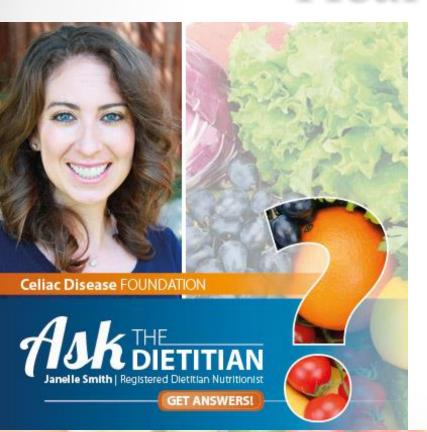
Gluten in Medications &

Heart Health



Special guest:

Steve Plogsted
PharmD, BCNSP, CNSC

Janelle Smith
CDF Registered Dietitian Nutritionist

February 11, 2015 12 pm PST



Today's Webinar

- Gluten in Medications with Steve Plogsted, PharmD
- Heart conditions in Celiac Disease
- Taking care of your heart



Steve Plogsted, Pharmd, BCNSP, CNSC

- Clinical pharmacist at Nationwide Children's Hospital in Cleveland, OH
- Involved in celiac disease since 1995, providing expert advice on gluten in medications
- Glutenfreedrugs.com





MEDICATIONS AND GLUTEN

Steve Plogsted, PharmD, BCNSP, CNSC



- Excipients can be obtained from any starch source, but are primarily derived from:
 - > Corn
 - > Potato
 - > Tapioca



 However, they have also been known to contain starch from Wheat



Frequently Used Excipients

The following are the most commonly used excipients in U.S.-manufactured drug products:

Magnesium Stearate >2500	Povidone
Lactose >2000	Pregelatinized Starch
Microcrystalline Cellulose >1500	Hydroxypropyl Methylcellulose
Starch (corn)	Coatings and Ink
Silicone Dioxide	Croscarmellose
Titanium Dioxide	Hydroxypropyl Cellulose >250
Stearic Acid	Ethycellulose
Sod Starch Glycolate	Calcium Phosphate
Gelatin	Crospovidine
Talc	Shellac (and Glaze)
Sucrose	Calcium Stearate



Starch

 US FDA regulations state that any product (used in drug manufacturing) labeled as starch can be derived from any source

Food starch is derived from corn only



Pregelatinized Starch

 A starch that has been chemically or mechanically processed. The starch can come from corn, wheat, potato or tapioca. Pregelatinized starch is a processed carbohydrate, used as a texturizer and/or binder. It is typically derived from corn, waxy corn, potato, or tapioca. It has nothing to do with gelatin. It is safe for vegetarians and vegans.



Sodium Starch Glycolate

 Sodium salt of carboxymethyl ether of starch. Usually from potato but can be from corn, wheat or rice.



Labeling Search Sept. 2008

- 4016 package inserts
- 1320 (33%) had "starch" as an ingredient
 - 399 pregelatinized starch
 - 53 pregelatinized starch (corn)
 - 383 corn (maize) starch
 - 141 starch
 - 8 potato starch
 - 3 wheat starch
 - 324 sodium starch glycolate



Maltodextrin-Wheat

(from the Glutenfree Dietitian Tricia Thompson)

- Wheat starch is not wheat grain and is not wheat protein
- Wheat starch hydrolysates (ie, maltodextrin and glucose syrups) have been tested to be below 20 PPM
- Benefiber, which contains wheat dextrin, has been tested by the Gluten Free Watchdog organization and is considered safe for celiacs



Clan Thompson

Mannitol: Gluten free: Yes. Vegetarian: Yes. Comments: Commercially produced by the electrolytic reduction or transition of sugar solutions or by fermentation of sugars. Can be produced from maltose. Although maltose is derived from barley - mannitol is refined so no protein remains in the final product.



Polyols/Sugar Alcohols

- Sugar alcohols or polyols, as they are also called, have a long history of use in a wide variety of foods
- Sugar alcohols are neither sugars nor alcohols. They are carbohydrates with a chemical structure that partially resembles sugar and partially resembles alcohol, but they don't contain ethanol as alcoholic beverages do.

- The polyols commonly used include sorbitol, mannitol, xylitol, maltitol, maltitol syrup, lactitol, erythritol, isomalt and hydrogenated starch hydrolysates
- Sugar alcohols occur naturally in a wide variety of fruits and vegetables, but are commercially produced from other carbohydrates such as sucrose, glucose, and starch.



Other Sources-The Drug Itself?

