Safety Profile of Delayed-Release Dimethyl Fumarate in Relapsing–Remitting MS: Long-term Interim Results from the ENDORSE Extension Study

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OBJECTIVE

To report safety findings (as of June 2013 data cut) from ENDORSE, investigating the longer-term effects of delayed-release DMF in patients with RRMS. 

METHODS

Study design

- ENDORSE is a multinational, parallel-group, placebo-controlled study with up to 1 year of follow-up.
- Inclusion criteria comprised key parent DEFINE and CONFIRM results.
- Patients who received 240 mg of delayed-release DMF twice daily (BID) or three times daily (TID) for up to 55 weeks in parent DEFINE and/or CONFIRM and continued into the ENDORSE extension study.

Patients in the TID/BID treatment arm of CONFIRM were permitted to remain on TID/BID treatment in ENDORSE.

At study initiation, 1,185 patients were randomized to DMF BID (n = 360), DMF TID (n = 354), GA/BID (n = 118), GA/TID (n = 118), PBO/BID (n = 248), and PBO/TID (n = 248), respectively.

The overall incidence of AEs, serious AEs (SAEs), and discontinuations due to AEs were similar among: patients on BID/BID and TID/TID, respectively.

Efficacy outcomes

Safety population grouped according to treatment received. One patient randomized to DMF TID took GA throughout the CONFIRM extension study. The safety profile for patients newly exposed to delayed-release DMF in ENDORSE is consistent with that of the parent DEFINE and CONFIRM studies.

Safety population and safety population treatment received. One patient randomized to DMF TID took GA throughout the CONFIRM extension study.

The mean most common individual AEs are summarized in Table 4. For patients continuing delayed-release DMF treatment, renal or urinary events were reported in 19% and 18% of patients, respectively. The mean overall incidence of renal or systemic infections was 13.3% in any treatment group.

CONCLUSIONS

There were no new or worsening safety signals identified among patients who continued treatment with delayed-release DMF in RRMS patients.

Neither the incidence of new or worsening some lab abnormalities was identified.

There was no evidence of an increased risk of malignancy among patients treated with delayed-release DMF.

The safety profile for patients newly exposed to delayed-release DMF in ENDORSE is consistent with that observed in DEFINE and CONFIRM studies.

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REFERENCES


