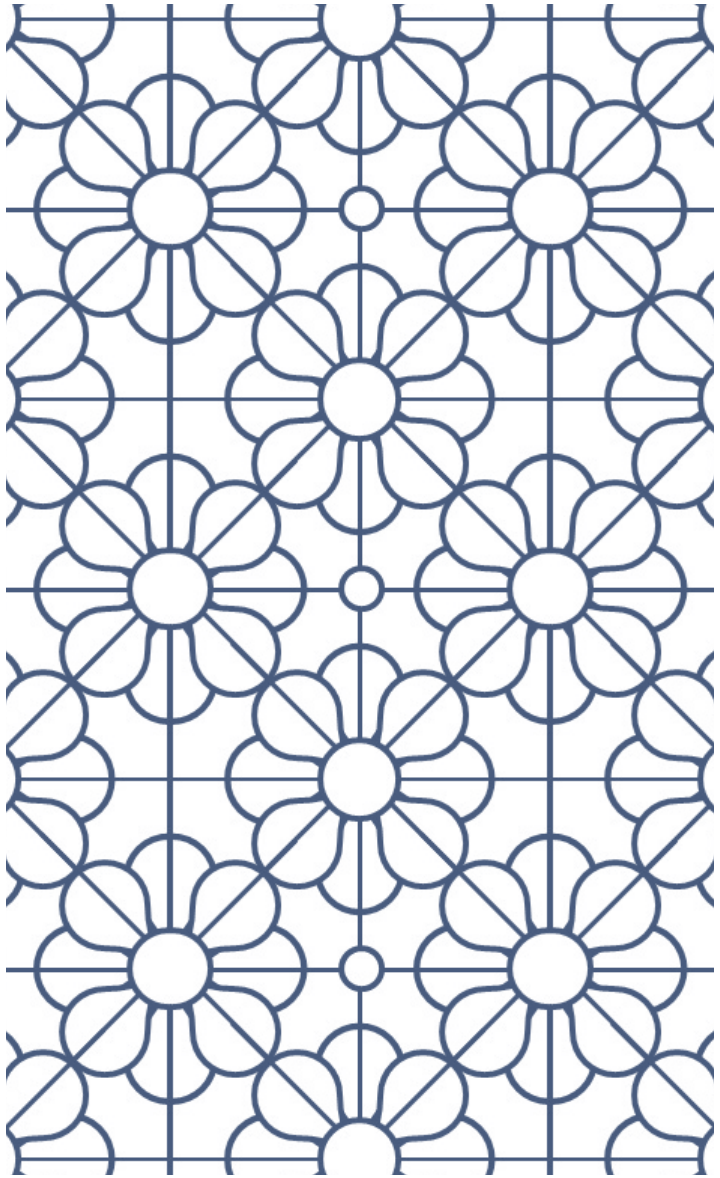


SAFE PRESCRIBING DURING PREGNANCY AND BREASTFEEDING

Silvia Duong, BScPhm PharmD CDE

McGill Annual Refresher Course for Family Physicians

December 6 2022

DECLARATION OF POTENTIAL CONFLICT OF INTEREST

Consultant and speaker for Novo Nordisk and Abbott

Consultant, speaker and advisory board for Eli Lilly

Once upon a time, during my training, I completed:

- Drug information rotation at Motherisk (Hospital for Sick Children, Toronto)
- Clinical rotation in high-risk pregnancy (CHU Sainte-Justine)

ABBREVIATIONS

ACEi	angiotensin-converting enzyme inhibitors
ARB	angiotensin-receptor blockers
BB	beta-blocker
BF	breastfeeding
DBP	diastolic blood pressure
G6PD	G6P deficiency
HDP	hypertensive disorders of pregnancy
NHP	natural health product
SBP	systolic blood pressure
TMP/SMX	trimethoprim/sulfamethoxazole
UTI	urinary tract infection

CHALLENGES IN CLINICAL PRACTICE

In Canada, 30-50% pregnancies are unplanned.

Use of drugs during pregnancy and while breastfeeding is understudied.

There are misinformation and misperceptions about fetal risks associated with use of medications during pregnancy and breastfeeding.

LEARNING OBJECTIVES

At the end of this session, the participant will be able to:

- Describe the key principles used in the assessment medication safety during pregnancy and breastfeeding.

- For the management of common conditions in primary care during pregnancy and while breastfeeding,
  - State the preferred treatment options.
  - Assess the efficacy/risk associated with a particular medication.
  - List medications that should be avoided.

- List useful resources that may be used to discuss efficacy and potential risk of medication use during pregnancy and while breastfeeding.

MEDICATION USE

Pregnancy

- In every healthy pregnancy, there is a 2 - 4% risk of having a child with a major malformation.
- Only about 1% of major malformations are attributed to drugs, chemical and physical exposures during pregnancy.

Breastfeeding

- Milk/plasma ratio: transfer of medications from maternal plasma compartment to milk
- Relative Infant dose
  - RID (%) = absolute infant dose (mg/kg/day) via milk / maternal dose (mg/kg/day)

Schaefer C *et al.* (2015). *Drugs During Pregnancy and Lactation treatment Options and Risk of assessment*. Academic Press.
https://mothertobaby.org

CASE 1 - CHARLENE

Age 38

PMHx:

- diabetes type 2 with proteinuria
- hypertension
- hypothyroidism

BP 145/92 HR 85

BMI 29

Rx:

Metformin 500 mg PO BID (not taking)

