

PRESCRIBING IN PREGNANCY & LACTATION

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Course objective

- To highlight some statistics on pregnancy/nursing mothers and medication use
- To review physiological systemic and ocular changes that can occur during pregnancy
- To review pathological ocular changes that can occur during pregnancy
- To review how pregnancy can affect pre-existing conditions
- To review pregnancy categories and labeling of medications
- To review medications to prescribe and avoid during pregnancy

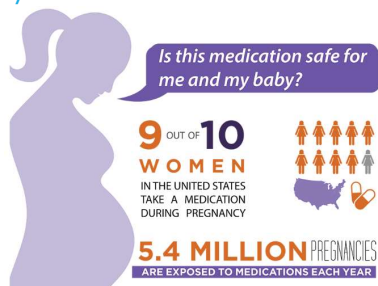
Outline

- Pregnancy Statistics
- Changes During Pregnancy
 - Physiological systemic changes
 - Physiological ocular changes
 - Pathological ocular changes
 - Pre-existing conditions
- Pregnancy Categories/Labeling of Medications
- Prescribing

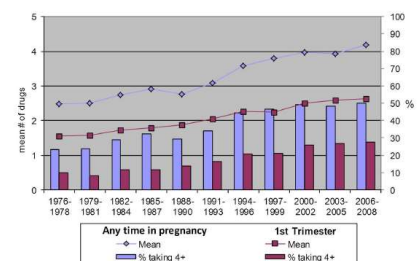
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Pregnancy Statistics



Pregnancy Statistics

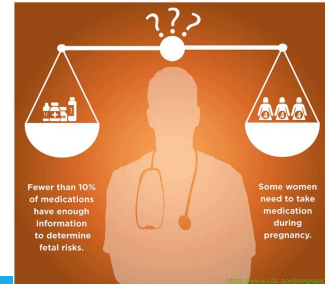


Pregnancy Statistics

HOW SOME MEDICATIONS CAN BE HARMFUL



Pregnancy Statistics



Pregnancy Statistics

**Women and healthcare providers
DON'T HAVE ENOUGH INFORMATION
to make INFORMED DECISIONS**

Pregnancy Statistics

Where are pregnant women getting their information from?

- Internet
 - 2011 study: Websites –
 - 50% women look for health information on the internet
 - 43% of meds listed "safe" – unable to determine fetal risk based on published scientific literature
 - Websites do not encourage women to seek information from health care providers
 - 2015 study: YouTube video content – inconsistent and not accurate
 - Law firm videos: 67%
 - Television segments: 10%
 - Physicians: 8%

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4048648/>

Prescription Medicines



Birth control pills
A medicine to prevent pregnancy

Amoxicillin
A medicine to treat infections

Progesterone
A hormone to treat many conditions

Albuterol
A medicine to help control asthma

Promethazine
A medicine to help with allergies or nausea

Over-the-Counter Medicines



Acetaminophen
A medicine to help with pain – Brand name: Tylenol®

Ibuprofen
A medicine to help with pain – Brand name: Advil®, Motrin®

Docusate
A medicine to soften stool

Pseudoephedrine
A medicine to treat cold symptoms

Aspirin
A medicine used to treat many conditions, including pain

Naproxen
A medicine to help with pain – Brand name: Aleve®

Statistics: Take home points

- Majority of pregnant women take medications
- Majority of medications do not have sufficient fetal safety data
- A lot of information on the internet on medications
- As a clinician, know the facts to help guide the management of pregnant patients

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Changes During Pregnancy

Physiological systemic changes

- Body water metabolism:
 - Water retention
- Hematologic:
 - ↑ Plasma volume, hypercoagulable state, venous stasis in lower limbs
- Cardiac:
 - ↑ Cardiac output, ↑ stroke volume



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581867/>

Changes During Pregnancy

Physiological systemic changes

- Renal:
 - ↑ Glomerular filtration rate, renal vasodilation, and renal plasma flow
- Respiratory changes:
 - ↑ O₂ demand & ↑ O₂ consumption
- Adaptive changes in digestive tract:
 - Displacement of digestive organs, GERD



