

## Recommendations and Reasons

Committee to Evaluate Drugs (CED)

### Risedronate sodium

**Product:**

RISEDRONATE SODIUM (Actonel®)  
75mg and 150mg tablets

**Class of drugs:**

Bisphosphonate

**Indication:**

Treatment of osteoporosis

**Manufacturer:**

Procter & Gamble Pharmaceuticals

#### CED Recommendation-

The CED recommended that risedronate sodium (Actonel®) 75mg and 150mg tablets not be listed on the ODB Formulary, on the basis that there is no proven advantage of these new strengths of risedronate sodium over existing formulary alternatives to justify the price premium.

#### Executive Officer Decision

Taking into consideration the CED's recommendation and based on a subsequent listing agreement that addresses price and utilization with the manufacturer, the Executive Officer decided list risedronate sodium (Actonel®) 150mg tablet.

Risedronate sodium (Actonel®) 75mg tablet has been discontinued by the manufacturer since the review.

#### Status

Funding of risedronate sodium (Actonel®) 150mg tablet through the Ontario Public Drug Programs on the ODB Formulary as General Benefit.

**Highlights of Recommendation:**

- ◆ Risedronate sodium 75mg and 150mg tablets belong to a class of drugs called bisphosphonates, used to treat osteoporosis. The formulations are new strengths of risedronate sodium being added to an existing line of products.
- ◆ Risedronate sodium 5mg, 30mg and 35mg are already listed on the ODB Formulary as General Benefits.
- ◆ Patients take risedronate sodium 75mg tablets on two consecutive days each month. Patients take risedronate sodium 150mg tablets once a month. Risedronate sodium 5mg is taken once daily and risedronate sodium 35mg is taken once weekly.
- ◆ According to the manufacturer, risedronate sodium 75mg and 150mg tablets were developed to improve treatment of osteoporosis by meeting the needs of patients who find it difficult to take the medication once a day or once a week. No data were available to support improved compliance or tolerability.
- ◆ There is no data demonstrating that risedronate sodium is better than other drugs in the same class already listed on the Ontario Drug Benefit Formulary.
- ◆ The CED was not convinced that adding the 75 mg tablets or 150mg tablets would be a cost saving for the Ministry, because there are lower cost alternatives available.
- ◆ **Overall, there is no evidence available to prove that risedronate sodium is better than available alternatives to treat osteoporosis, and a price premium for the 75mg and 150mg tablets is not warranted. The CED recommended that risedronate sodium 75mg and 150mg tablets not be listed on the ODB Formulary.**

**Background:**

Osteoporosis is a condition in which bones lose mass and density, becoming brittle and vulnerable to fractures, most commonly in the hips, wrists and spine. It is a disease of aging, more common in women than in men. Treatment and prevention of osteoporosis includes making sure patients consume enough calcium and vitamin D and strengthen their muscles through weight-bearing exercises.

Bisphosphonates are a class of drugs taken to maintain bone density and strength. They include etidronate, alendronate, risedronate, and zoledronic acid. Etidronate (which is packaged in a kit with calcium), alendronate and risedronate are currently listed on the Ontario Drug Benefit Formulary. Funding of zoledronic acid is available via the Exceptional Access Program (EAP) according to specific criteria.

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### Detailed Discussion:

- ◆ This is a line-extension product; risedronate sodium 5mg, 30mg and 35mg tablets are already reimbursed on the Formulary as a General Benefits.
- ◆ Risedronate sodium 75mg tablets are taken on two consecutive days per month and risedronate sodium 150mg tablets are taken once monthly. The manufacturer implies that this would improve patient compliance, but has not provided any published data to support this contention.
- ◆ The submitted evidence demonstrates similar efficacy and side-effect profile as risedronate sodium 5mg taken once daily. Improvements in gastrointestinal tolerance and compliance have not been proven.
- ◆ In addition, there is no data demonstrating that risedronate sodium is more effective in reducing fracture rates or causes fewer side effects than alendronate, a less expensive alternative listed on the Formulary.
- ◆ **Overall, the CED noted that there is no proven advantage over Formulary alternatives to justify the price premium of risedronate sodium 75mg and 150mg tablets. The CED expressed a willingness to reconsider this recommendation if risedronate sodium 75mg and 150mg tablets are available at a cost advantage compared with generic alendronate.**

### CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Drug Advisory Committee (CEDAC) did not review this product.



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