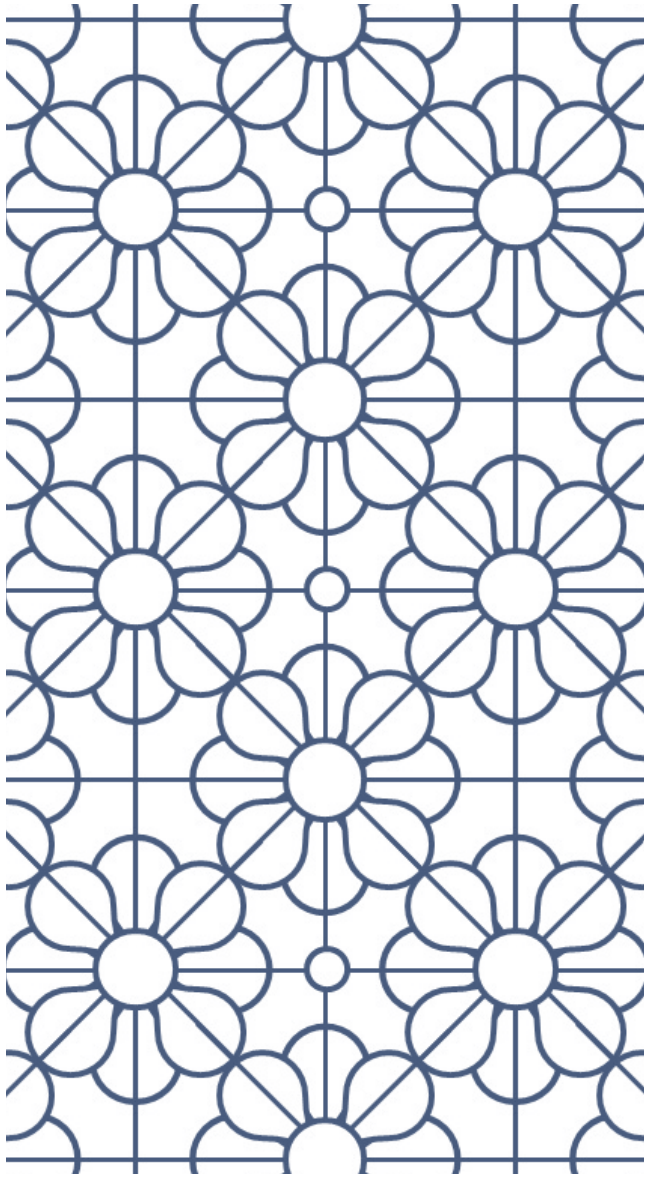
Empagliflozin (Jardiance®) 10 mg PO daily

Perindopril (Coversyl®) 16 mg PO daily

Amlodipine (Norvasc®) 5 mg PO daily

Levothyroxine (Synthroid®) 100 mcg PO daily

	Today	6 months ago
HbA1c	8.2%	7.2%
GFR	79	82
ACR	5.6	2.8
TSH	2.36 mIU/L	



- Metformin should not be used for the treatment of diabetes during pregnancy and breastfeeding.

- For the treatment of hypertension during pregnancy, perindopril should be stopped but amlodipine may be continued.

- For the management of hypothyroidism, the dose of levothyroxine should be increased by 50% when Charlene becomes pregnant.

TRUE OR FALSE ?

DIABETES

Women with pre-existing diabetes (Diabetes Canada)

Target:

- when planning pregnancy, HbA1c ≤ 7% (ideally ≤ 6.5% if possible), or
- during pregnancy, HbA1c ≤ 6.5% during pregnancy (ideally ≤ 6.1% if possible)
- optimal weight (start weight loss before pregnancy with healthy eating)

Start folic acid 1 mg PO daily at least 3 months preconception

Review medications and discontinue those that are potentially embryopathic.

Can J Diabetes 2018;42:S255-2282

Preferred	Alternative	Lack of Data

• Basal Insulin
  • NPH *
  • Determir (Levemir®)
  • Glargine (Lantus®)
  • Degludec (Tresiba®)
• Prandial Insulin
  • Aspart (Novorapid®
  • Lispro (Humalog®)
	• Metformin
	• Glyburide (Diabeta®)
		• Repaglinide
		• Other sulfonylureas
		• Acarbose
		• Thiazolidinediones
		• GLP1 receptor agonists
		• DPP4-inhibitors
		• SGLT2-inhibitors

TREATMENT OF DIABETES DURING PREGNANCY AND BREASTFEEDING

Can J Diabetes 2018;42:S255-2282F
Ferreira E *et al.* (2013) Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine

HYPERTENSION DUIRNG PREGNANCY

Hypertension Canada and SOGC Clinical Practice Guidelines :

- Antihypertensive therapy is recommended for average SBP ≥ 140 mm Hg and DBP ≥ 90 mm Hg in pregnancy with chronic hypertension, gestational hypertension or preeclampsia
- A DBP of 85 mm Hg should be targeted for pregnant women receiving antihypertensive therapy with chronic hypertension or gestational hypertension

Replacing ACEi or ARBs with other antihypertensives in women planning pregnancy is recommended unless there is a compelling clinical indications not to.