- Olmesartan (Benicar)
- Report of gluten like enteropath
- 22 patients reported (Mayo Clinic)
- Biopsies demonstrated villous atrophy and varying degrees of inflammation
- tTG antibodies were normal



Benicar® (olmesartan)

- Mayo Clinic reported on 22 patients taking the drug long term who developed severe celiac symptoms and intestinal changes that mimicked celiac disease
- The drug contained the following fillers:
 - hydroxypropyl cellulose, hypromellose, lactose monohydrate, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, talc, titanium dioxide, and (5 mg only) yellow iron oxide.



What about injectable drugs

Generally not a problem

Minimal excipients

Not ingested



Sources of Information

- Pharmaceutical manufacturer's drug information department
- Package insert
- Drug company web site
- Internet web sites
- Chat rooms/Blogs
- Your local pharmacist?
 - Besides asking the pharmacist about the gluten status don't forget to ask if the drug itself will cause intestinal issues



Internet Resources

- Glutenfree Drugs <u>http://www.glutenfreedrugs.com</u>
- Celiac Sprue A Guide Through the Medicine Cabinet, by Marcia Milazzo, http://www.celiacmeds.com
- Wheaton Gluten Free Support Group <u>http://homepage.mac.com/sholland/celiac/GFmedlist.pdf</u>
- DailyMed Provides high quality information about marketed drugs (US)
 http://dailymed.nlm.nih.gov/dailymed/about.cfm
- Pillbox Provides a way to search by ingredient http://pillbox.nlm.nih.gov/



NIH/NLM Pillbox Website

- Starch-8739 records
- Corn-6518 records
- Sodium Starch Glycolate-3207 records
- Potato-2934 records
- Maltodextrin-844 records
- Lactose-7955 records
- Soy-368 records
- Wheat-11 records







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Identify or Search for a Pill

letters or numbers on either side of the pill		Drug Name or	
Pill does not have an in	nprint.	Ingredient(s):	
Select Shape	•	Inactive Ingredient(s):	Find pills WITHOUT this ingredient.
Select Color	▼	Label Author:	
Select Size (search +/- 2	mm) 🔻	DEA Schedule:	Select DEA Schedule ▼
● Unknown □ 1 □ 2 □	3 0 4	Product Code:	
		☑ Do not sear	rch repackaged and relabeled medicati
	Select Shape Select Color Select Size (search +/- 2	☐ Pill does not have an imprint. Select Shape	Pill does not have an imprint. Select Shape ▼ Inactive Ingredient(s): Select Color ▼ Label Author: Select Size (search +/- 2mm) ▼ DEA Schedule: ● Unknown ● 1 ● 2 ● 3 ● 4 Product Code:

Celiac Disease FOUNDATION

Show Search Criteria

Search Results: 11 record(s) for "wheat".



Name: Tekturna HCT (aliskiren 150 MG / HCTZ 12.5 MG) Oral Tablet

Ingredient(s): Aliskiren mixture with Hydrochlorothiazide

Imprint: NVR;LCI Label Author: Novartis Pharmaceuticals

Corporation

Show More Information Drug Label Drug Information Links



Name: Tekturna HCT (aliskiren 300 MG / HCTZ 12.5 MG) Oral Tablet

Ingredient(s): Aliskiren mixture with Hydrochlorothiazide

Imprint: NVR; CVI Label Author: Novartis Pharmaceuticals

Corporation

Show More Information Drug Label Drug Information Links



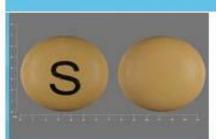
Name: Grifulvin V 500 MG Oral Tablet

Ingredient(s): Griseofulvin

Imprint: ORTHO;214 Label Author: Ortho-McNeil Pharmaceuticals

Show More Information Drug Label Drug Information Links

Drug Label



Name: Sanctura 20 MG Oral Tablet

Ingredient(s): Trospium

Show More Information

Imprint: S Label Author: Allergan, Inc.

Laber Author: Allergan, Inc.

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FOUNDATION

Drug InformatiCeliac Disease

Search Results: 1 record(s) for "Wheat | 0078-0521".