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581867/>

Changes During Pregnancy

Physiological systemic changes

- Endocrine:
 - Thyroid: fluctuations in TSH levels, ↓ iodine
 - Adrenal gland: hypercortisolism
 - Pituitary gland: pituitary gland enlarges
 - Glucose metabolism: insulin resistance (2nd and 3rd trimester)
 - Lipid metabolism: ↑ total serum cholesterol and triglyceride
 - Protein metabolism: ↓ protein catabolism
 - Skeletal and bone density changes: maternal skeletal changes to accommodate growing fetus and child birth

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581867/>

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Changes During Pregnancy

Physiological ocular changes:

- Lid/Skin:
 - Chloasma (5%-70%)
- Conjunctiva:
 - Subconjunctival hemorrhages (10%)
- Cornea:
 - Reduced sensitivity, increased thickness (14%), change in refractive strength, change in tear composition (14%), Krukenberg's spindles (3%)
- Lens:
 - Increased thickness, refractive change (14%), transient loss/weakness/paralysis in accommodation
- Optic nerve/optic pathway:
 - Enlargement of pituitary gland
- IOP:
 - Decreased IOP (~10% IOP decrease)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4581867/>
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Changes During Pregnancy

New pathological changes:

- Ptosis (unilateral)
- Central serous chorioretinopathy (CSCR)
- Preeclampsia (HTN, edema, proteinuria)/Eclampsia
 - 40%-100% show signs of hypertensive retinopathy
 - 25-50% report visual symptoms: blurred to decreased vision, photopsia, VF defects, diplopia, blindness
- Occlusive vascular disorders:
 - Purtscher-like retinopathy, branch and central retinal artery occlusion, branch and central retinal vein occlusion
- Idiopathic intra-cranial hypertension (IIH):
 - Precipitated/aggravated in pregnancy

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC451589/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863459/>
<https://www.aao.org/eye/article/ocular-changes-during-pregnancy>

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Changes During Pregnancy

Pre-existing conditions:

- Diabetes: worsening of DR or ME
 - Gestational diabetes: not risk factor for DR
- **Improve:**
 - Uveitis, Vogt Koyanagi Harada syndrome (VKH), sarcoidosis, spondyloarthropathy, rheumatoid arthritis
- **Worsen:**
 - Toxoplasmosis, posterior scleritis, Graves' disease, intracerebral tumors

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC451589/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3863459/>
<https://www.aao.org/eye/article/ocular-changes-during-pregnancy>

Changes during pregnancy: Take home points

- Many physiological systemic changes during pregnancy will impact the metabolism of medications
- Be able to identify physiological vs pathological changes
- Some pre-existing conditions might improve or worsen during pregnancy

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- Example

Lactation

Free Content for

The Centers for Disease Control and Prevention recommend that HIV-infected mothers, not breastfeed their infants, to avoid risking postnatal transmission of HIV.

PTC has been shown to be present in human breast milk; it is not known if TdF is present in human breast milk (see Data (R.2)). Tenofovir has been shown to be present in the milk of lactating rats and rhesus monkeys after administration of TdF (see Data (R.2)). It is not known if TdF is present in animal milk.

It is not known if *Decevy* affects milk production or has effects on the breastfed child. Because of the potential for: 1) HIV transmission (in HIV-negative infants); 2) developing viral resistance (in HIV-positive infants); and 3) adverse reactions in a breastfed infant similar to those seen in adults, instruct mothers not to breastfeed if they are receiving *Decevy* (see [Data \(8.2\)](#)).

→ Code

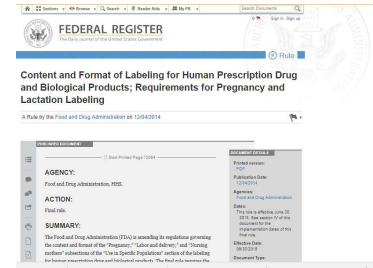
Human Date

Emtricitabine/Sample of breast milk obtained from five HIV-1 infected mothers show that emtricitabine is present in human milk. Breastfeeding infants whose mothers are being treated with emtricitabine may be at risk for developing viral resistance to emtricitabine. Other emtricitabine-associated risks in infants breastfed by mothers being treated with emtricitabine are unknown.

Animal Data  Terephthalaldehyde: Studies in rats and monkeys have demonstrated that terephthalaldehyde is secreted in milk. Terephthalaldehyde was excreted into the milk of lactating rats following oral administration of TPA (up to 600 mg/kg/day) at up to approximately 24% of the median plasma concentration in the highest dose animals at lactation day 11 (see Data 6.7.1). Terephthalaldehyde was excreted into the milk of lactating monkeys following a single subcutaneous (30 mg/kg) dose of terephthalaldehyde at concentrations up to approximately 4% of plasma concentration, resulting in exposure (AUC) of approximately 20% of plasma exposure.