Canadian Journal of Cardiology 2018;34:526-531
J Obstet Gynaecol Can 2022 May;44(5):547-571

TREATMENT OF HYPERTENSION DURING PREGNANCY

1st line agents	2nd line	Not recommended
• Methyldopa • Labetalol • Long-acting oral nifedipine • Other BBs (acebutalol, metoprolol, pindolol, and propranolol)	• Hydralazine • Clonidine • Thiazide diuretics	• ACE inhibitors • ARBs

Ferreira E *et al.* (2013) Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine

TREATMENT OF HYPERTENSION IN BREASTFEEDING

	Comments	Preferred Agents
Methyldopa	Compatible with BF	
Clonidine	Compatible with BF	May be used as add-on treatment
Beta-blockers	If possible, avoid atenolol and acebutalol Avoid bisoprolol in premature infants	Prioritize BB with short half-life and strong protein binding: labetalol, propranolol, metoprolol
Calcium channel blockers	Low transfer with verapamil, diltiazem	nifedipine
Hydralazine	Less documented, but transfer seem low	
Diuretics	Thiazide diuretics are not 1st line therapy	Hydrochlorothiazide, furosemide, spironolactone
ACE inhibitors ARBs	ACEi preferred over ARB Lack of data with cilazapril, lisinopril, perindopril, trandolapril	Ramipril, enalapril

Ferreira E *et al. (2013)* Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine

HYPOTHYROIDISM

Before Pregnancy

- Target TSH < 2.5 mUI/L
- At pregnancy, increase dose of levothyroxine by 30% (take extra 2 tablets weekly of their usual daily levothyroxine dosage)

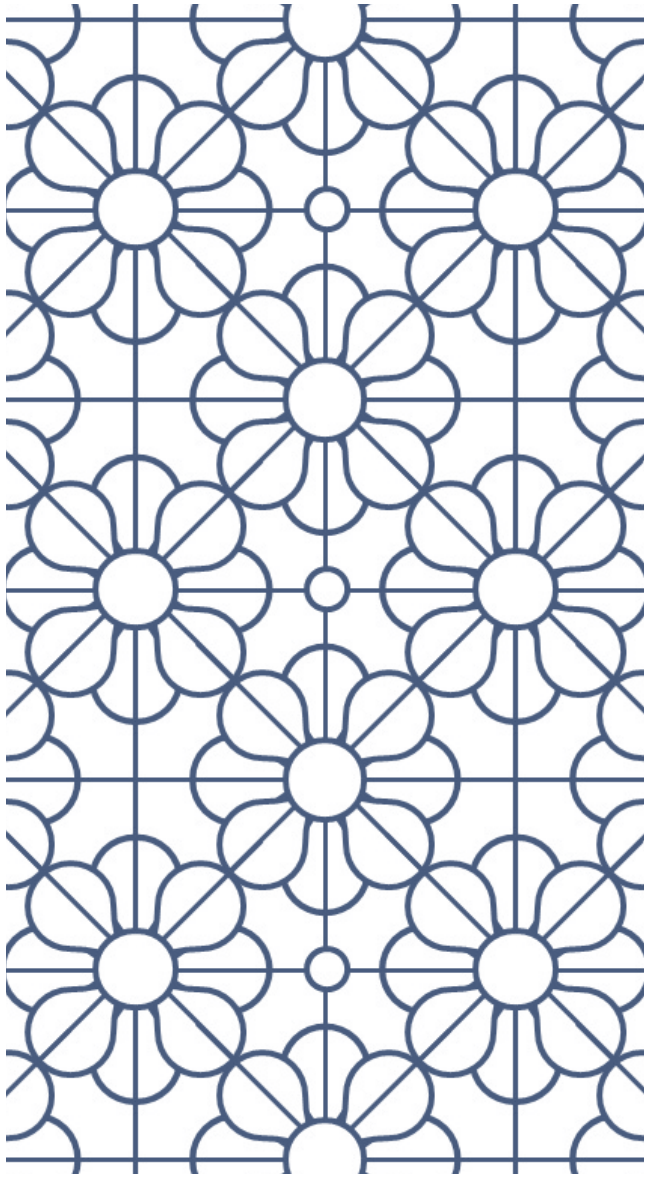
Pregnancy

- Target TSH < 2.5 mUI/L in 1st trimester; < 3 mUI/L in 2nd and 3rd trimester
- Monitor TSH at least at every trimester

Post-partum

- Restart pre-pregnancy levothyroxine dose
- Repeat TSH 6 – 8 weeks post-partum

www.thyroid.org/hypothyroidism-in-pregnancy/
Ferreira E *et al.* (2013) Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine



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	Today	6 months ago
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TREATMENT OF COLD

		Pregnancy	Breastfeeding
Analgesics	Acetaminophen	Drug of choice	
	ASA Ibuprofen	ASA and NSAIDs may be used in 1st and 2nd trimester Low-dose ASA (40-150 mg/day) is considered safe in all trimesters	
Systemic decongestants	Pseudoephedrine	It may be prudent to avoid use in 1st trimester Use lowest dose ands shortest duration possible	Systemic decongestants are best avoided.
Inhaled decongestants	Oxymetazoline Xylometazoline	May be used at appropriate doses for short durations	Drug of choice
Antitussives	Codeine	Avoid	Avoid
	Dextromethorphan	Preferred antitussive in pregnancy and lactation	
Antihistamines	Diphenhydramine Chlorpheniramine	1st generation is preferred If not tolerated, 2nd generation may be considered	2nd generation agents are preferred
Lozenges		Safe	Safe
Herbals for coughs and cold		AVOID – echinacea and gingseng Vitamin C up to 2000 mg/day Zinc lozenges – up to 40mg/day	

Canadian Family Physician. 2008;54:687-689
Ferreira E *et al. (2013)* Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine

