EnBraceHR® **Rx**

EnLyte for Women

Small Gel Cap | All-Natural | Root Cause Management

INNOVATIONS IN **WOMEN'S MENTAL & REPRODUCTIVE HEALTH**

Women of All Ages and their HCPs, Desire Treatment Options Designed to Address their Unique Mental and Reproductive Health Needs Effectively and Safely

References can be found at the end of this presentation

Clinically Proven Effectiveness for:

- Depression and Anxiety
- Including in and Around Pregnancy
- PMS/PMDD & Menopause
- High or Low Risk Prenatal Vitamin

EnBrace HR Small Gel Cap

INGREDIENTS

"EnBrace HR contains the exact clinically recommended vitamin coenzymes, mineral cofactors and omegas needed to normalize uterine and CNS intracellular methylation for normal mental and reproductive clinical outcomes."

Towny Robinson, CEO JayMac Pharmaceuticals
Inventor of EnBrace HR

Most Diverse Natural Folates: FDA 15mg DFE

L-Methylfolate Magnesium	7mg
Folinic Acid	2.5mg
Folic Acid	1mg

B Vitamins in their Bioactive Coenzyme Form

B12 (Adenosylcobalamin)	50mcg
B6 (Pyridoxal-5-Phosphate)	25mcg
B1 (Thiamine Pyrophosphate)	25mcg
B2 (Flavin Adenine Dinucleotide)	25mcg
B3 (Nicotinamide Adenine Dinucleotide)	25mcg
Piperine (B Vitamin Bioenhancer)	500mcg

Minerals in their Bioactive Cofactor Form

Magnesium Ascorbate	24mg
Magnesium L-Threonate	1mg
Zinc Ascorbate	1mg
Iron (Ferrous Glycine Cysteinate)	1.5mg

