بسم الله الرحمن الرحيم

حافظ شیرازی

سلامی چو بوی خوش آشنایی

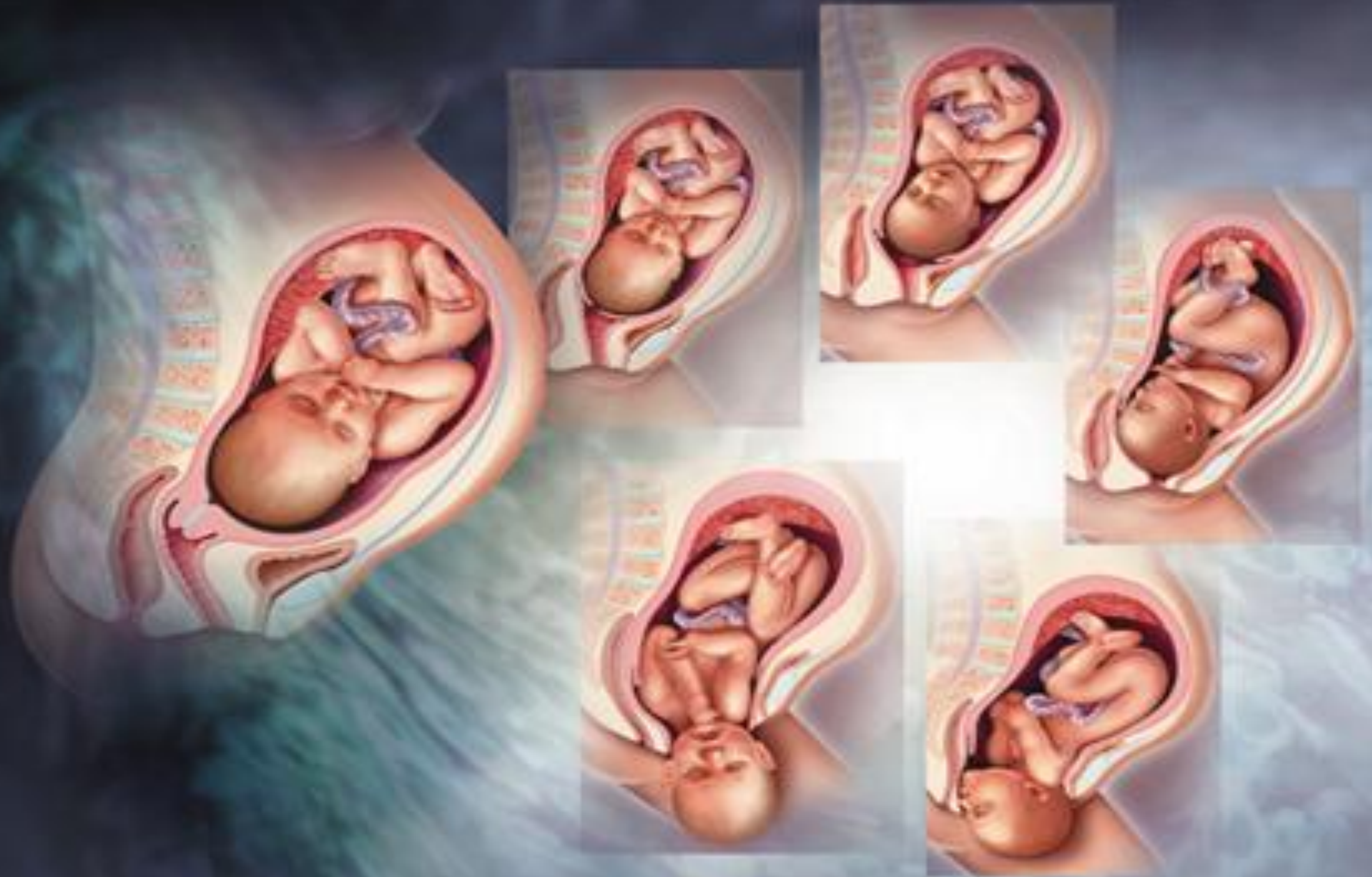
بدان مردم دیده روشنایی

درودی چو نور دل پارسایان

بدان شمع خلوتگه پارسایی

instagram.com/mohsenzaker63

Pregnancy& Autoimmune Di.