CASE 2 - JUDY

Age: 29

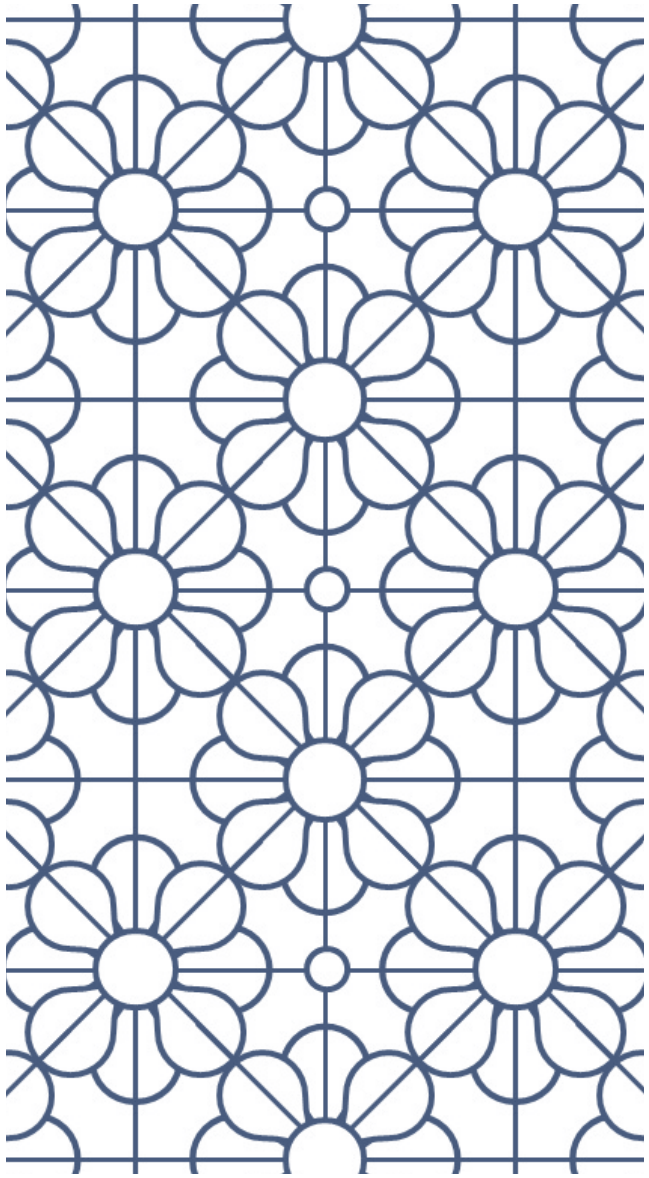
PMHx:

- Depression/anxiety
- Seizure
- Insomnia

Rx:

- Bupropion XL (WellbutrinXL) 300 mg PO daily
- Leviteracetam (Keppra®) 500 mg PO BID
- Zopiclone (Imovane®) 7.5 mg PO HS PRN

Others: cannabis (1 joint daily)



- Bupropion should not be used during pregnancy and breastfeeding.
- Leviteracetam is not the preferred treatment choice for the management of seizures during pregnancy.
- For management of insomnia during pregnancy, off-label use of dimenhydrinate is preferred to zopiclone.

TRUE OR FALSE ?

TREATMENT OF DEPRESSION DURING PREGNANCY

Preferred Options	Seem safe	Lack of data	Avoid
• SSRI – Citalopram, fluoxetine, sertraline • SNRI - Venlafaxine	• Bupropion • Duloxetine • Mirtazapine • Quetiapine	• Desvenlafaxine • Vortioxetine • Levomilnacipran • Vilazodone • Aripiprazole	• MAOIs • SSRI - Paroxetine

Ferreira E *et al.* (2013) Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine

TREATMENT OF DEPRESSION DURING BREASTFEEDING

Preferred Options	Seem safe (less data)	Not first line
• SSRI –Citalopram, paroxetine sertraline • SNRI - Venlafaxine	• Bupropion • Mirtazapine • Quetiapine • Duloxetine	• Fluoxetine

Ferreira E *et al.* (2013) Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine

SEIZURES

- Monitoring of drug levels at the beginning of each trimester and during the last month of pregnancy for women whose seizures are controlled.
- Additional monitoring is recommended if seizures are not controlled.

	Pregnancy	Breastfeeding
1st generation anti-epileptic drugs		
Valproic acid (VPA)	Highest associated with higher risk of congenital malformation (10%)	Compatible Monitor for sedation, hepatoxicity and signs of bleeding
Carbamazepine	Risk is comparable to other 1st generation antiepileptics Teratogenic risk is lower than than VPA	compatible
Phenobarbital, primidone		Caution if not used during pregnancy
Phenytoin		compatible
2nd generation anti-epileptic drugs		
Lamotrigine	Not associated with higher risk of malformation	seem compatible (caution)
Leviteracetam	Not associated with higher risk of malformation	seem compatible
Topiramate	Limited data suggest that it is safe	seem compatible

www.epilepsy.com

Ferreira E *et al.* (2013) Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine

Pregnancy & Anti-seizure Drugs

Women who take anti-seizure drugs need to plan well ahead for pregnancy

1-2 Years Before Pregnancy

Avoid valproate

- Valproate has the highest risk of birth defects
- Change it to a safer anti-seizure drug

Minimize the number and doses of anti-seizure drugs

- Use the lowest effective dose
- Use only one anti-seizure drug if possible

Start up to 5mg of folic acid daily

Aim to be seizure-free for at least 9 months before pregnancy to lower risk of seizures during pregnancy

During Pregnancy

Avoid stopping or switching anti-seizure drugs during pregnancy

Check serum drug levels if there are more seizures

- Especially with lamotrigine and levetiracetam
- Adjust phenytoin doses using free concentrations, not total concentrations

Watch for new drug interactions

- Folic acid may decrease phenytoin serum concentrations
- Antacids may decrease phenytoin absorption

After Delivery

Doses of anti-seizure drugs may need to be adjusted

It is generally safe to breastfeed with anti-seizure drugs

Watch baby for side effects such as:

- Poor suck
- Poor weight gain
- Drowsiness
- Hyperexcitability

Developed by: Kelly Grindrod, PharmD; Tejal Patel, PharmD. Design by Adrian Poon, BA; Allysa Misola.
Acknowledgements: Jessica Ivo, Sadaf Faisal, Rosemary Killeen, Dr. Eduard Bercovici, and 11 other women with epilepsy, pharmacists, and family physicians.