Phospholipid Form – Brain Ready

PS-Omega-3 (Phosphatidylserine, EPA, DHA)	20mg

Absorption Enhancer

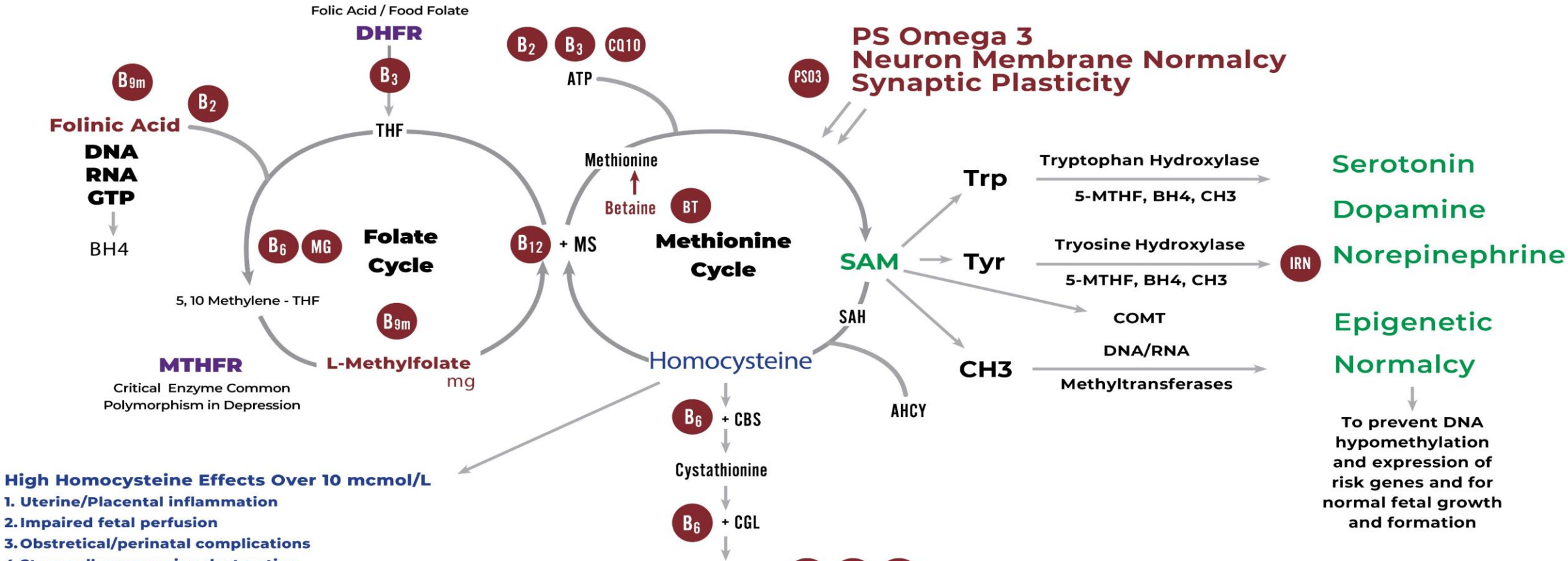
Sodium Citrate	10mg

Energizer

CoQ10	500mcg

Intracellular Biochemical Root Cause Methylation Chart

EnBrace HR Normalizes All Co-Enzyme/Cofactor Deficiencies and Methylation Disruption, No Matter the Cause and Converts to