Name: Tekturna HCT (aliskiren 150 MG / HCTZ 12.5 MG) Oral Tablet

Ingredient(s): Aliskiren mixture with Hydrochlorothiazide

Imprint: NVR;LCI Label Author: Novartis Pharmaceuticals

Corporation

Hide More Information

Drug Label

Drug Information Links

Color(s): White

Shape: Oval

Size (mm): 15.00

Score: 1

Inactive Ingredient(s): silicon dioxide / crospovidone / hypromelloses / ferric oxide red / lactose / magnesium stearate / cellulose, microcrystalline / polyethylene glycols / povidone / talc / titanium dioxide /

starch, wheat

DEA Schedule: Non-scheduled

Product Code: 0078-0521

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Accessibility

Data updated: November 4, 2013





celiac.org

Contacting the Drug Manufacturer

Ask specific questions

- Does the medication contain any gluten
- Does the drug contain any starch
- Is there any special coating



Heart Health





What heart conditions are related to celiac disease?

- Arrhythmias
- Ischemic heart disease
- Idiopathic dilated cardiomyopathy –
 5.7% risk in those with CD

And now..... coronary artery disease



Risk of CAD in Celiac Disease

2014 study: "Celiac disease linked to almost doubled risk of CAD". Medscape. Mar 29, 2014

Age	CAD prevalence in CD (n=24,530)	CAD prevalence without CD (n=22.35 million)		
All ages 18+	9.5	5.6		
>65 yo	28.6	13.2		
18-65 yo	4.5	2.4		

Risk of stroke 1.4 times higher



Theory

"People with celiac disease have some persistent low-grade inflammation in the gut that can spill immune mediators into the bloodstream, which can then accelerate the process of atherosclerosis and, in turn, CAD"

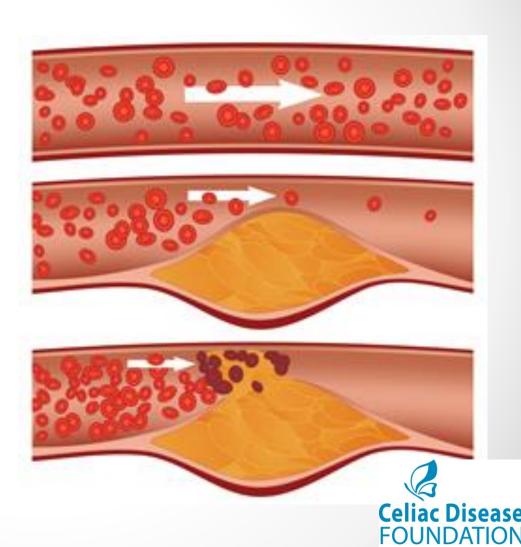
Risk also seen in "other inflammatory states like lupus erythematosus, rheumatoid arthritis, and inflammatory bowel disease"

- Dr. Rama Dilip Gajulapalli, Cleveland Clinic, OH



Atherosclerosis & CAD

- Inflammatory cells circulating through the blood stream can damage walls
- Healing process hardens, creates plaque
- Can burst, form blood clot and block blood flow



Protecting your Heart

Follow the gluten-free diet if you have CD!

- Minimal gluten intake may perpetuate low-level chronic inflammation....?
- Degree of villous atrophy seems to be unrelated to risk of heart disease

Lebwohl B, Emilsson L, Frobert O, Einstein AJ, Green PH, Ludvigsson JF. Mucosal healing and the risk of ischemic heart disease or atrial fibrillation in patients with celiac disease; a population-based study. PLoS One. 2015 Jan 30; 10(1):e0117529.



Heart-Protective Diet

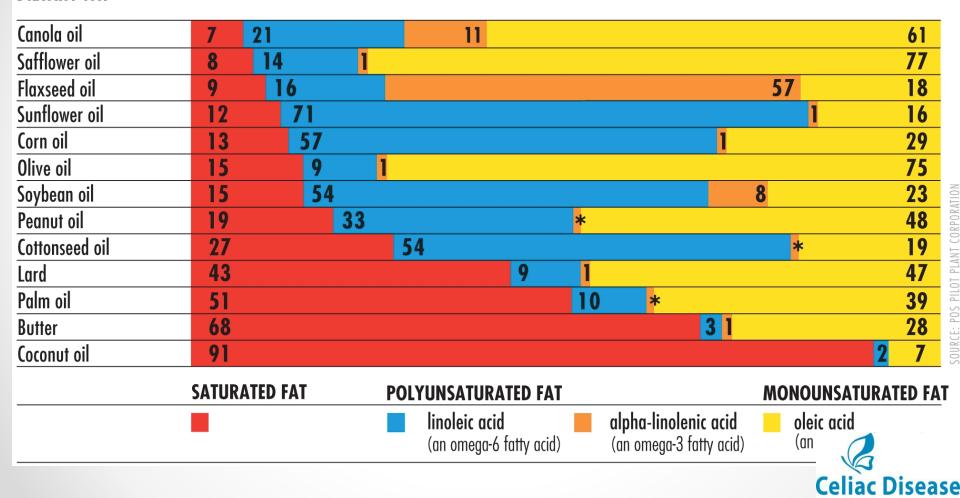
Balance omega-3's with omega-6's

- Polyunsaturated fatty acids found in both plant and animal sources
- Omega-6's are more common in US diet:
 - Vegetable oil, butter, lard