Pregnancy& Autoimmune Di.

- The influence of the diseases upon fertility
- The influence of the diseases upon pregnancy
- The influence of pregnancy upon the diseases
- Management of the diseases during conception & pregnancy
- Management of the diseases during lactation

RHEUMATOID ARTHRITIS & PREGNANCY

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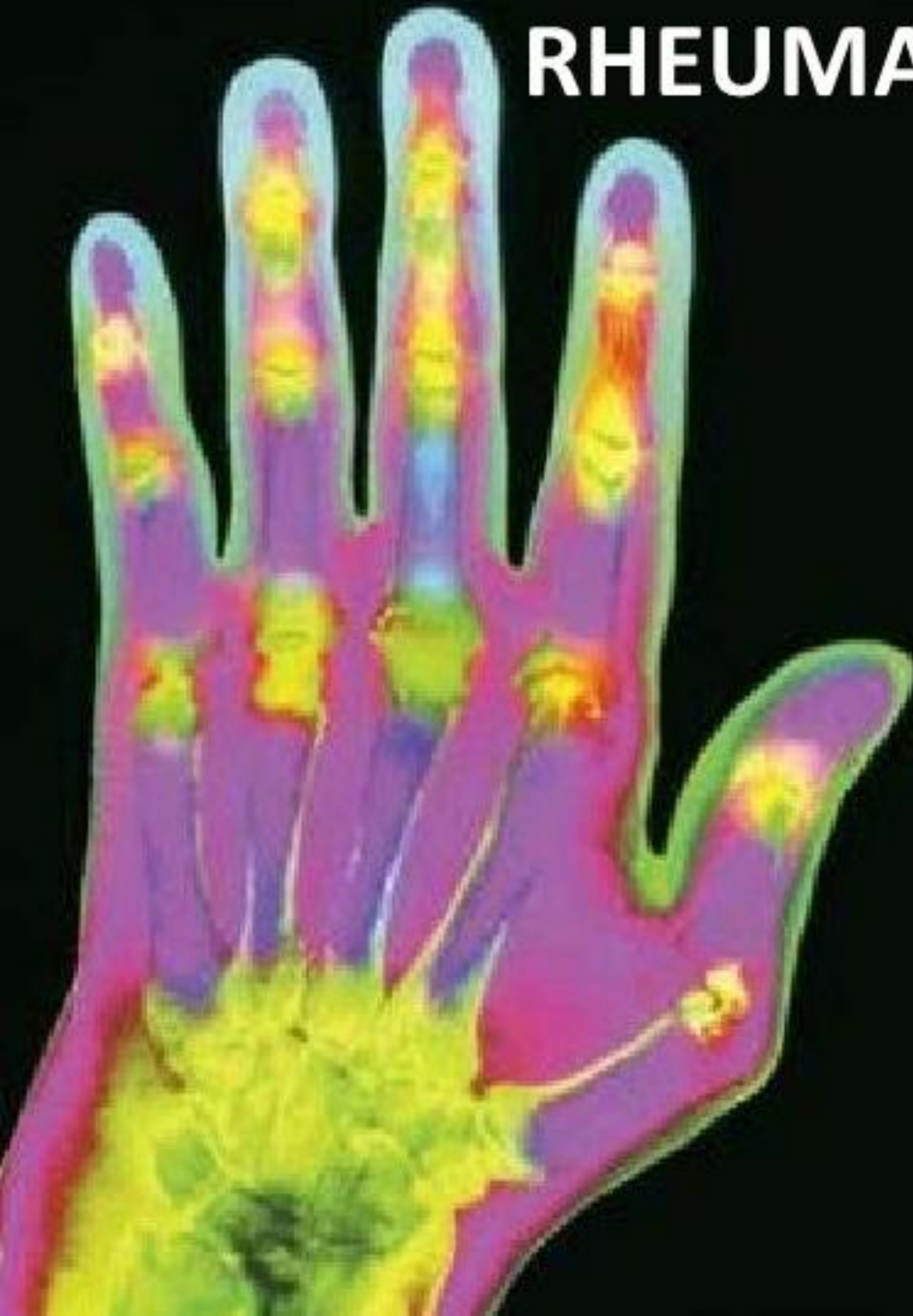
RHEUMATOID ARTHRITIS