Normal Mental and Reproductive Health Outcomes Based on Well-Controlled Clinical Trials.



High Homocysteine Effects Over 10 mcmol/L

1. Uterine/Placental inflammation
2. Impaired fetal perfusion
3. Obstretical/perinatal complications
4. Stem cell suppression destruction
5. Small vascular toxicity
6. Impaired myelination

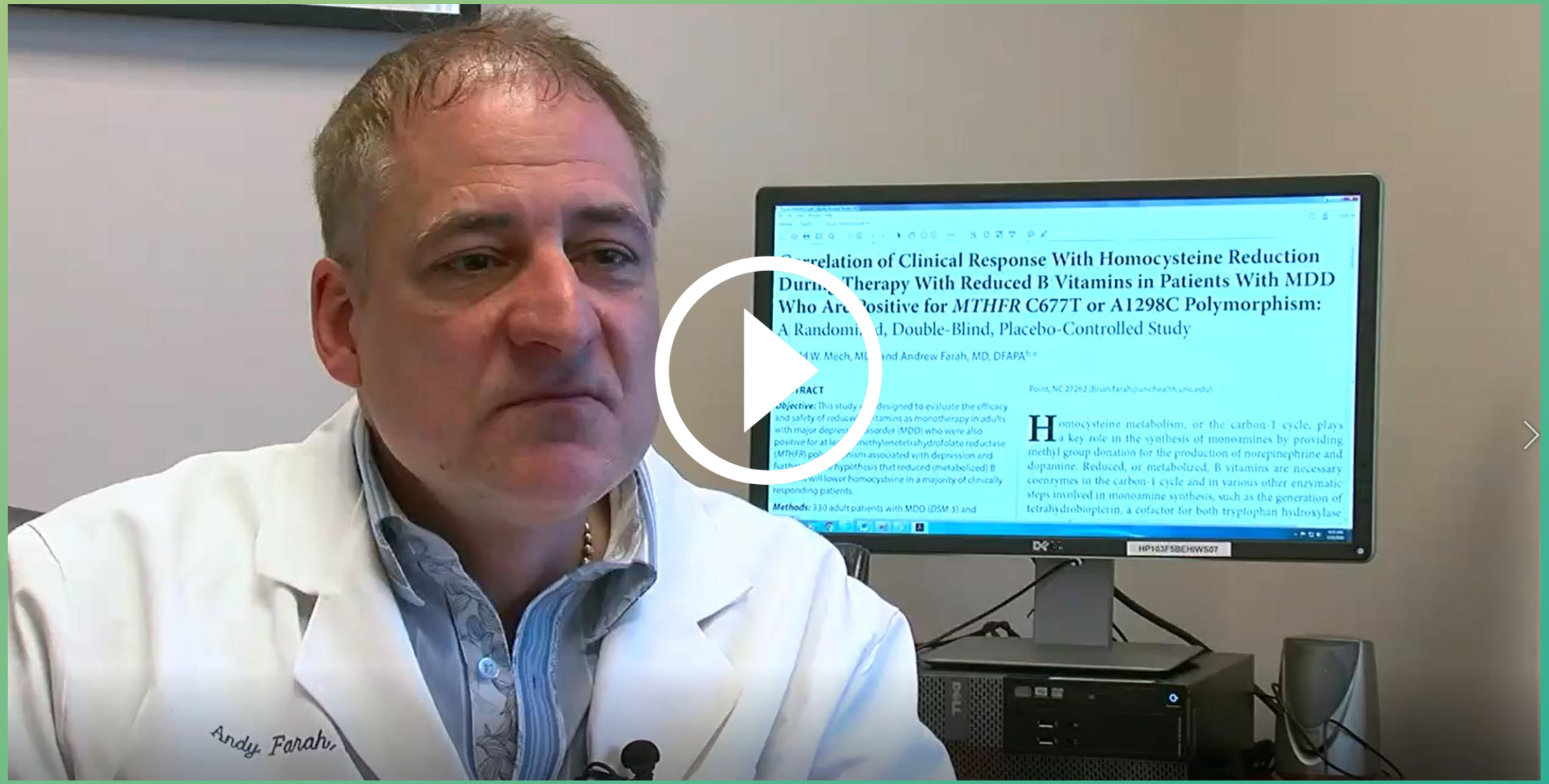
NOTE:

