La Renon

SYNERGISED EFFECT FOR

Lasting Happiness

1ST TIME IN INDIA

BROPIDEX

Dextromethorphan Hydrobromide 45 mg and Bupropion Hydrochloride (As Extended Release) 105 mg Tablets

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INTRODUCTION:

Major depressive disorder (MDD) affects millions of people and is the leading cause of disability worldwide.

Currently approved oral antidepressants work primarily via monoamine pathways. Partial or inadequate response is common with these agents, and they typically take several weeks to produce clinically meaningful effects.

To address the limitations of existing antidepressants, there is an imperative for the development of novel pharmacotherapies.

DEXTROMETHORPHAN + BUPROPION:

NOVEL, ORAL NMDA RECEPTOR ANTAGONIST WITH MULTIMODAL ACTIVITY

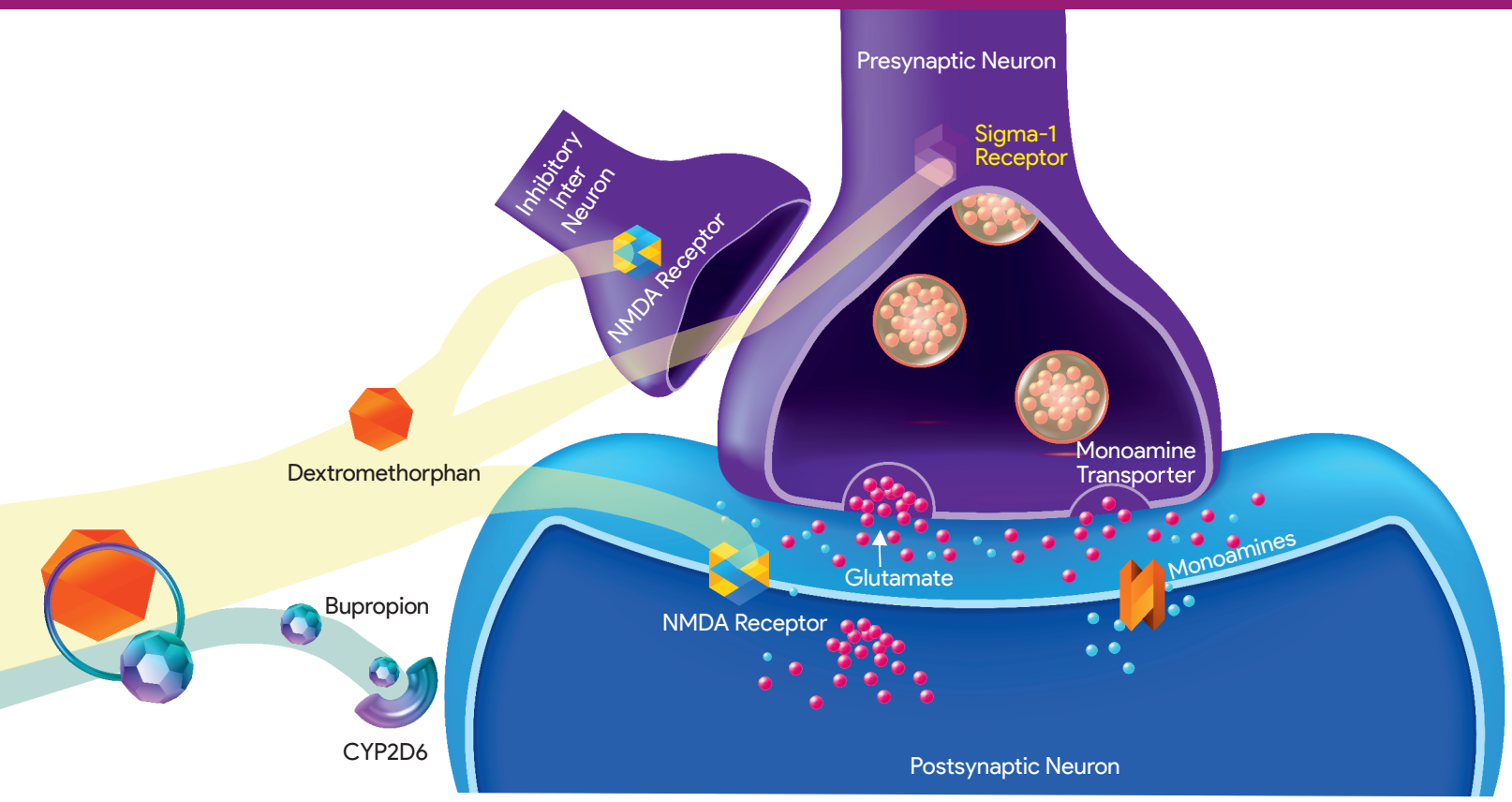

