CD20 protein ("antigen") on surface of B cells
Glucocorticoids	Effects T-cells and cell messenger systems
Tacrolimus	Calcineurin Inhibitor (T-cells)
Mycophenolate	IMPDH (enzyme) Inhibitor (T-cells & B-cells)
Sirolimus	mTOR inhibitor (T-cells)
Methotrexate	Antimetabolite immunosuppressant – effects an enzyme at cell level
Azathioprine	Antimetabolite immunosuppressant – effects an enzyme at cell level
Avacopan	Blocks complement (Ca5) receptor

### Antigens, Antibodies & B-cells.....

- Antibodies are part of our immune system, our body uses them to kill infecting organisms like bacteria and viruses
- Antibodies are made by special B-lymphocytes (B-cells)
- We are born with millions of B-cells, each of which recognises a different antigen through its B-cell receptor
- An antigen could be a protein on a bacteria or virus
- When the B-cell recognises an antigen, it releases its B-cell receptor into the bloodstream, which is now called an antibody
- The antibody triggers an immune response against the antigen





## Cyclophosphamide

#### Infection risk

Effect on bladder and urinary tract – fluid intake

**Blood in the urine** 

Nausea & vomiting

Monitor blood count, kidneys, liver

Monitor lungs and heart

**Contraception & fertility issues** 

Hair loss (Alopecia)

Effect on blood sugars

Stomach upset

## **Rituximab**

#### **Drug Reactions**

Effects on the heart

**Infection Risk** 

PML

**Hepatitis B Infection screen** 

**Tuberculosis (TB) infection screen** 

**Monitor blood count** 

Avoid in pregnancy & breast-feeding

Stomach upset

Rash



## **Mycophenolate**

Monitor kidneys & liver	Effect mood & sleep
Infection	Headaches, dizziness
Stomach upset – nausea, diarrhoea, ulcers	Gout
Drug Interactions	Joint/muscle pain
Contraception – avoid in pregnancy	
Monitor electrolytes	
Monitor blood sugars	
Monitor cholesterol/lipids	
Monitor blood pressure	



### **Methotrexate**

Protect from sunlight

## Azathioprine

	•
Monitor kidneys/liver/lungs	Interaction with medication used to treat Gout
	(Allopurinol & Febuxostat)
Drug interactions	
Monitor full blood count	Monitor full blood count – TPMT enzyme check
	•
Infection risk	Infection risk
Monitor closely if retaining fluid	Monitor kidneys, lungs, & liver
Mouth/stomach ulcers & upset	Take one hour before or 2 hours after milk or dairy
Vaccines	Drug Interactions
Contracention/Pregnancy	Protect skin
contraception, regnancy	
Vitamin B12 & folic acid	



### **Steroids**

Increased appetite, leading to weight gain

Mood changes – irritable/anxious

**Difficulty sleeping – "alerting"** 

Indigestion/heartburn

**Increased risk of infections – chickenpox, shingles** 

High blood sugars or diabetes

Weakening of the bones

Skin thinning

**Cataracts/Glaucoma** 

**High blood pressure** 

Affect wound healing





Avacopan interferes with the inflammatory response by blocking the protein C5a.

C5a is a member of the complement system, a family of proteins that plays an important role in immune response.

Complement proteins help recruit white blood cells to areas of infection or injury, to defend the body and promote healing. But in autoimmune diseases, white blood cells are recruited to healthy tissue, where they build up and cause damage.

It blocks the effects of C5a by targeting its receptor, C5aR. Blocking C5aR interferes with messages to white blood cells, so fewer are attracted to inflammation sites.



## **Biosimilar Agents...what's "similar" about them**

**Biological medicine** – medicine derived from living cells or organisms, consisting of large highly complex molecular entities which may be difficult to characterise.

A **biosimilar medicine (or 'biosimilar')** is a biological medicine that is developed to be highly similar, but not identical, to the licensed originator biological medicine and shows no clinically meaningful difference in terms of quality, safety, & efficacy.

Biosimilars must demonstrate that there are **no clinically meaningful differences** compared to the originator biological medicine in order to be approved by the European Medicines Agency (EMA).

The evidence acquired over ten years of clinical experience with biosimilars demonstrates that they can be used as safely and effectively in all their approved therapeutic indications as their originator biological medicines (1st biosimilar 2006)

**Regulatory bodies,** including the EMA and the Health Products Regulatory Authority (HPRA), have published guidance and information for healthcare professionals and patients in relation to biosimilars.



### Where can I look form more information?

#### www.ema.europa.eu

#### www.hpra.ie



## Biological and biosimilar medicines: What patients should know

The questions and answers in this document have been edited and approved for NALA's Plain English Mark.