EnBrace HR Product Ingredients - Maroon

End Point Benefits - Green

*Kennedy, David O., B vitamins and the Brain: Mechanisms, Dose and Efficacy – A Review, Figure 2. The interlinked folate and methionine cycles.

CLINCAL STUDY OVERVIEW



THE JOURNAL OF CLINICAL PSYCHIATRY

330 ADULT PATIENT
RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED STUDY

OBJECTIVE:
This 8-week study was designed to evaluate the efficacy and safety of EnLyte/EnBrace HR as monotherapy in adults with major depressive disorder (MDD) who were also positive for at least 1 methylenetetrahydrofolate reductase (MTHFR) polymorphism associated with depression and further test the hypothesis that EnLyte/EnBrace HR will lower homocysteine in a majority of clinical responding patients.

MAY 2016
Correlation of Clinical Response With Homocysteine Reduction During Therapy With EnLyte/EnBrace HR in Patients With MDD Who Are Positive for MTHFR C677T or A 1298C Polymorphism - Andrew Farah, MD

1) Mean MADRS Symptom Score of EnBrace HR Versus Placebo

2) 30% Reduction in Homocysteine Levels (Compared to Placebo)

NO SIDE EFFECT WAS REPORTED AT GREATER RATE THAN PLACEBO

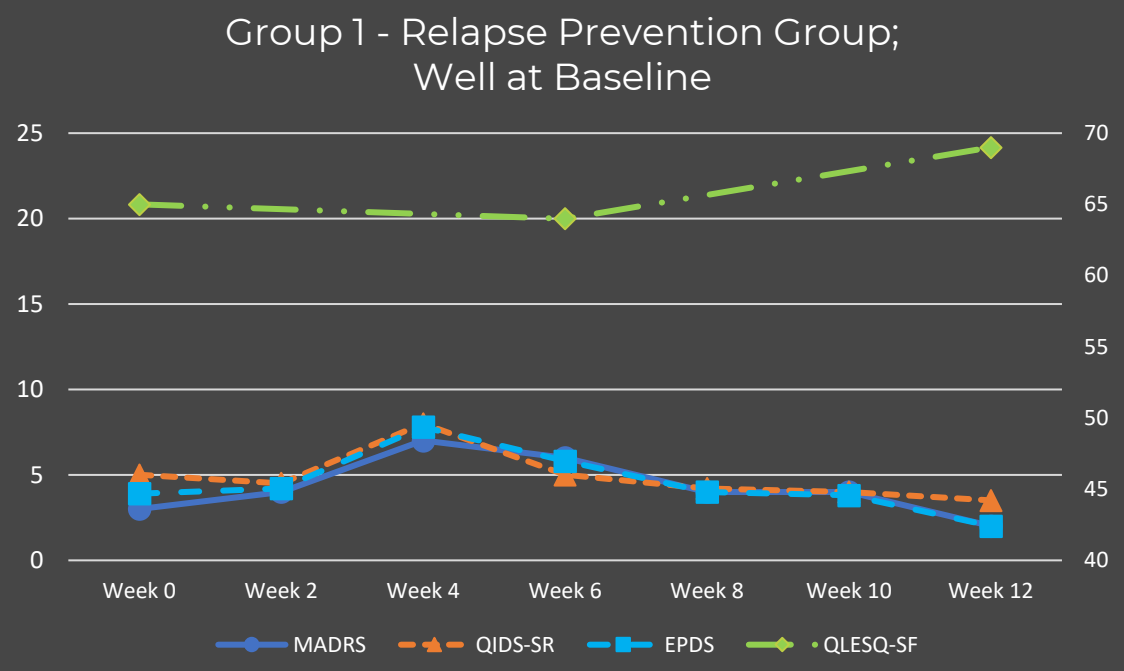
ONSET OF ACTION: 2 WEEKS

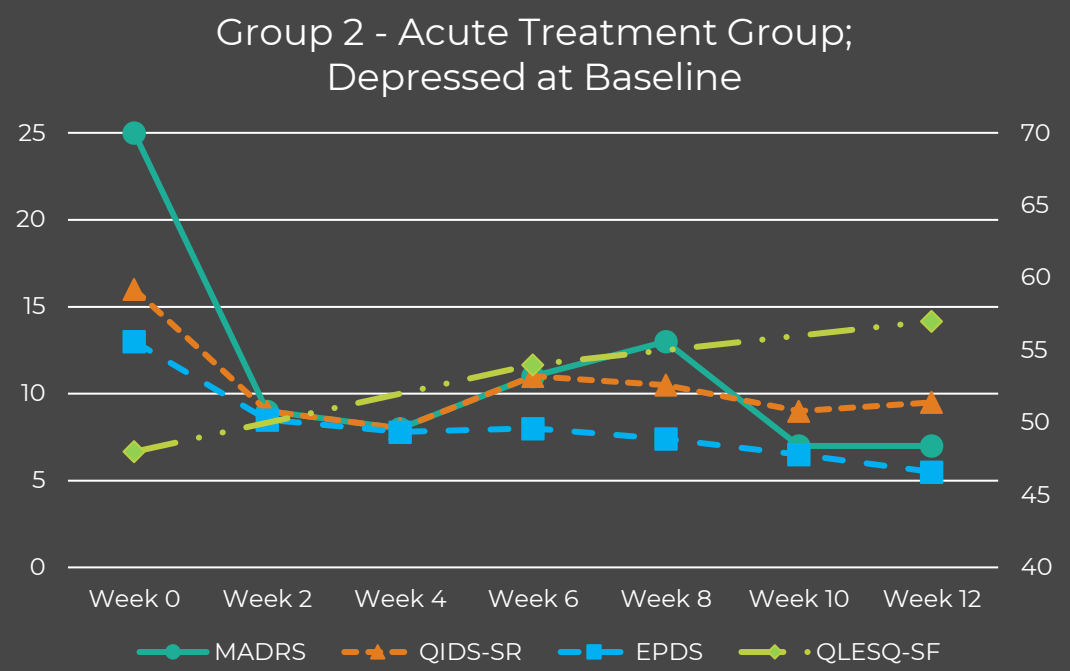
ENBRACE HR STUDY

EnBrace HR For The Treatment and Prevention of Depression in Women

Trying to Conceive and During Pregnancy

Marlene P. Freeman, MD et al, Annals of Clinical Psychiatry February 2019





CONCLUSION

Study results suggest EnBrace HR is a novel and well tolerated intervention with efficacy for the prevention and treatment of depression among women planning pregnancy and who are pregnant.