Fig1. Bupropion + Dextromethorphan Mechanism of action in MDD

*For Illustrative Purposes only

ANTIDEPRESSANT (DEXTROMETHORPHAN - BUPROPION) THAT WORKS RAPID AND LASTING

RAPID

Significant improvements in depressive symptoms compared to placebo starting 1 week after treatment initiation.[1]

Early and substantial achievement of remission on the MADRS (total score ≤10), with statistically significant separation from placebo demonstrated at week 2 and at every subsequent time point.[1]

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LASTING

Sustained Symptom improvement: At the end of the 6-week treatment period, patients in the dextromethorphan-bupropion group had significantly larger reductions from baseline in their MADRS total score with a statistically significant effect.[2]

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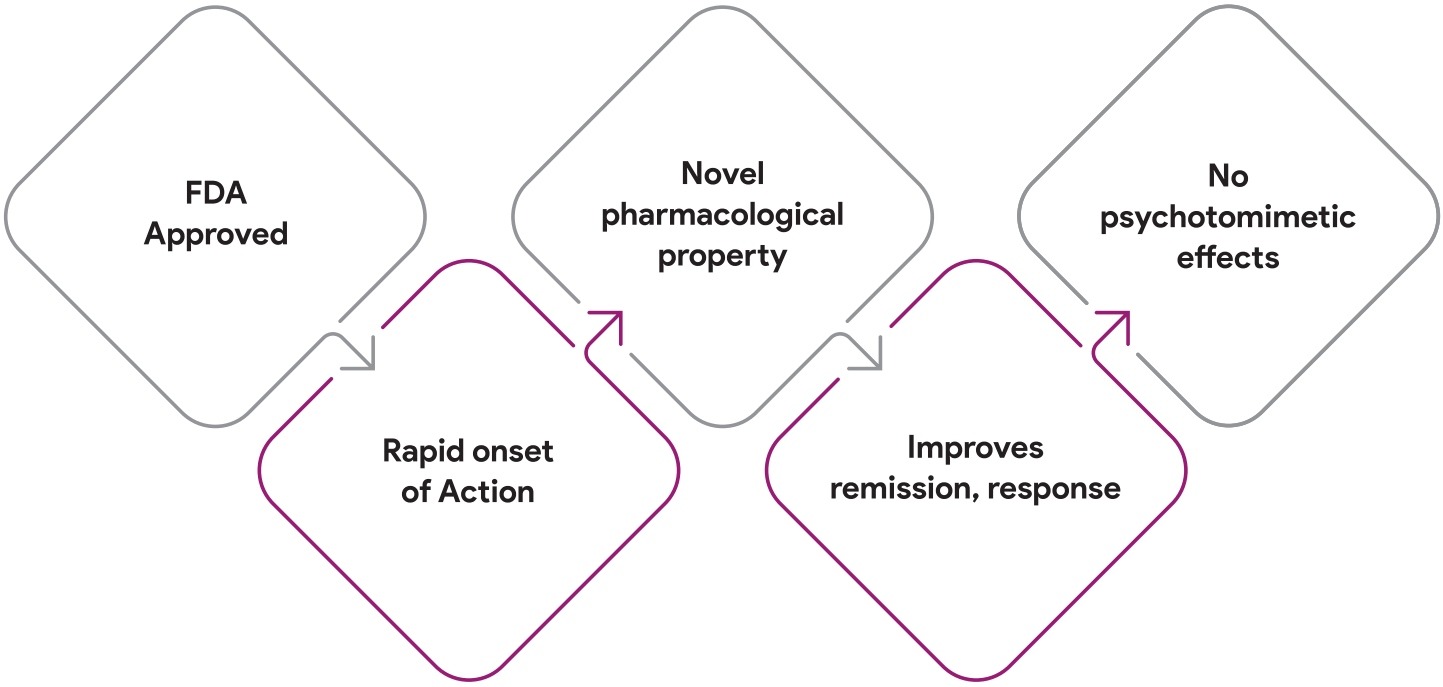


