

EnLyte®
Small Gel Cap
FDA Medical Food
EnLyterx.com

SAME INGREDIENTS
3 BRANDS

ENL

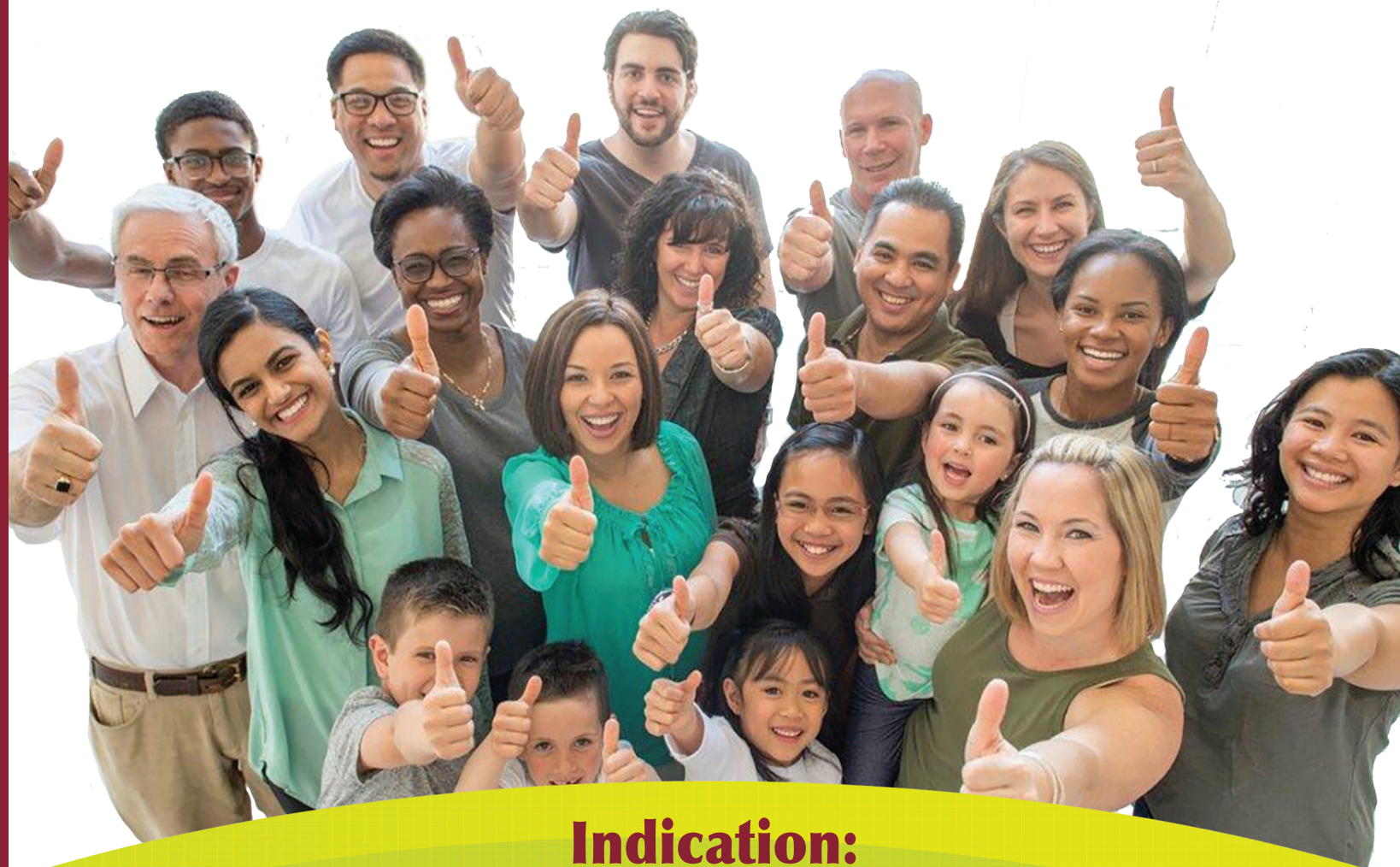
FDA MEDICAL FOOD
CASH PAY

TM ®

EnBraceHR®
Small Gel Cap
PRESCRIPTION ONLY
EnBraceHR.com

Can Keep Them “Happy For Life”