Figure 1. The aim for Group 1 was to prevent depression relapse, and the aim for Group 2 was to improve depression symptoms, measured through several mood and quality of life questionnaires. Trends shown by group for the primary mood outcome measure, the MADRS (Montgomery-Asberg Depression Rating Scale) in dark blue; for secondary mood measures, the QIDS-SR (Quick Inventory of Depressive Symptomatology-Self Report) in orange and the EPDS (Edinburgh Postnatal Depression Scale) in light blue; and for a quality of life outcome, the QLESQ-SF (Quality of Life Enjoyment and Satisfaction Questionnaire -Short Form) in green. Group 1 experienced no significant changes in any of the four measures, and Group 2 experienced significant improvements in the mood questionnaires but not the quality of life questionnaire. All ANOVAs indicating significance are reported in Table 3.

PMS
(Premenstrual Syndrome)
Mild/Moderate

Menopause
Cyclic hormonal changes of the menstrual cycle causes fluctuations of serotonin levels leading to adverse symptomology
– Mayo Clinic –

PMDD
(Premenstrual Dysphoric Disorder)
Severe (DSM-5)

Tension/Anxiety, Depressed Mood – Irritability/Anger – Appetite Changes – Cravings – Insomnia – Social Conflict Withdrawal– Feeling overwhelmed – Hopelessness – Hot Flashes

Biochemical Wellness

EnBrace HR normalizes serotonin levels and is an effective, all-natural, safe, root cause monotherapy option or adjunct to SSRIs, oral contraceptives, NSAIDs, diuretics, and/or HRT in the prevention or treatment of PMS/PMDD/MENOPAUSE.

Dietary B Vitamin Intake and Incident of Premenstrual Syndrome. Manson et al. Am J Clin Nutr. 2011

Clinical Result Example

A 17-year-old on Paxil for PMDD experienced side effects and withdrawal symptoms after discontinuing Paxil. She was hesitant to resume antidepressant medications after presenting again with PMDD depression, and a MADRS of 20. The patient elaborated she was “putting on a happy face”. She was prescribed EnBrace HR and within 4 weeks her MADRS dropped from 20 to 6.

Coenzyme Treatment of Childhood and Adolescent Depression: A Case Series. Farah et al. Clinical Psychiatry Vol 7 #5S3:93 April 2021

“For the emotional dysregulation of PMS, PMDD, and Menopause we turned first-line to the natural, broad spectrum B vitamin coenzymes and mineral cofactor agent, EnBrace HR. This product has provided safe and effective relief for countless patients with female hormonal fluctuations or deficiency”

Andrew Farah, MD
Attending Psychiatrist, Novant Health System, Winston-Salem, NC
Medical Director of Strategic Mental Health Interventions

EnBraceHR® **Rx**

Provides the most diverse combination of folates and methylation vitamin coenzymes and mineral cofactors for maximum prevention of NTDs and other birth defects in low or high-risk pregnancies.

An optimal serum folate level for birth defect prevention should be reached 4 weeks prior to conception, 50% of pregnancies are unplanned.

Mechanism of Cellular Action

Normalize impaired cellular “homocysteine/methionine” metabolism disorders than can lead to placental inflammation, impaired fetal perfusion, impaired nucleotide and DNA synthesis and faulty epigenetic expression.

To Prevent or Reduce Risk For:

- All Neural Tube Defects
- Congenital Heart & Kidney Disorders
- Down Syndrome
- ADHD
- Autism Spectrum Disorders
- Orofacial Clefts
- Drug Related Birth Defects
- Pregnancy Complications
- Congenital Structural Malformation

EnBrace HR Helps Eliminate the Risk for Adverse Pregnancy Outcomes, NTDs, and Other Birth Defects Associated with the effects of MTHFR Gene Variant

MTHFR gene variants prevent the production of the enzyme that converts folate to methylfolate leading to high homocysteine and low neurotransmitter production causing negative reproductive and CNS outcomes.