References:
1.J Clin Psychiatry. 2022 May 30;83(4):21m14345.
2.Clinical Psychopharmacology and Neuroscience 2023;21(4):609-616

CLINICAL EVIDENCE

1 EFFICACY AND SAFETY OF DEXTROMETHORPHAN-BUPROPION IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER: A PHASE 3 RANDOMIZED CLINICAL TRIAL (GEMINI)

Ref: J Clin Psychiatry. 2022 May 30;83(4):21m14345.

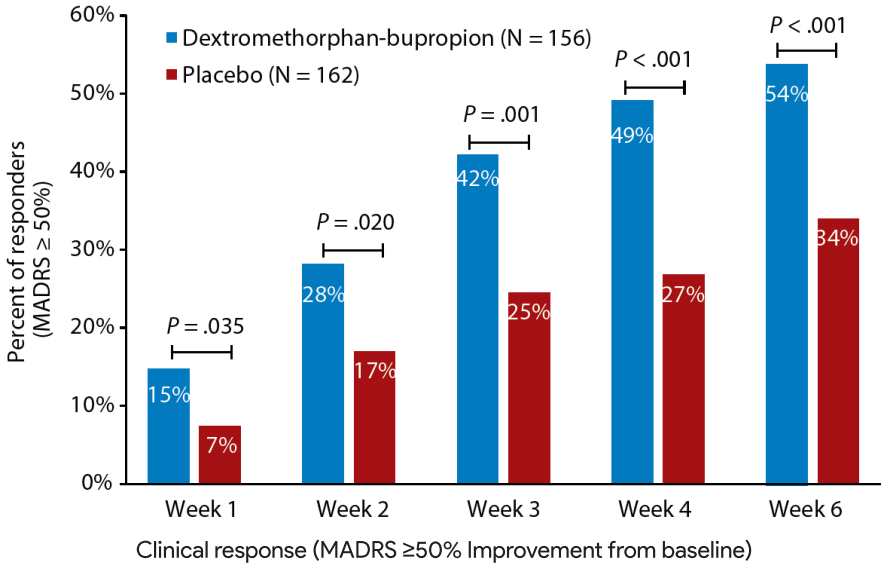
No. of Participants: 327 patients

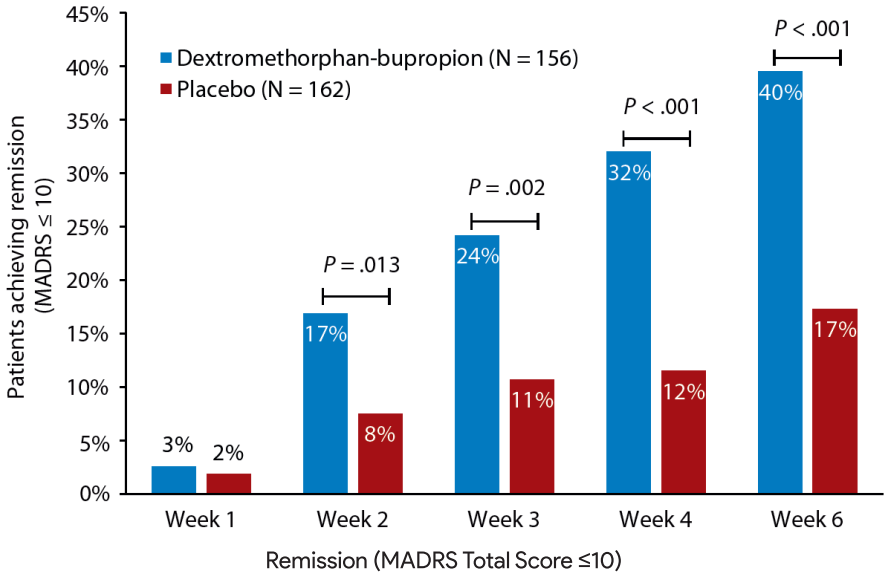
Dose: Dextromethorphan-bupropion (45 mg-105 mg tablet) or placebo, (once daily for days 1-3, twice daily thereafter)