- Prevalence 0.5 percent
- F>M
- Childbearing age

Rheumatoid Arthritis patient wants to get
Pregnant
(Clinical Scenario)

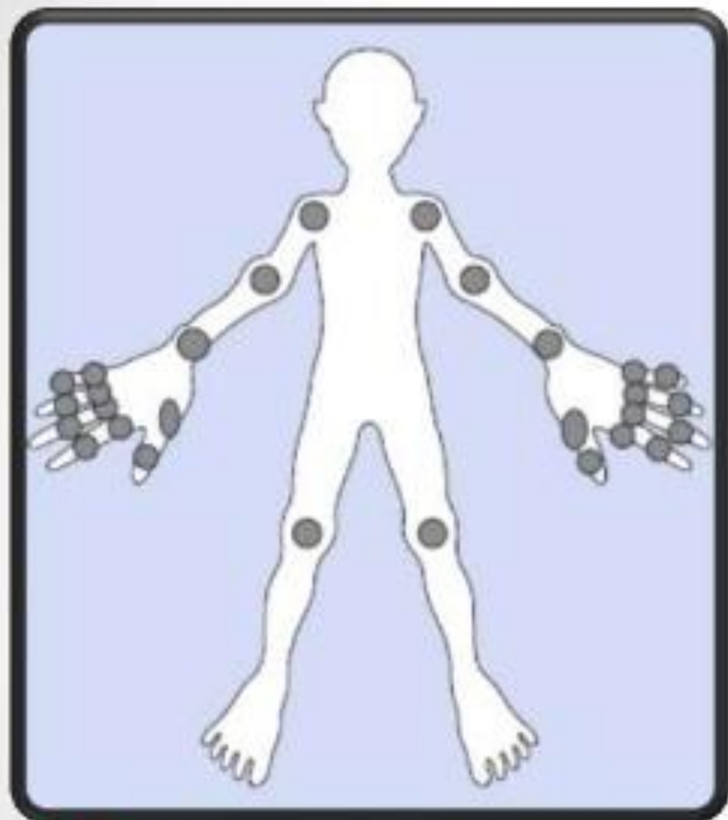
Personal History

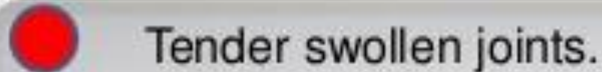
- 25 years old , housewife.
- Single

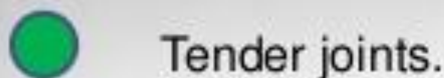
On the Current Medications

Leflunomide 20mg	1 tab/day	orally
Methotrexate vial (50mg / 2ml)	1ml(25mg)/week	IM
Folic acid 1mg	1 tab /day	orally
Prednisolone 5mg	1 tab/day	orally
Calcium carbonate + Vit D	1 tab/day	orally
Diclofenac 150mg MR	1 tab/day	orally

Joints Examination







- No tender or swollen joints for 3 month duration.
- No morning stiffness for 3 month duration.

Then the patient and her fiancé wanted to discuss the possibility of having a baby as they were planning to marry in 3 month.

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Does RA affect t
of getting pr

Does RA affect the
pregnancy outcome ?

Does RA affect the chances of getting pregnant?

No, RA does not affect fertility

Decreased sex drive & less frequent intercourse due to chronic pain are likely the causative factors.

Ostenson M et al Pregnancy and reproduction in autoimmune rheumatic diseases Rheumatology. 2011;50(4):657-664

Does RA affect the pregnancy outcome?

There is no increase in the rate of miscarriage or stillbirth in patients with RA

Ostenson M et al Pregnancy and reproduction in autoimmune rheumatic diseases Rheumatology. 2011;50(4):657-664

Does RA affect the Baby?