*By Effectively Addressing The Root Causes of
Depression, Anxiety and ADHD Naturally and Safely*



Indication:

***Clinical Dietary Management
of Major Depressive Disorder***

Once-a-day dosing / No age restriction

TEAM METHYLATION

PRE-METABOLIZED COENZYMES AND COFACTORS: BRAIN READY INGREDIENTS

Reduced Folates

L-Methylfolate Magnesium	7mg
Folinic Acid	3.5mg

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
Bioperine (B Vitamin Bioenhancer)	500mcg
Betaine (Trimethyl Glycine)	1mg

Minerals in their Bioactive Cofactor Form

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

Phospholipid Form–Brain Ready

PS-Omega-3 (Phosphatidylserine, EPA, DHA)	23.3mg
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Absorption Enhancer

Sodium Citrate.....	6mg
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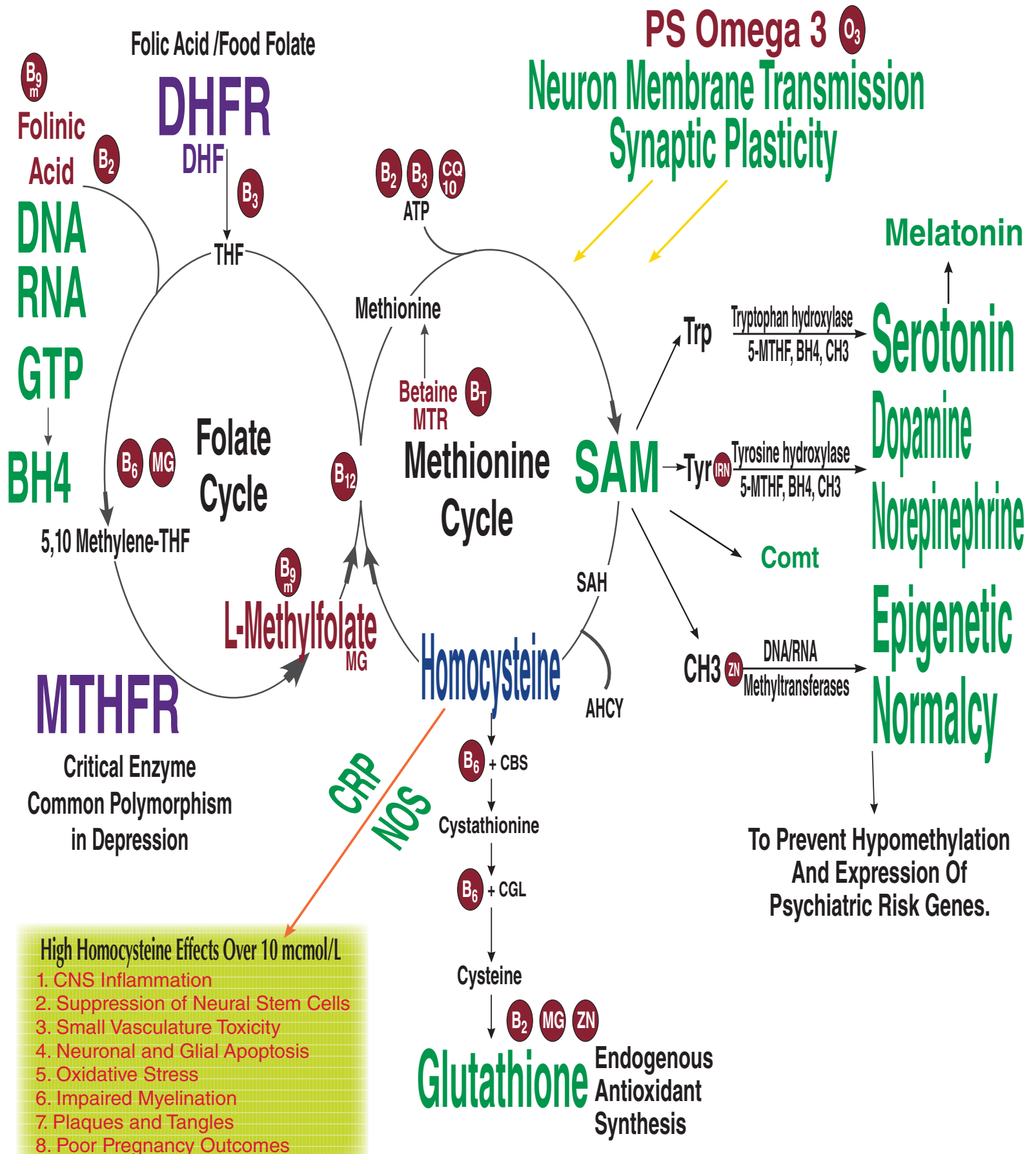
Energizer