<https://www.drugs.com/pro/descovy.html>

- Learn more!
- Federal Register
- FDA



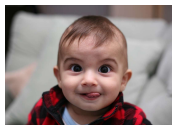
- Moving away from pregnancy categories
- Start getting familiar with pregnancy labeling

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- **Considerations:**
 - Prescribing for mother and fetus/infant
 - Fetus/infant:
 - Immature organs – low elimination, drug accumulation, longer half-life
 - Consult with OB/GYN before starting any new therapy

- **Topical medication recommendation:**

- Use minimal concentration
- Use minimal dose
- Punctual occlusion ~2mins
- Wipe off extra drug



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3862469/>

Dilation

- Pregnancy Category C:
 - Proparacaine
 - Phenylephrine
 - Tropicamide
- No literature to support harm to fetus
- Once in a while is safe
 - Use shorter half-life: tropicamide or cyclopentolate
- Avoid homatropine, atropine, scopolamine
- Avoid dilation unless necessary

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3862469/>
<https://www.reviewofoptometry.com/article/pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers>
https://online.ccc.norwalk.edu/view_course.php?courseid=133

Prescribing

IOP measurement

- Pregnancy Category C:
 - Proparacaine or Benoxinate
 - Sodium Fluorescein
- No literature to support harm to fetus
- Avoid unless necessary
- Use iCare or NCT if possible

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>
<https://www.researchprotocols.org/2017/1/e100000.html>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>



Safe

Prescribing

Overall considered **SAFE**:

Antibiotics	Oral Antivirals	Topical Antifungal
• Penicillin: Augmentin (amoxicillin/clavulanic acid) • Cephalosporin • Erythromycin • Topical or oral azithromycin • Clindamycin • Topical tobramycin • Oral vancomycin • Polymyxin B • Topical gentamicin (C)	• Acyclovir • Valacyclovir • Famciclovir	• Amphotericin B

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>
<https://www.researchprotocols.org/2017/1/e100000.html>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>

Prescribing

Overall considered **SAFE**:

Glaucoma

- Alphagan (brimonidine)
- ****avoid** when nursing (apnea in infants)
- Try to **avoid** during 1st trimester
- Consider **surgery** if IOP is not controlled with meds or meds are a concern

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>
<https://www.researchprotocols.org/2017/1/e100000.html>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>

Prescribing

Overall considered **SAFE**:

Allergies	Category B
	Lastacaft (alcaftadine) ^{combo}
	Crolom, Opticrom (cromolyn sodium)
	Alomide (lodoxamide tromethamine)
	Alocril (nedocromil sodium)
	Emadine (emedastine difumarate) ^{AH}

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>
<https://www.researchprotocols.org/2017/1/e100000.html>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>

Consider:

- Avoid allergen if possible
- Cool compresses or cold mask
- ATs

Prescribing

Overall considered **SAFE**:

Pain management

Acetaminophen

Acetaminophen with codeine (short-term) during pregnancy

Local anesthetics: lidocaine + vasoconstrictor

Proparacaine (category C but in low dose + punctal occlusion, mostly safe)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>
<https://www.researchprotocols.org/2017/1/e100000.html>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC381449/>



Prescribing

- Overall should **AVOID**:

Antibiotics	Topical Antivirals
Tetracycline (abnormalities to bone and teeth) Fluoroquinolones (abnormal cartilage development) Topical fluoroquinolone (category C) - Zymar (gatifloxacin), Vigamox (moxifloxacin), Ciloxan (ciprofloxacin) - Chloramphenicol (Gray baby syndrome) - Neomycin (category D)	Category C: Viroptic (trifluridine), Zigran (ganciclovir) Less studied Use with caution

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC396349/>
https://www.researchgate.net/publication/304934940_pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers
<https://www.cdc.gov/patients/education/course.php?courseid=22>

Prescribing

- Overall should **AVOID**:

Glaucoma			
Topical and systemic CAIs: - Azopt (brinzolamide) - Trusopt (dorzolamide) - Potential teratogenic effects and hepato-renal effects on infants	Prostaglandins: - Xalatan (latanoprost) - Travatan (travaprost) - Lumigan (bimatoprost) - Zioptan (Tafluprost) - Vyzulta (Latanoprostene bunod) - Can lead to abortion and labor induction	Beta Blockers: - Category C - Occasionally used with pregnancy with few reported side effects	Rho Kinase Inhibitors - Rhopressa (Netarsudil) - FDA approved 2017 - No available data

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC396349/>
https://www.researchgate.net/publication/304934940_pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers
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8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on RHOPRESSA use in pregnant women to inform any drug associated risk; however, systemic exposure to netarsudil from ocular administration is low [see *Clinical Pharmacology* (12.3)]. Intravenous administration of netarsudil to pregnant rats and rabbits during organogenesis did not produce adverse embryofetal effects at clinically relevant systemic exposures [see *Data*].

Data

Animal Data

Netarsudil administered daily by intravenous injection to rats during organogenesis caused embryofetal lethality and decreased fetal weight at 5 mg/kg/day (1480-fold the plasma exposure at the RHOD, based on C_{max}). Malformations were observed at ≥ 3 mg/kg/day (1330-fold the plasma exposure at the RHOD, based on C_{max}). Malformations included thoracogastroschisis, umbilical hernia and absent intermediate lung lobe. The NOAEL for embryofetal development toxicity was 0.5 mg/kg/day (214-fold the plasma exposure at the RHOD, based on C_{max}).

Netarsudil administered daily by intravenous injection to rabbits during organogenesis caused embryofetal lethality and decreased fetal weight at 5 mg/kg/day (1480-fold the plasma exposure at the RHOD, based on C_{max}). Malformations were observed at ≥ 3 mg/kg/day (1330-fold the plasma exposure at the RHOD, based on C_{max}). Malformations included thoracogastroschisis, umbilical hernia and absent intermediate lung lobe. The NOAEL for embryofetal development toxicity was 0.5 mg/kg/day (214-fold the plasma exposure at the RHOD, based on C_{max}).

8.2 Lactation

Risk Summary

There are no data on the presence of RHOPRESSA in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to netarsudil following topical ocular administration is low [see *Clinical Pharmacology* (12.3)], and it is not known whether measurable levels of netarsudil would be present in maternal milk following topical ocular administration.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RHOPRESSA and any potential adverse effects on the breast-fed child from RHOPRESSA.

https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209434Orig1s01.pdf

Prescribing

- Overall should **AVOID**:

Allergies	Category C
	Pataday (olopatadine)
	Patanol (olopatadine)
	Pazeo (olopatadine)
	Zaditor (ketotifen fumarate) Yombo
	Elestat (epinastine)
	Alamast (pemirolast potassium)
	Optivar (azelastine)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC396349/>
https://www.researchgate.net/publication/304934940_pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers
<https://www.cdc.gov/patients/education/course.php?courseid=22>

Prescribing

- Overall should **AVOID**:

Corticosteroids

- Category C
- Topical Prednisolone
- Oral Prednisolone
- Fluorometholone

- Lack of well-controlled studies in pregnancy
- Topical steroids:** no human studies to support harm to fetus; rats have shown teratogenic effect
- Oral steroids:** orofacial defects, conotruncal heart defects, and neural tube defects

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC396349/>
https://www.researchgate.net/publication/304934940_pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers
<https://www.cdc.gov/patients/education/course.php?courseid=22>

Prescribing

- Overall should **AVOID**:

Pain Management

Aspirin: bleeding concern

Oral NSAID: bleeding concern, spontaneous abortion and fetal malformations early in pregnancy, induce premature closure of the ductus arteriosus and oligohydramnios late in pregnancy

Topical NSAID: category C, not well studied

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC396449/>
<https://www.researchforternity.com/articles/pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers>
https://online.cetpacific.edu/view_course.php?courseid=111
https://online.cetpacific.edu/view_course.php?courseid=111

Prescribing

- Overall should **AVOID**:

Dry eyes

Restasis:

Category C

Not found in bloodstream from topical use

Xiidra (FDA approved 2016)

No pregnancy category

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC396449/>
<https://www.researchforternity.com/articles/pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers>
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https://online.cetpacific.edu/view_course.php?courseid=111

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on Xiidra use in pregnant women to inform any drug associated risks. Intravenous (IV) administration of lifitegrast to pregnant rats, from pre-mating through gestation day 17, did not produce teratogenicity at clinically relevant systemic exposures. Intravenous administration of lifitegrast to pregnant rabbits during organogenesis produced an increased incidence of omphalocele at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the recommended human ophthalmic dose [RHOD], based on the area under the curve [AUC] level). Since human systemic exposure to lifitegrast following ocular administration of Xiidra at the RHOD is low, the applicability of animal findings to the risk of Xiidra use in humans during pregnancy is unclear [see *Clinical Pharmacology* (12.3)].