Women's College Hospital women's xchange | epilepsy south central ontario | University of Waterloo School of Pharmacy

Contraception & Anti-seizure Drugs

Women who take anti-seizure drugs need to carefully consider their birth control options

The problem:

In most cases, anti-seizure drugs can make hormonal birth control less effective, but in some cases hormonal birth control can make anti-seizure drugs less effective. So...

What should you do?

Option 1 — Change the anti-seizure drug

Likely to cause hormonal failure	Less likely to cause hormonal failure
Carbamazepine	Brivaracetam*
Eslicarbazepine	Clobazam
Oxcarbazepine	Ethosuximide
Perampanel (≥12mg/day), including levonorgestrel	Gabapentin
Phenobarbital	Lacosamide
Phenytoin	Levetiracetam
Primidone	Lamotrigine
Rufinamide	Pregabalin
Topiramate	Vigabatrin
	Stiripentol

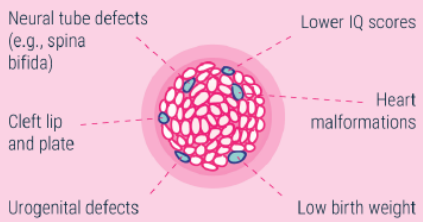
*No effect on estrogen at 100mg/day. Does decrease estrogen concentrations at 400mg/day but does not appear to affect ovulation.

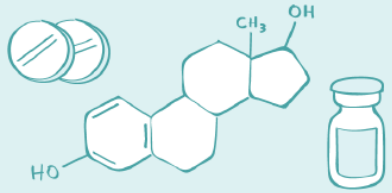
Option 2 — Change the contraception

In Canada, birth control options that are safer with anti-seizure drugs include:

1. Levonorgestrel/copper intrauterine device (IUD)
2. Medroxyprogesterone depot injection every 10 - 12 weeks + condoms/vaginal diaphragms
3. Continuous cycle estrogen-progestin pill
   - Containing at least 30µg of estrogen
   - Taken every day of the month
   - With a 4 day break every 3 months
   - Plus condoms/vaginal diaphragms

Anti-seizure drugs can cause birth defects if taken during pregnancy.





Did you know? Estrogen makes the body break lamotrigine and valproate down faster, which can lead to more seizures[1]. In women taking lamotrigine and/or valproate, use a higher dose or choose a birth control that doesn't contain estrogen.

1. Gaffield ME et al. Contraception 2011; 83:16 – 29.
2. Landmark CJ et al. Expert Rev. Neurother 2010; 10: 119 – 140.
3. Zaccara G et al. Epileptic Disord 2014; 16: 409 – 432.
4. Gooneratne IK et al. BMJ 2017; 357:j2010
5. Schwenkhagen AM et al. Seizure 2008; 17: 145 – 150.
6. Harden CL et al. Neurology 2009; 73: 133 – 141.
7. Tomson T et al. Lancet Neurol 2012; 11: 803 – 13.
8. Gooneratne IK et al. Postgrad Med J 2016; 92: 554-559.
9. Harden CL et al. Neurology 2009; 73: 126 – 132.
10. National Institute for Health and Care Excellence. NICE Clinical Guideline [CG 137]. Available at https://www.nice.org.uk/guidance/cg137/resources [Accessed Feb 6, 2019]

Developed by: Kelly Grindrod, PharmD; Tejal Patel, PharmD. Design by Adrian Poon, BA; Allysa Misola.

INSOMNIA

	Pregnancy	Breastfeeding
Benzodiazepine	Data suggest use is not associated with increased risk of malformation May limit use week 7 - 14 Preferred agent: lorazepam and oxazepam for regular use	PRN use Preferred: lorazepam, oxazepam
Zolpidem, zopiclone	Current data suggest that it is safe PRN use	Low transfer PRN use
2nd and 3rd generation antipsychotics	Preferred: olanzapine Other options: quetiapine, risperidone, paliperidone	Preferred: olanzapine, quetiapine
Trazodone	Available data suggest that it is safe	Lack of data May be used if other agents not effective
Melatonin	Lack of data (probably safe)	
Mirtazapine	Available data suggest that it is safe	Limited suggest low transfer Monitor for awakening, weight of baby

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CANNABIS DURING PREGNANCY AND BREASTFEEDING

Research continues to show that cannabis may negatively impact a mother and developing baby.

There is no known amount of cannabis that is safe to consume during pregnancy and breastfeeding.

It is safest to avoid cannabis products during pregnancy and while breastfeeding.

www.pregnancyinfo.ca/wp-content/uploads/2019/12/SOGC_13333_cannabis_posters_1_faq_EN2.pdf
www.perinatalsservicesbc.ca/Documents/Resources/cannabis-in-pregnancy-practice-resource.pdf

CASE 2 - JUDY

Age: 29

PMHx:

- Depression
- Seizure
- Insomnia

Rx:

- Bupropion XL (Wellbutrin XL) 300 mg PO daily
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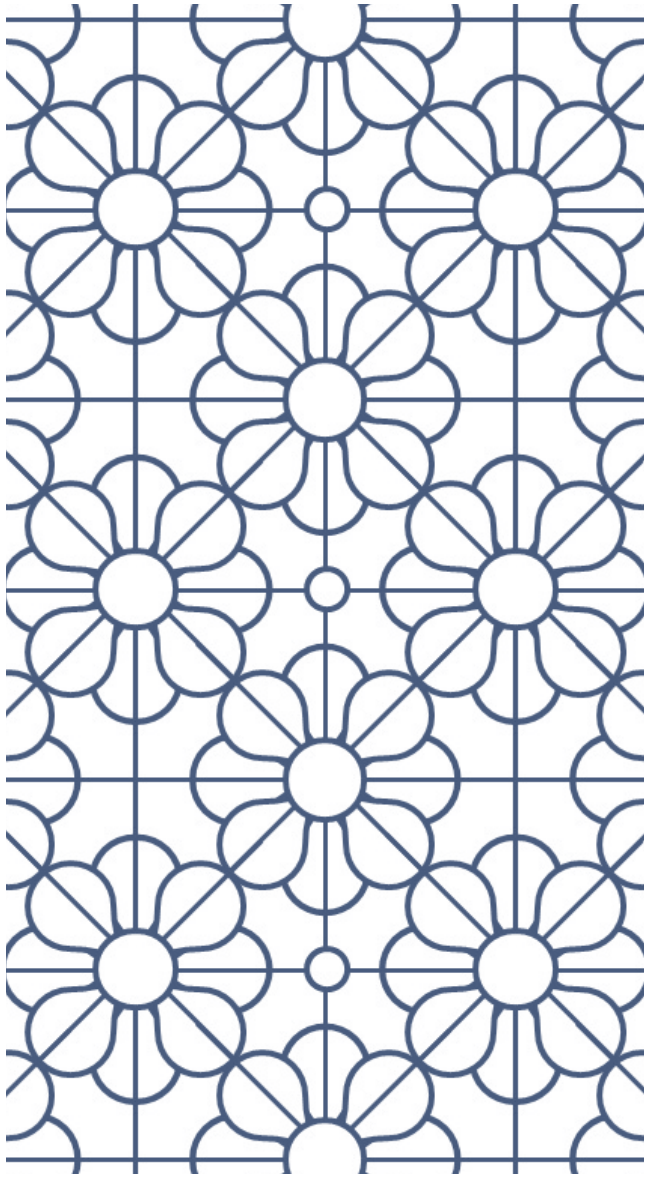
Others: cannabis (1 joint daily)



- Bupropion should not be used during pregnancy and breastfeeding.
- Leviteracetam is not the preferred treatment choice for the management of seizure during pregnancy.
- For management of insomnia during pregnancy, off-label use of dimenhydrinate is preferred to zopiclone.

TRUE OR FALSE ?

CASE 3 – CHARLOTTE

Age: 30

PMHx: migraine, anemia

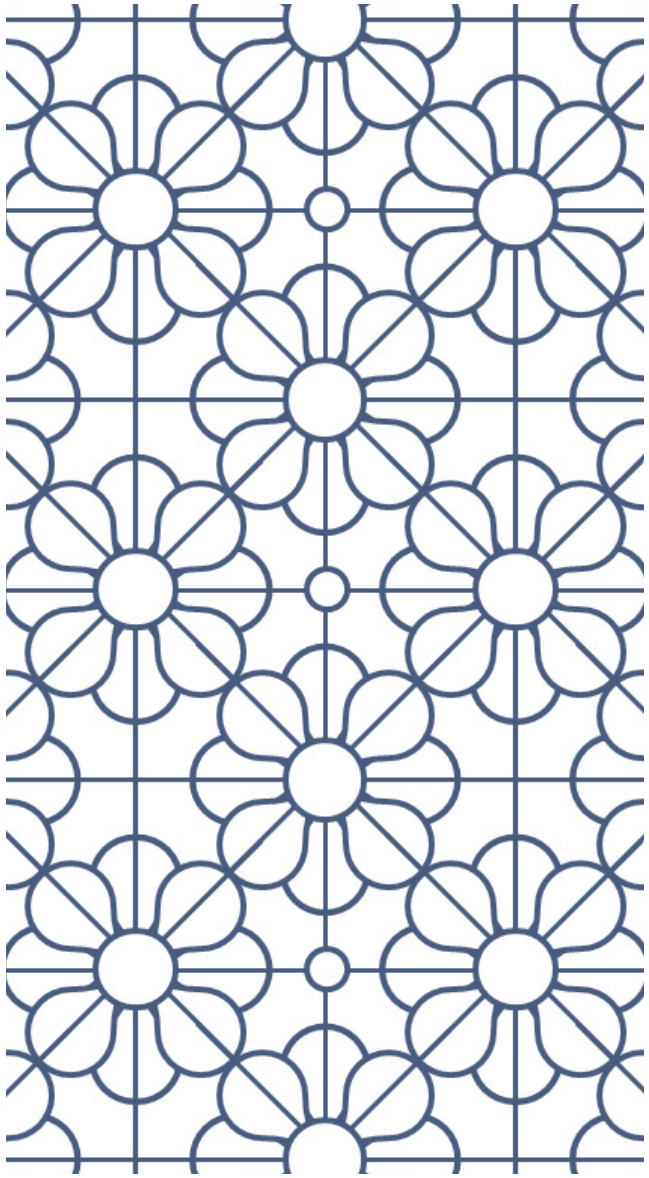
Pregnancy - 8 week

Reason for consultation:

- Sx of UTI
- Constipation

Rx:

- Sumatriptan (Imitrex®) 50 mg PO daily PRN
- Ibuprofen 400 mg PO TID PRN
- Prenatal multivitamin 1 tablet PO daily
- Ferrous fumarate 300 mg PO daily



- For the management of migraines, triptans may be used during pregnancy but should be avoided during breastfeeding.
- For the treatment of UTI, nitrofurantoin may be prescribed during pregnancy.
- For the treatment of constipation, polyethylene glycol 3350 should be used to relieve constipation during pregnancy.

TRUE OR FALSE ?