60% of women have the heterozygous form of MTHFR gene variant

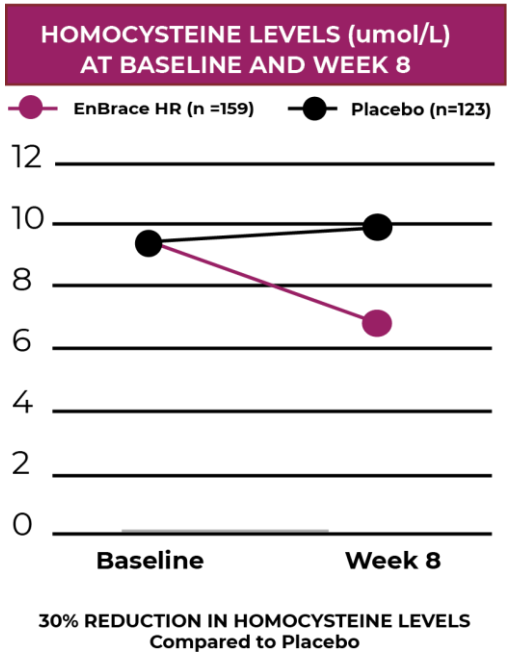
25% of women have the homozygous form of MTHFR gene variant

50% of folate related NTDs and other birth defects are linked to MTHFR

85% of depressed and addicted women have an MTHFR gene variant

MTHFR Polymorphisms are Documented Risk Factors for these Adverse Pregnancy Outcomes:

- Miscarriage
- Perinatal/ Post-Partum Depression
- Pre-Term Delivery
- Low Birth Weight
- Pre-Eclampsia
- Placental Inflammation
- Impaired Fetal Perfusion
- Chromosomal Abnormalities



EnBrace HR is proven in a 330 patient, randomized, controlled trial in patients with an MTHFR variant to lower homocysteine 30% compared to placebo group.

Andrew Farah, MD et al.
Journal of Clinical Psychiatry, May 2016

HOW TO PRESCRIBE

STEP 1

USE OUR ONLINE PRESCRIBER FORM

Fill in prescriber and patient information and then hit “submit”

CLICK HERE

STEP 2

WE WILL OFFER YOUR PATIENT THEIR FIRST 60 DAYS FOR $60

We will also provide them with the insurance steps and help determine the most cost-effective option moving forward

STEP 3

IF IT’S COVERED ON INSURANCE, WE WILL CONTACT YOUR OFFICE WITH PRESCRIBING INFO

If your patient does not have coverage or has a high co-pay, we will offer our discounted cash-pay option for EnBrace HR. No further action is needed for your office.

References

1.Freeman·et al., A prenatal supplement with methylfolate for the treatment and prevention of depression in women trying to conceive and during pregnancy, Annals of Clinical Psychiatry, Feb. 2019

2.Farah et.al, Correlation of Clinical Response with Homocysteine Reduction During Therapy With Reduced B Vitamins in Patients With MDD Who Are Positive for MTHFR C677T or A1298C Polymorphism, Journal of Clinical Psychiatry, May 2016

3.MRC Vitamin Group, Prevention of neural tube defects: Results of the Medical Research Council Vitamin Study, Lancet, 1991

4.Czeizel et al., Periconceptional Folic Acid and Multivitamin Supplementation for the Prevention of Neural Tube Defects and Other Con-genital Abnormalities, Clinical and Molecular Teratology, 2008

5.FDA, 21 CFR-101.79- Health Claims: Folate and neural tube defects, CFR Text. 2019

6.Kirk E et al., Impact of the MTHFR C677T polymorphism on risk of neural tube defects: case-control study, BMJ, 2004

7.Ufriend et al., The C677T polymorphism of the methylenetetrahydrofolate reductase gene and idiopathic recurrent miscarriage, Obstetrics & Gynecology, April 2002