#### WHAT IS A BIOLOGICAL MEDICINE?

A **biological medicine** contains an active substance that is produced from a biological source such as living cells. The active substance in a biological medicine is what makes the medicine work. Biological medicines are also called **biologics**.

Here are some biological medicines that you may have heard of:

- The hormone insulin, which is used to treat diabetes;
- Vaccines;
- Monoclonal antibodies, which are a type of protein that can bind to substances in the body. They are used to treat a wide variety of conditions such as cancer or arthritis.

Biological medicines are different to chemical medicines such as paracetamol or aspirin.

Chemical medicines are smaller and less complex than biological medicines. When chemical medicines are made, the active substance is identical in every batch and every brand.

## What I need to know about Biosimilar Medicines Information for patients

European

Commission



## **Informing Patients**



Focus groups prior to adoption

One to one patient consultation by trained clinician, nurse or pharmacist in lead up to the adoption

The utilisation of a patient information leaflet with Q&A section and contact details of relevant HCP if patients wish to discuss further

Patient letter to be sent out to patients explaining:

- 1. The planned change
- 2. How the decision has been undertaken
- 3. That clinical efficacy and safety have not been affected
- 4. That significant financial benefits will be achieved for the NHS and/or the trust



### **Video: EMEA Biosimilar Medicines**

https://www.youtube.com/watch?v=YPIvVI4xwFg&list=PL7K5 dNgKnawb3IQri7lIr5wbaWxP71jQJ&index=1

### "Drugs don't work in patients who don't take them"

C. Everett Koop, US Surgeon General



Could we all just go for coffee now, or, is there anything else to consider?

European Journal of Heart Failure 2017;19:1412–1413

### **The Medication Journey**



#### Step 3

Medications: Side-effects Change of brands Change of drugs Dose changes Interactions

Step 1 Diagnosis Medicines prescribed Time of change

#### Step 4 Follow up appointments Blood Tests

Other test

#### Step 5

The journey and commitment to your medication and managing your condition is ongoing..... "The road is long"

#### We understand

#### Step 2

Developing understanding of your condition Learn what your medicines are for Adapting – time of change Questions

#### **Emotions**

? Concern? Confusion? Fear? Uncertainty? Anxiety

### If it's a journey.....



Don't be a passenger



Be the driver





My Medicines is a list of all of the medicines and supplements you take and some of their details.

Please fill in the My Medicines information inside this leaflet.

This is your record of your medicines. Please keep this document safe and bring it with you when coming to Tallaght Hospital or attending any healthcare appointment. If you become ill, you or a family member can bring this record to hospital.

We also ask that you bring all of your medicines, in their original boxes and containers if you have them, with you when coming to the hospital.

#### Your medicines list will help hospital staff treat you safely.



#### IMPORTANT

To fill out **My Medicines** you need **all your medicines in front of you** including prescribed, non-prescribed and over the counter medicines. If you don't know what medicines you take or you need help filing out **My Medicines** ask your pharmacist, doctor, friend or relative to help you.

TALLAGHT HOSPITAL www.tallaghthospital.ie

working together to improve safety

# **My Medicines** (∎€ ZER **1** HARM

Information for patients and families

working together to improve safety

Name:			My Family Doct	or:	My Pharmacy is		
Date of Birth:	ate of Birth:		My Family Doct Phone No.:	or	My Pharmacy's Phone No.:		
The medicine I ar	n allergic to:			Other Allergies:			Date I filled out
							this form:
Nam	e of Medicine	The strength	How much medicine I take each time	i take it	l take it every day (Yes / No)	Why I ta	ke it?
A	BC Tablets	25mg	2 tablets	Twice a day every morning & evening	Yes	For my heart	
	War.						
752							

#### Helps you to keep track of your medicines

#### **More informed**

Allows you to have more time with your consultant/doctor/nurse/ pharmacist/dietician and focus on you





#### **Original containers**



**Blister pack** 



Look	Medication	Dose	Amount	Frequency	Started
	Atenolol	50 mg	1/2 Tablets	in the morning	02/27/13
93	Carvedilol Coreg	25 mg	1 Tablets 1 ½ Tablets	Wake Night	02/27/13
a st	Hydralazine Apresoline	25 mg	1/4 Tablets 1 1/2 Tablets 1 Tablets	Breakfast Dinner Night	02/15/13
	Insulin Exubera	100 units/mL	on sli Injection 15 Injection 20 Injection 20 Injection	Wake Lunch Dinner Night	02/09/13
RX S 3 S	Lisinopril	10mg	<sup>3</sup> ⁄4 Tablets	2x/day	02/10/13
	Morphine		1/2 Tablets	Wake	

#### What do you medicines look like?