MIGRAINES IN PREGNANCY

- Identify and avoid triggers
- Good sleep hygiene
- Maintain good hydration
- Have a treatment plan and back up plan

	Pregnancy	Breastfeeding
Acetaminophen	Drug of choice	
NSAIDs	Avoid after week 20	Compatible Preferred choices: diclofenac, ibuprofen, indomethacine, naproxen
Triptans	Preferred agent : sumatriptan	Compatible
Ergotamine Dihydroergotamine	Avoid	
Opioids	Safe Prioritize codeine and morphine during 1st trimester	
Prophylaxis (preferred choices)	- Propranolol - Metoprolol - Amitriptyline - nortriptyline	- Propranolol - Metoprolol - Amitriptyline - nortriptyline
NHP	Not recommended: Co-enzyme Q10, feverfew, riboflavine	Lack of data

Ferreira E *et al.* (2013) Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine
Canadian Family Physician. 2010;56(6):5370539

PAIN MANAGEMENT

	Pregnancy	Breastfeeding
Acetaminophen	Drug of choice	
NSAIDs	Avoid after week 26 Diclofenac – preferably avoid during 3rd trimester	Compatible Preferred: diclofenac, ibuprofen, indomethacin, naproxen
Celecoxib	Not recommended (lack of data)	
Cyclobenzaprine	May be used	PRN use generally compatible
Opioids	Most data with codeine, morphine	PRN use generally compatible Monitor for adverse effects (sedation, lethargy, constipation, nausea) when treatment is longer than 3-4 days, especially when BF premature child or child < 2 months

Ferreira E *et al.* (2013) Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine
Canadian Family Physician. 2010;56:25-26

TREATMENT OF UTI

		Pregnancy	Breastfeeding
Asymptomatic bacteriuria Acute cystitis	1st line treatment	Amoxicillin Cephalexin nitrofurantoin	Nitrofurantoin TMP/SMX
	2nd line	TMP-SMX Trimethoprim	Ciprofloxacin, levofloxacin Amoxicillin/clavulanate Ofloxacin Trimethoprim
	Group B Streptococcal infection	Penicillin V Amoxicillin Clindamycin	
Pyelonephritis (oral)	Cephalexin Cefprozil Amoxicillin/clavulanate TMP-SMX		Ciprofloxacin, levofloxacin, ofloxacin, TMP/SMX Cephalaxin, Cefprozil Amoxicillin/clavulanate

Ferreira E *et al.* (2013) Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine
https://www.rxfiles.ca/RxFiles/uploads/documents/members/CHT-Peri-Pregnancy-DrugTx.pdf

ANTIBIOTICS

	Pregnancy	Breastfeeding
Cephalosporins	safe	compatible
Clindamycin	safe	compatible
Fluoroquinolones	Prioritize other antibiotics with more safety data Preferred: ciprofloxacin, norfloxacin	compatible
Macrolides	Azithromycin, erythromycin - safe	azithromycin, clarithromycin, erythromycin are compatible
Metronidazole	safe	compatible with doses of 200-500 mg Stop BF x 24-48 hrs after dose of 2 g
Nitrofurantoin	safe	compatible if not G6PD
Penicillin, amoxicillin, cloxacillin, clavulanic acid	safe	compatible
Sulfamethoxazole	Not recommended in 1st trimester	compatible if not G6PD
Trimethoprim		compatible
Tetracyclines	Avoid starting from week 6	compatible if duration of treatment < 3 months

Ferreira E *et al. (2013)* Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine
https://www.rxfiles.ca/RxFiles/uploads/documents/members/CHT-Peri-Pregnancy-DrugTx.pdf

CONSTIPATION

Treatment	Examples	Pregnancy	Breastfeeding
Bulk-forming agents	Psyllium, bran	1st line	compatible
Stool softeners	Docusate sodium	1st line	
Lubricant laxatives	Mineral oil	Not recommended	
Osmotic laxatives	Lactulose, polyethylene glycol	Lactulose – 1st line PEG 3350 recommended for chronic constipation	
	Salts Magnesium sulfate or citrate Hydroxide magnesium Sorbitol	Not recommended	
Stimulants	Senna	1st line	
	Bisacodyl	2nd line	
Glycerin suppository		1st line	

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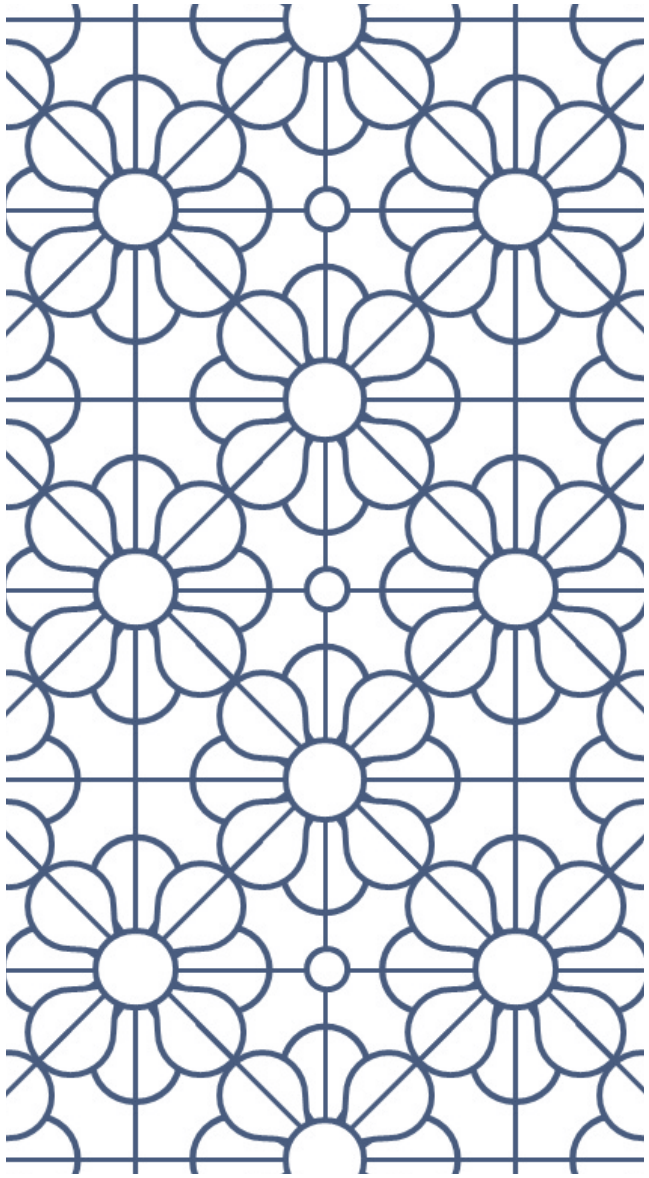
Canadian Family Physician. 2012;58(8):836-838