- *No , RA does not affect the unborn baby. R.A need not to be inherited by the baby from the mother even if it is active during pregnancy.*
- *Our concern is all about the medications which will need to be changed.*

Ostenson M et al Pregnancy and reproduction in autoimmune rheumatic diseases Rheumatology. 2011;50(4):657-664

Am I ready for pregnancy ?

1. *Your RA has to be fairly controlled for 3-4 months before getting pregnant.*

2. *New laboratory investigations.*

3. *Reviewing your current medications.*

I will stop all medications during pregnancy ?

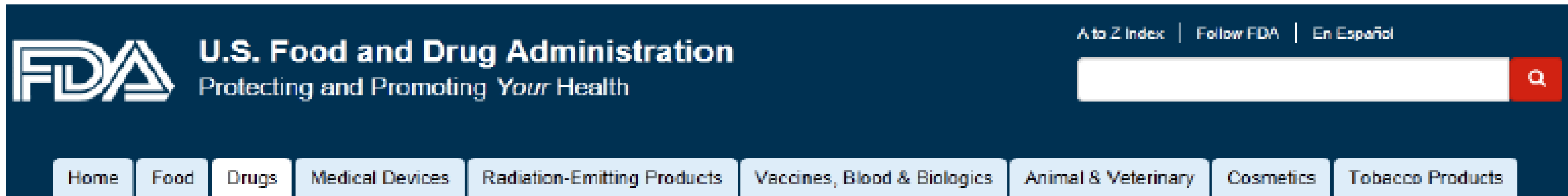
Medication during Pregnancy

- Sources for the pregnancy data presented come from the FDA classification of drugs and experts reporting.

FDA category	Classification
A	Controlled studies showed no risk
B	No evidence of risk in humans
C	Risk cannot be ruled out
D	Positive evidence of risk
X	Contraindicated in pregnancy
N	Not rated

Temprano KK, Bandlamudi R, Moore TL. Antirheumatic drugs in pregnancy and lactation. Semin Arthritis Rheum. Oct 2005;35(2):112-21

PLLR Website



Drugs

Home > Drugs > Development & Approval Process (Drugs) > Development Resources > Labeling

Development & Approval Process (Drugs)

Development Resources

Labeling

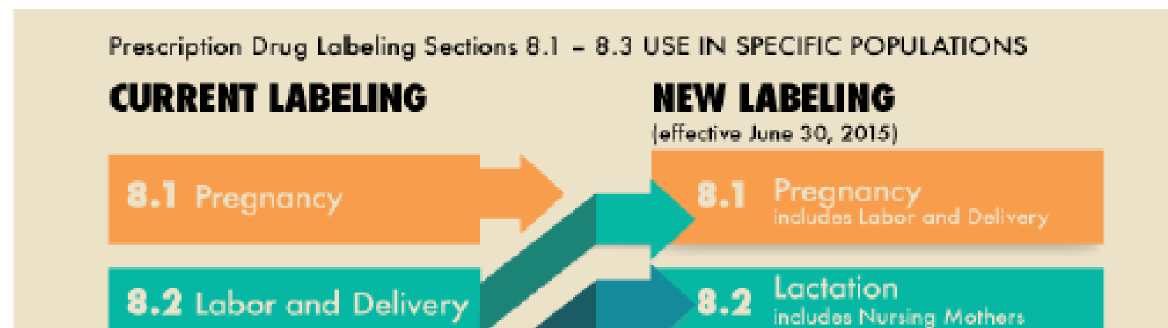
Pregnancy and Lactation Labeling Final Rule

Pregnancy and Lactation Labeling Final Rule

[12/3/14] The FDA published the *Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling*, referred to as the "Pregnancy and Lactation Labeling Rule" (PLLR or final rule).

The PLLR requires changes to the content and format for information presented in prescription drug labeling in the Physician Labeling Rule (PLR) format to assist health care providers in assessing benefit versus risk and in subsequent counseling of pregnant women and nursing mothers who need to take medication, thus allowing them to make informed and educated decisions for themselves and their children. The PLLR removes pregnancy letter categories – A, B, C, D and X. The PLLR also requires the label to be updated when information becomes outdated.