CoQ10	500mcg
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METHYLATION CHART

EnLyte/EnBrace HR provides all the downstream coenzymes, cofactors, and omegas needed to normalize and balance biochemical endpoints which correlates into clinical remissions in well-controlled clinical trials.

EnLyte, EnBrace HR Product Ingredients **Maroon** | Biochemical End Points **Green**



THE JOURNAL OF CLINICAL PSYCHIATRY

MAY 2016

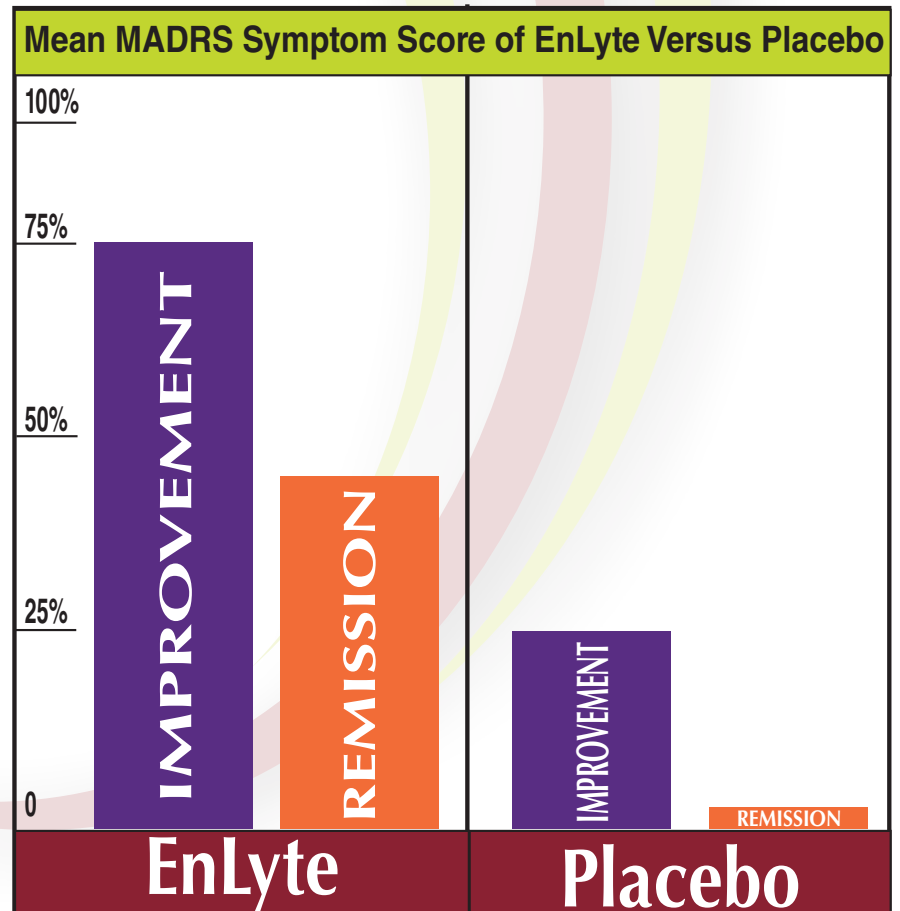
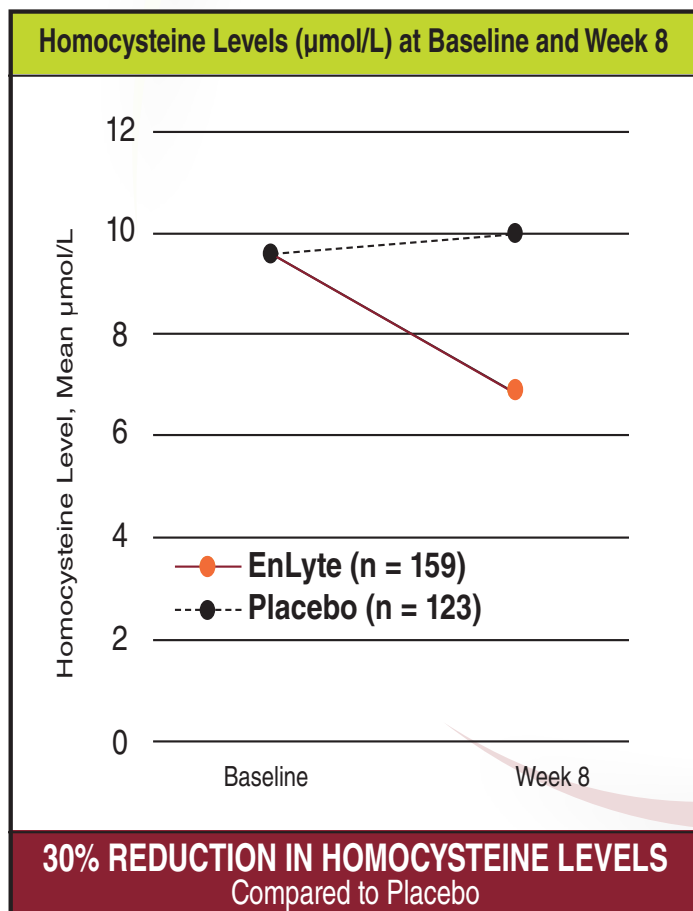
Correlation of Clinical Response With Homocysteine Reduction During Therapy With EnLyte/EnBrace HR
in Patients With MDD Who Are Positive for MTHFR C677T or A1298C Polymorphism