Fatty acid content of different fat sources

DIETARY FAT



FOUNDATION

Heart-Protective Diet

- Omega-6 fatty acids are precursors to inflammatory response
- Eating enough omega-3's may slow down/limit the inflammation response to life

Sources of Omega-3 fatty acids:

- Fish oil
- Flaxseed
- Walnuts
- Soybeans
- Canola oil



Benefits of Omega-3's

- Lower blood triglycerides (another risk factor for heart disease)
- Improve brain health:
 - o for growing infants and children
 - o for the aging dementia, Alzheimer's
- Mental health and depression
- Decrease inflammation in autoimmune diseases?



Fish oil is utilized better than vegetable oils



Meatless Mondays & Fatty Fish Fridays

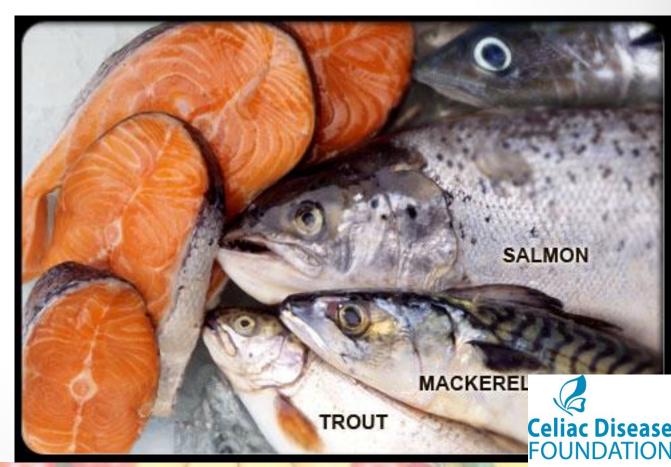
- Help you to get more plant and fish sources of fatty acids
- By default, decrease ratio of animal and omega-6 fatty acids
- Decrease dietary cholesterol and saturated fat
- Increase phytosterols plant "cholesterol" that block absorption of dietary cholesterol

Sun	Mon	Tues	Veq	Thur	Fri	Sat
	*				*	Cel FO

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Fatty Fish

- Salmon (wild is higher in omega-3's)
- Anchovies
- Bluefish
- Herring
- Mackerel
- Sardines
- Sturgeon
- Lake trout
- Tuna



More on plants and antioxidants

- Get 7 servings/day of fruits and vegetables
- Neutralize free radicals that would roam the body and damage cardiovascular system





Limit Sodium & Simple Sugars

- Sugar intake known to increase triglycerides and disrupt LDL/HDL balance
- Excess salt contributes to high blood pressure
- Choose whole foods over packaged foods
- Cook at home more than eating out





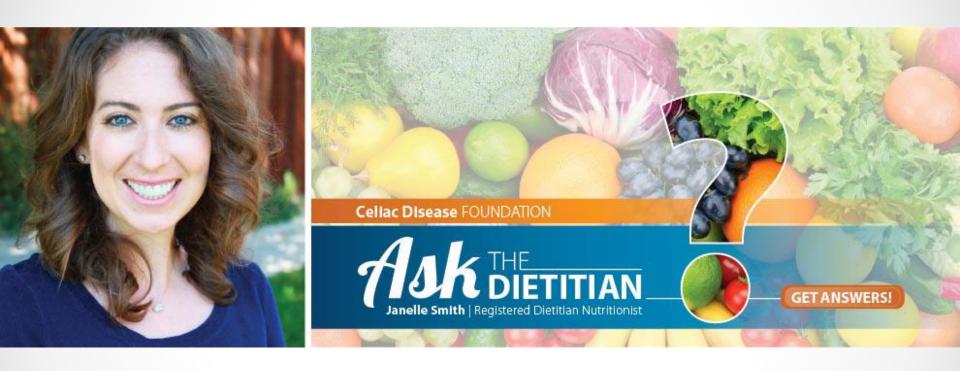
Physical Activity

- Take a walk on your lunch break
- Stand up at work and stretch 10 minutes/day
- If you're already active: balance your type of activity
- Incorporate yoga and stretching





Celiac.org/Webinars Celiac.org/Ask



Next CDF Ask the Dietitian Webinar:

To be announced