Duration: 6 weeks

Result:

- Dextromethorphan-bupropion was superior to placebo for MADRS improvement at all time points including week 1 (P = .007) and week 2 (P < .001).
- Remission was achieved by 39.5% of patients with dextromethorphan-bupropion versus 17.3% with placebo, and clinical response by 54.0% versus 34.0%, respectively at week 6.





**MADRS: Montgomery-Asberg Depression Rating Scale*

CONCLUSION: Dextromethorphan-bupropion shows significant improvements in depressive symptoms compared to placebo starting 1 week after treatment initiation and is generally well tolerated.

2 EFFECT OF DEXTROMETHORPHAN-BUPROPION IN MAJOR DEPRESSIVE DISORDER: A RANDOMIZED DOUBLE-BLIND CONTROLLED TRIAL

Ref: Am J Psychiatry 2022; 179:490–499

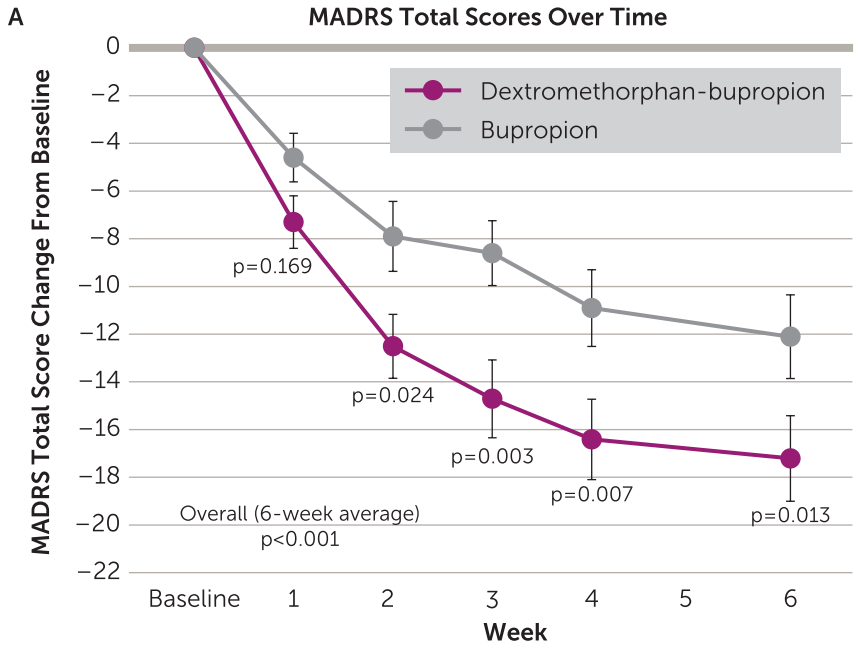
No. of Participants: 97 patients

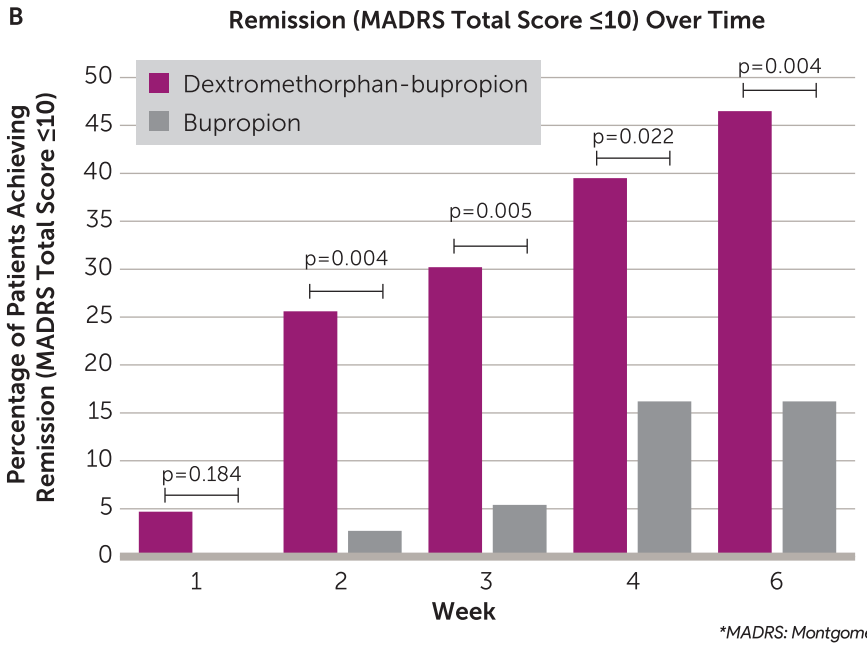
Dose: Dextromethorphan bupropion (45 mg/105 mg tablet) or bupropion (105 mg tablet), once daily for the first 3 days and twice daily thereafter.

Duration: 6 weeks

Result:

- The mean change from baseline in MADRS score over weeks 1–6 (overall treatment effect) was significantly greater with dextromethorphan bupropion than with bupropion.
- Remission rates were significantly greater with dextromethorphan-bupropion at week 2 and every time point thereafter (week 6: 46.5% vs. 16.2%; least-squares mean difference = 30.3%, 95% CI=11.2, 49.4).





**MADRS: Montgomery-Asberg Depression Rating Scale*

CONCLUSION: Dextromethorphan-bupropion significantly improves depressive symptoms compared with bupropion and is generally well tolerated.

BROPIDEX

Dextromethorphan Hydrobromide 45 mg and Bupropion Hydrochloride (As Extended Release) 105 mg Tablets

DESCRIPTION:

BROPIDEX contains Dextromethorphan Hydrobromide 45 mg and Bupropion Hydrochloride (As Extended Release) 105 mg available in the tablet. Dextromethorphan- bupropion combination tablet represents a novel rapid-acting oral treatment option for depression in adults.[1]

INDICATION:

It is indicated for the treatment of major depressive disorder (MDD) in adults.[1]

MECHANISM OF ACTION:

Dextromethorphan modulates glutamate signaling through uncompetitive antagonism of N-methyl-D-aspartate receptors and sigma-1 agonism, while bupropion (a dopamine and norepinephrine reuptake inhibitor) increases the bioavailability of dextromethorphan by CYP2D6 inhibition.[1]

DOSAGE AND ADMINISTRATION:

- The starting dosage is one tablet once daily in the morning.
- After 3 days, increase to the maximum recommended dosage of one tablet twice daily, separated by at least 8 hours. Do not exceed two doses within the same day.

PRESENTATION:

Available as a strip of 10 tablets.

STORAGE:

Store at a temperature below 30°C.

KEY POINTS:

- It is an effective and fast-acting oral treatment option for depression.[1]
- It not only demonstrated a reduction in depressive symptoms but substantial benefit in achieving remission and response.[1]
- The formulation achieves pharmacologic synergy by simultaneously targeting monoamines, NMDA receptors, and sigma-1 receptors, resulting in more rapid and robust decreases in depression rating scale scores than bupropion treatment alone.[2]
- Unlike other NMDA receptor antagonists, dextromethorphan bupropion is not associated with psychotomimetic effects.[3]

References:
1.Clinical Psychopharmacology and Neuroscience 2023;21(4):609-616
2.CNS Spectrums (2019), 24, 461–466.
3. Am J Psychiatry 179:7, July 2022

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