Andrew Farah, MD

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ADULT PATIENT RANDOMIZED DOUBLE
BLIND PLACEBO CONTROLLED STUDY

OBJECTIVE: This 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.



NO SIDE EFFECT WAS REPORTED AT GREATER RATE THAN PLACEBO

ONSET OF ACTION 2 WEEKS

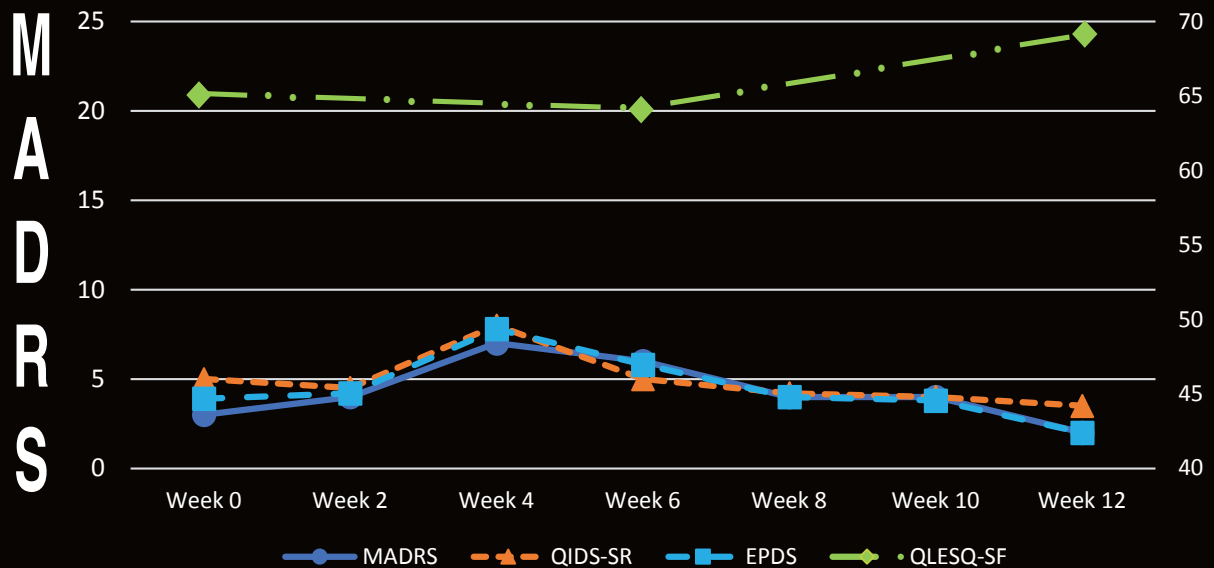


EnBrace HR For The Treatment and Prevention of Depression in Women Trying to Conceive and During Pregnancy



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

Relapse Prevention Group: MDD, But Well at Baseline Due to SSRIs/SNRIs, Drug ADs Replaced With EnBrace HR at Pregnancy



RESULTS:

Patients did not relapse to a major depressive episode or state compared to 63% that did in the Cohen Comparator.

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.

Female Hormones Regulate Serotonin in The Female Brain!
EnBrace HR normalizes and balances neurotransmitters in times of fluctuation and deficiency to manage:

PMS

(Premenstrual Syndrome)
Mild/Moderate



Menopause



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

Coenzyme Treatment of Childhood and Adolescent Depression and ADHD:

A Case Series

A. Farah MD, Gauri Madan MD, April 21, 2021

In Depression

- Indicated for MDD
- No Age Restriction
- Majority in Study Remitted
- No Side Effects Reported
- No Suicidal/Violent Thoughts

In ADHD

Treat “**Adjunctively**” with Stimulants to Address the “Whole Symptom Complex”

- Root Biochemical Cause
- Emotional Dysregulation
- Psychiatric Comorbidities
- Nutritional Deficiencies

“Monotherapy”

- Root Biochemical Cause
- In MTHFR SNP
- To Avoid Drug Side Effects
- During Drug Holiday

MDD Algorithm:

Andrew Farah MD, DFAPA

1. EnLyte 1 a day
