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To Study Regulatory Requirements for Marketing authorization of Febuxostat Tablet in India

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Abstract

Febuxostat has been approved for the treatment of hyperuricemia in patients with/without gout. This meta-analysis and systematic review assessed the efficacy and tolerability of febuxostat in hyperuricemia patients with/without gout. Major electronic databases were searched for articles of all publication years (up to February 2012), as were the Web sites of the American College of Rheumatology, the European League Against Rheumatism, and the Chinese State Food and Drug Administration, and clinical trials. gov for unpublished studies. Only randomized, controlled trials (RCTs) were included. Ten trials were included. A significantly greater proportion of patients achieved the target serum urate level (sUA ≤6.0 mg/dL) at the final visit in the febuxostat group compared with the placebo (OR = 235.73; $P < 0.01$) and allopurinol groups (OR = 3.14; $P < 0.01$). In subgroup analysis, the proportion of patients who achieved target sUA at the final visit was significantly greater in the febuxostat-treated group (40 mg/d) compared with the allopurinol-treated group (100–300 mg/d) (50.9% vs 45.6%; OR = 1.25; 95% CI, 1.05–1.49; $P = 0.01$). As the dosage was increased (40, 80, 120 mg/d), the proportion of patients who achieved targets UA in the febuxostat-treated group increased gradually (50.9%, 71.4%, 82%, respectively). There was no significant difference in the occurrence of adverse events (AEs) between the febuxostat- and allopurinol-treated groups.

Key words: Febuxostat, hyperuricemia, gout, meta-analysis

Introduction

Marketing authorization: Process of reviewing and assessing the dossier to support a medicinal product in view of its marketing licensing, registration, approval, etc. obviously finalized by granting of a document also called marketing authorization. This process is performed within a legislative framework which defines the requirements necessary for application to the concerned (competent) regulatory authority, details on the assessment procedure (based on quality, efficacy and safety criteria) and the grounds for approval or rejection of the application, and also the circumstances where a marketing authorization already granted may be withdrawn, suspended or revoked. The application dossier for marketing authorization is called New Drug Application (NDA) in the USA or Marketing Authorization Application (MAA) in the European Union and other countries, or simply registration dossier. The application is filed with the competent drug regulatory authority in the concerned country, which can be either an independent regulatory body or a specialized department in the ministry of health. In accordance with local legislation, the resulting document allowing to the applicant to market the product may be more detailed (in addition to data identifying the product and its holder it may contain addresses of all manufacturing sites, appended labeling, artwork of packaging components, etc.) until a one-page document called certificate of registration (and containing minimal data identifying the product and its source).

Methods

Major electronic databases were searched for articles of all publication years (up to February 2012), as were the Web sites of the American College of Rheumatology, the European League Against Rheumatism, and the Chinese State Food and Drug Administration, and clinical trials.gov for unpublished studies. Only randomized, controlled trials (RCTs) were included.

Procedures for obtaining a marketing authorization

Authorization processes follow either a purely national procedure, with rules and requirements as per national legislation in force, as it occurs in most of countries worldwide, or should follow a centrally approval or a mutual recognition or decentralized procedure within the European Union.

Types of applications

The type of application may vary according to status of the active ingredient. Thus, if the application concerns a new active ingredient one talks about a full application. Once a new active ingredient authorized, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations changes to the existing marketing authorization and extensions shall be granted an authorization or be included in the initial marketing authorization. radionuclide generators, kits, radionuclide precursor radiopharmaceuticals and industrially prepared radiopharmaceuticals; in such instances, requirements are specific, in the meaning that they are special, more or less detailed, as per the nature of active ingredient.

Validity of marketing authorizations

In most countries, a marketing authorization is valid for a period of 5 years. After this period, one should apply for renewal of the marketing authorization, usually by providing minimal data proving that quality, efficacy and safety characteristics are maintained and the risk-benefit ratio of the medicinal product is still favorable. The European Union, after one renewal, the marketing authorization shall remain valid for an unlimited period, unless the competent regulatory authority decides otherwise. If the marketing authorization is not renewed in a due time as requested by the local legislation, in order to maintain the pharmaceutical product on a market, one can apply for re-authorization. Marketing authorization may be withdrawn, suspended, revoked or varied by regulatory authorities if under normal conditions of use the benefit over risk ratio is no more favorable, the product is harmful, or if it lacks therapeutic efficacy; also, one of the above actions can be taken if the qualitative and quantitative composition or other qualitative aspects are not as currently declared. Marketing authorization may also be withdrawn, suspended or revoked if the marketing authorization holder or its representative does not fulfill other legal or regulatory.

Contents

1. Febuxostat (Mfg & Mkt - Rule 122-B):
2. Form 29 for R&D
3. Initiation of R&D batches (3 batches)
4. Submission of Application for Mfg & Mkt (CMC Data, 3 batches stability data,
5. Specification, STP, BE Study protocol,
6. ICF, CRF, EC approval, PI Undertaking as per Schedule Y) - BE Study
7. Initiation of BE Study & Submission of BE Study Report
8. Mfg & Mkt permission

Results

Ten trials were included. A significantly greater proportion of patients achieved the target serum urate level (sUA ≤6.0 mg/dL) at the final visit in the febuxostat group compared with the placebo (OR = 235.73; $P < 0.01$) and allopurinol groups (OR = 3.14; $P < 0.01$). In subgroup analysis, the proportion of patients who achieved target sUA at the final visit was significantly greater in the febuxostat-treated group (40 mg/d) compared with the allopurinol-treated group (100–300 mg/d) (50.9% vs 45.6%; OR = 1.25; 95% CI, 1.05–1.49; $P = 0.01$). As the dosage was increased (40, 80, 120 mg/d), the proportion of patients who achieved target sUA in the febuxostat-treated group increased gradually (50.9%, 71.4%, 82%, respectively). There was no significant difference in the occurrence of adverse events (AEs) between the febuxostat- and allopurinol-treated groups.

Conclusion

Febuxostat was effective in reducing serum urate in hyperuricemia patients with/without gout, and febuxostat (40–120 mg/d) was more efficacious compared with allopurinol (100–300 mg/d). The doses of allopurinol to which febuxostat has been compared, although commonly prescribed, are low in the range of approved doses of allopurinol. The tolerability of febuxostat for the treatment of hyperuricemia with/without gout is similar to that of allopurinol.

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