Below is a comparison of the current prescription drug labeling with the new PLLR labeling requirements.



Categories

- Drugs with a moderate to high risk of fetal harm
- Drugs that may be used selectively during pregnancy
- Drugs with minimal fetal and maternal risk
- Drugs with an unknown level of risk

Moderate to high risk of fetal harm

- Methotrexate (MTX)
- Leflunomide (LEF)

Selective use allowed during pregnancy

- **Glucocorticoids**
- **NSAIDs**
- **Anti-TNF**

Minimal fetal and maternal risk

- Hydroxychloroquine (HCQ)
- Sulfasalazine (SSZ)
- Azathioprine (AZA)

- ***We will need to stop Methotrexate & Leflunomide.***

- *How to stop them?*
- *when will I be ready for pregnancy?*

Protocol of stopping Drugs.

- Methotrexate

- MTX should be stopped 3 cycles prior to conception.
- Folic Acid should be continued.

Protocol of stopping Drugs.

- Leflunomide washout

- Give Cholestryramine 8g tds for 11 days.
- Then measure metabolite twice at intervals of at least 14 days.
- This should fall to less than 0.02 mg/I.
- It is recommended to wait at least 3 months before considering conception.

- ***Then I will be on a drug holiday during pregnancy ?***

- ***No***
- ***There are Drugs considered safe during pregnancy.***

- ***Here is your prescription …***

Here is your prescription

- **Sulfasalazin 2g/day**
- **Folic acid 1mg/day**
- **Hydroxychloroquine 400mg/day**
- **Prednisolon 5mg/day**
- **Calcium+vit D**
- **NSAIDs when needed**

Follow up is important by the Rheumatologist and Obstetrician during the pregnancy

- ***What to expect after pregnancy?***

Immunologically pregnancy has 3 phases

1. **Implantation**, an inflammatory state
2. **Fetal growth**, a relative anti-inflammatory T-helper-2 predominant phase
3. **Parturition**, where there is an increase locally in inflammatory cells and cytokines

What to expect during pregnancy

<u>First trimester & second trimester:</u>

RA tends to improve and patients who improve are more likely to stay in remission during pregnancy.

What to expect during pregnancy

<u>*Third trimester:*</u>

- You may experience *fatigue* due to *weight gain*.
- *Swelling* of feet / ankles
- Hand *numbness* / *tingling*.

They need not always mean a flare, Consult Rheumatologist.

Delivery

- Hip involvement due to RA may prelude normal vaginal delivery in few R.A patients.
- Cesarean operation may be required in this case.

- ***Will I stop lactation then?***

What to expect after pregnancy

- ***Hygiene and wound*** ***care after delivery is extremely important. You may be on steroids or other DMARDs which may impair immunity & make you prone to infections if appropriate care is not taken.***

What to expect after pregnancy

- *Caring for the baby requires a great deal of energy, feeding multiple times in the night can add up to the fatigue & exhaustion.*

- *Carrying the baby around can be difficult if the hand joints are inflamed.*

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What to expect after pregnancy

- *Sleep deprivation happens to every Mom; however can add to your joint pain & fatigue*
- *You will not be able to take MTX / Leflunomide to control RA activity when you are breast feeding.*

Breast Feeding

Drug	Official recommendation	Clinical practice recommendation
NSAIDs	Considered safe; small amounts in breast milk ; avoid acetyl salicylic acid due to bleeding risk in infant	Safe except acetyl salicylic acid.
Steroids	Excreted in milk but still safe; wait 4 hr if on prednisolone >20mg	Safe (consider delaying feed by 4 hr)

Breast Feeding

Drug	Official recommendation	Clinical practice recommendation
Sulfasalazine	Probably safe, One case of bloody diarrhea	Safe
Hydroxychloroquine	Small amount 2% in breast milk; but generally safe	Safe

- ***If these safe medication failed to control RA activity we may need to stop lactation and switch back to***

  MTX / Leflunomide.