2. Partial Goal, Week 3
Add Prozac 5-10 mg. a day
3. Partial Goal, Week 6, Each BID

ADHD Step-Care Algorithm:

Arwen Podesta MD, DFAPA, DFASAM

1. EnLyte 1 a day
2. Partial Goal, Week 4
Add Drug Non-Stimulant
Or Low Dose Drug Stimulant
3. Partial Goal, Week 8
Increase Drug Stimulant

ALL NATURAL SAFETY PROFILE

FDA Reported Side Effects	<u>EnLyte</u>	SSRI's	SNRI's
<i>Weight Gain</i>	No!	Yes	Yes
<i>Loss of Libido, difficulty achieving erections, inability to reach orgasm</i>	No!	Yes	Yes
<i>Increased thoughts of suicide and aggression in adolescents & adults</i>	No!	Yes	Yes
<i>Drowsiness or Confusion</i>	No!	Yes	Yes
<i>Nervousness & Agitation</i>	No!	Yes	Yes

Adapted from: Consumer Reports Best Buy Drugs. Using antidepressants to treat depression: comparing efficacy, safety and price. 2012

"90% of individuals with depression have lower CNS folate levels than their non depressed counterparts"

CONTRIBUTORS TO FOLATE AND OTHER B VITAMIN COENZYME DEFICIENCIES

GENETIC	CONDITIONS	DRUGS	POPULATIONS
MTHFR SNPS C677T A1298C	Gastric Bypass	Lamictal	Pregnant
	Celiac Disease	Metformin	Post Partum
	Kidney Disease	Methotrexate	Breast Feeding
	Liver Disease	Corticosteroids	Elderly
	Diabetes	NSAIDs	ADHD/ASD
Family History	Cancers	Antibiotics	Hispanic
Mental Illness	Anemias	Anticonvulsants	Alcoholic
Miscarriages	Crohn's	Oral Contraceptives	Drug Addiction
Birth Defects	Psoriasis		Smokers
Heart Disease	Eczema	Cholesterol Lowering	Child Bearing Age
Diabetes	Infection Viral / Bacterial		Depression
		Diuretics	Contaminants
B-Vitamin		Viral / Bacterial	H2 Antagonists
Non Tested	Phenytoin		
Methylation	Cardiac	SSRIs	Poor Nutrition
Polymorphisms	Epilepsy	SNRIs	Vegetarian
Suspected	Seizures	Aspirin	Stressed