8.MTHFR Living, Preparing for Pregnancy with MTHFR Mutations, Jan. 2014

9.Garilli, Bianca ND, MTHFR Mutation: A Missing Piece in the Chronic Disease Puzzle, Huffington Post, Summer, 2012

10. Wald et al, Public health failure in the prevention of neural tube defects: time to abandon the tolerable upper intake level of folate,

11.Farah et al., The Prevalence and Role of MTHFR Polymorphism in Opiate Dependency, Journal of Addiction and Therapies, Feb. 2018

12.EI-Hadidy et al., Methylene tetra hydrofolate reductase C677T Gene Polymorphism in Heroin Dependence, Addiction Research & Therapy, 2015

13.Mararwa et al., Prenatal exposure to SSRIs and SNRIs and risk for pulmonary hypertension of the newborn: a systemic review, meta-analysis, AJOG, 2018

14.Chambers et al., SSRI and Risk of Persistent Pulmonary Hypertension of the Newborn, The New England Journal of Medicine, 2011

15.Kieviet et al., Use of antidepressants during pregnancy in The Netherlands: observational study into post-partum interventions, BMC Pregnancy & Childbirth, 2017

16.MGH Center for Women's Health, womensmentalhealth.org, SSRIs and Poor Neonatal Adaptation: How Long do Symptoms Last, 2015

17.Liu et al., Antidepressant Use During Pregnancy and Psychiatric Disorders in Offspring, BMJ, 2017

18.Lugo-Candelas et al., Association Between Brain Structure and Connectivity in Infants and Exposure to SSRIs During Pregnancy, JAMA Pediatrics, 2018

References cont'd

20.WebMD. www.webmd.com, pregnancy-and-antidepressants, 2018

21.FDA A Appendix NIH, Antidepressant Drug Labels for Pregnant and Postpartum Women, 2014

22.EnBrace HR Pl, FDS Daily Med, Dec. 2018

23.Turgal et al. MTHFR Polymorphisms and Pregnancy Outcome, PMC 6138472, Sept. 2018

24.Duprey Robert P. MTHFR Gene Polymorphism positive treatment-resistant depression, Neuropsychiatry 2019

25. Imbard A, Benoist JF, Blom HJ. Neural tube defects, folic acid and methylation. Int J Environ Res Public Health. 2013

26. Obeid R, Holzgreve W, Pietrzik K. Is 5-methyltetrahydrofolate an alternative to folic acid for the prevention of neural tube defects? J. Perinatal Med, 2013

27. Greenberg JA, Bell SJ, Guan Y, Yu YH. Folic Acid supplementation and pregnancy: more than just neural tube defect prevention. Rev Obstet Gynecol. 2011

28. NIH, Folate Fact Sheet for Professionals, 2022

29. MGH Center for Women's Mental Health, Folic Aid Supplements Before and After Conception: Prevention of Autism, 2022

30. Bjørk M, Riedel B, Spigset O, Veiby G, Kolstad E, Daltveit AK, Gilhus NE. Association of Folic Acid Supplementation During Pregnancy With the Risk of Autistic Traits in Children Exposed to Antiepileptic Drugs In Utero. JAMA Neurol. 2018 Feb

31. Sah AK, Shrestha N, Joshi P, Lakha R, Shrestha S, Sharma L, Chandra A, Singh N, Kc Y, Rijal B. Association of parental methylenetetrahydrofolate reductase (MTHFR) C677T gene polymorphism in couples with unexplained recurrent pregnancy loss. BMC Res Notes. 2018 Apr

32. MGH Center for Womens' Mental Health Folic Acid and Risk of Perinatal Depression: Is there an Association? 2012

33. Methylenetetrahydrofolate Reductase Polymorphisms and Pregnancy Outcomes, Obstetrics and Gynecology, 2018

34. Zhang L, Sun L, Wei T. Correlation between MTHFR gene polymorphism and homocysteine levels for prognosis in patients with pregnancy-induced hypertension. Am J Transl Res. 2021 Jul