Data

Animal Data

Lifitegrast administered daily by intravenous (IV) injection to rats, from pre-mating through gestation day 17, caused an increase in mean preimplantation loss and an increased incidence of several minor skeletal anomalies at 30 mg/kg/day, representing 5,400-fold the human plasma exposure at the RHOD of Xiidra, based on AUC. No teratogenicity was observed in the rat at 10 mg/kg/day (460-fold the human plasma exposure at the RHOD, based on AUC). In the rabbit, an increased incidence of omphalocele was observed at the lowest dose tested, 3 mg/kg/day (400-fold the human plasma exposure at the RHOD, based on AUC), when administered by IV injection daily from gestation days 7 through 19. A fetal No Observed Adverse Effect Level (NOAEL) was not identified in the rabbit.

8.2 Lactation

Risk Summary

There are no data on the presence of lifitegrast in human milk, the effects on the breastfed infant, or the effects on milk production. However, systemic exposure to lifitegrast from ocular administration is low [see *Clinical Pharmacology* (12.3)]. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Xiidra and any potential adverse effects on the breastfed child from Xiidra.

https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/20160101Orig1s001.pdf

Prescribing

- Meds to **AVOID** during Pregnancy:

• 1st trimester:

- Avoid meds in first trimester if possible
- Greater risk for iatrogenic anatomic malformations
- Use with caution **beta blockers**

• 3rd trimester:

- Avoid **ibuprofen** b/c of possible adverse circulatory effects
- Avoid **codeine** b/c possible fetal respiratory depression and withdrawal symptoms

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC396449/>
<https://www.researchforternity.com/articles/pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers>
https://online.cetpacific.edu/view_course.php?courseid=111

Prescribing

- Nursing/Lactating mothers:

• **Avoid:**

- Beta blockers** (concentrated in breast milk)
 - D/C beta blockers 2-3 days prior to delivery to avoid beta blockade in infant
- Brimonidine** b/c induce apnea and CNS depression
- NSAIDs**: naproxen, sulindac, piroxicam

• **Safe:**

- Hydrocodone** is preferred
- (**Bactrim**) **Trimethoprim/sulfamethoxazole** – ok for infants over than 2 months
- Codeine, morphine, hydrocodone** (short term)
- NSAIDs**: use ibuprofen

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC396449/>
<https://www.researchforternity.com/articles/pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers>
https://online.cetpacific.edu/view_course.php?courseid=111

Prescribing

- Diagnostic imaging:

- Safe**: chest x-rays, little risk with MRI (but NHI recommends 2/3rd trimester)
- Avoid**: IV contrast-concern for effects on fetal thyroid



<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC396449/>
<https://www.researchforternity.com/articles/pregnancy-precautions-how-to-prescribe-safely-for-new-and-expectant-mothers>
https://online.cetpacific.edu/view_course.php?courseid=111

Prescribing: Take home points

Antibiotics	Oral Antivirals	Topical Antifungal	Allergies
• Penicillin: Augmentin (amoxicillin/clauvulanic acid) • Cephalosporin • Erythromycin • Topical or oral azithromycin • Clindamycin • Topical tobramycin • Oral vancomycin • Polymyxin B • Topical gentamicin (C)	• Acyclovir • Valacyclovir • Famciclovir	• Amphotericin B	• Lastacast (alcaftadine) • Crolom, Opticrom (cromolyn sodium) • Alomide (lodoxamide tromethamine) • Alocril (nedocromil sodium) • Emadine (emedastine difumarate)
	Glaucoma • Alphagan (brimonidine)	Pain Management • Acetaminophen • Acetaminophen with codeine • Local anesthetics: lidocaine + vasoconstrictor • Proparacaine	

In Conclusion

- Explore risks vs benefits before treating!
- Do your research!
- Be conservative
- Maternal concern is high
- Liability is high
- If in doubt, consult with OB/GYN