EnLyte / EnBrace HR

Meet The Ingredient Requirements For American Psychiatric Association

Complementary and Alternative Medicine in Major Depressive Disorder: The American Psychiatric Association Task Force Assessment of Evidence, Challenges and Recommendations

APA Taskforce: Marlene Freeman MD, Maurizio Fava MD, J Lake MD, MH Trivedi MD, David Mischoulon MD

"Folate: Folate and several related compounds have received study to ascertain if there is a potential role in the treatment of MDD. There is consistent and growing evidence of a role for various folate forms in the prevention and treatment of depression. Studies to date demonstrate efficacy of augmentation of antidepressants with folic acid, folinic acid (leucovorin), and 5-methyltetrahydrofolate (5-MTHF). Similar findings may be attributable to the fact that these folate forms share an interconversion potential in the complex set of pathways that comprise the one-carbon or methylation cycles. These reactions, which in turn depend on B12 and homocysteine availability, are postulated to exert an antidepressant effect by impacting the synthesis of neurotransmitters such as serotonin, dopamine, and norepinephrine."

#1

"Folate augmentation should be used to enhance antidepressant efficacy from the start of treatment or, for patients who are already on antidepressant treatment, to convert partial or non-responders into responders or remitters."

#2

"Folate and methylfolate monotherapy may benefit certain depressed populations."

#3

"APA advocates for, folate/methylfolate with B12 and Omega 3s as monotherapy or augmentation strategy for MDD."

MDD Algorithm:

Andrew Farah MD, DFAPA

Adult MDD/Mild – Moderate

EnLyte/EnBrace HR 1 a Day

Partial/non-response at 4 weeks, Enlyte/EnBrace HR twice a day

Partial/non-response add SRI or SNRI, continue EnLyte/EnBrace HR (BID)

Adult MDD/Severe

EnLyte/EnBrace HR with SRI or SNRI [from Day 1]

Partial/non-response at 3 weeks – increase Enlyte/EnBrace HR to BID /
increase dose of antidepressant @ clinician discretion

Partial/non-response 6 weeks - Enlyte/EnBrace HR BID/switch AD/or
escalate dose at discretion

No response 12 weeks to BID Enlyte/EnBrace HR and >3

ADs: TMS or ketamine + Enlyte/EnBrace HR

MDD in Pregnancy

EnLyte/EnBrace HR 1 a Day

Partial/non-response - 3 weeks Enlyte/EnBrace HR BID

Partial/non-response 6 weeks- continue Enlyte/EnBrace HR,
add SRI [Not Paxil/Wellbutrin]

Partial/non-response 9 weeks: cont. Enlyte/EnBrace HR with new AD
or with TMS

HOW TO PRESCRIBE

STEP #1

USE OUR ONLINE PRESCRIBER FORM

Visit www.enlyterx.com and click on “Prescribe Now!” Fill in prescriber and patient information and then hit “submit”

STEP #2

WE WILL OFFER YOUR PATIENT THEIR FIRST 60 DAYS FOR \$60 (2 BOTTLES AT \$29.95 EACH)

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 INFORMATION

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

INSURANCE COVERAGE

MEDICAID COVERAGE:

- LOUISIANA:** EnBrace HR / EnLyte Preferred on La MCD with no PA
- TEXAS:** EnLyte Preferred on Texas MCD with no PA
- SOUTH DAKOTA:** Enlyte is Preferred on SD MCD.
- NEW YORK:** EnBrace HR Preferred.

COMMERCIAL COVERAGE:

COMMERCIAL COVERAGE IS DEPENDENT ON INDIVIDUAL INSURANCE PLANS

DISCOUNTED CASH PAY OPTION:

If EnLyte is not covered on an individual insurance plan, patients have the option of purchasing the non-prescription version called “ENL” through Direct Value Dispense at an affordable cost. Call 985.629.5825 For More Information.

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