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TRUE OR FALSE ?

DRUG INFORMATION

- Briggs Drug in Pregnancy and Lactation (via Lexicomp)
- Drugs and Lactation Database (LactMed)
- MothertoBaby.org
  - Fact sheets
- Shaefer C *et al*. Drug During Pregnancy and Lactation: Treatment Options and Risk Assessment (3rd edition)
- Ferreira E *et al*. Grossesse et Allaitement Guide Thérapeutique (2e edition)

MEDICATIONS TO AVOID DURING PREGNANCY

- ACE inhibitors and ARBs
- antineoplastic agents – to be verified
- amiodarone (starting from week 12)
- androgens (starting from week 9)
- antiepileptics: valproic acid, carbamazepine, phenobarbital, phenytoin
- iodine (starting from week 12)
- isotretinoin
- lithium
- methimazole
- misoprostol, mycophenolate
- NSAIDs (3rd trimester)
- tetracyclines (week 16)
- trimethoprim
- warfarin (week 6)

Ferreira E *et al. (2013)* Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine

MEDICATIONS TO AVOID DURING BREASTFEEDING

amiodarone

antineoplastic drugs

beta-blockers – preferred agents: labetalol, metoprolol, propranolol

iodine 131

lamotrigine

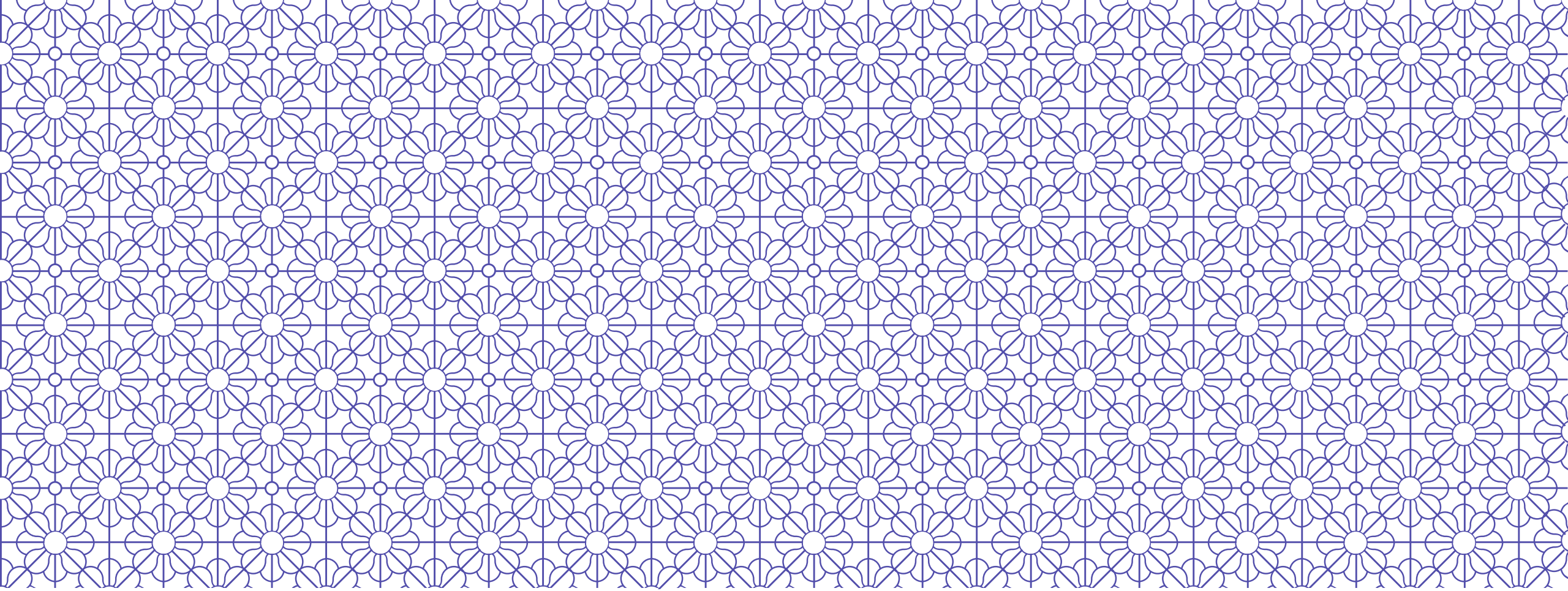
lithium

tetracyclines (>3 weeks)

Ferreira E *et al. (2013)* Grossesse et allaitement. Guide thérapeutique 2e edition. Editions CHU Sainte-Justine

IN SUMMARY

- Preconception counselling
- Discuss benefit/risk with pts
- Establish whether monitoring parameters are needed.



QUESTIONS?