

Risedronate/Calcium

Product:

RISEDRONATE/CALCIUM (Actonel Plus Calcium®), 35mg/1250mg tablets

Class of drugs:

Bisphosphonate

Indication:

Treatment of osteoporosis

Manufacturer:

Procter & Gamble Pharmaceuticals Canada

CED Recommendation

The CED recommended that risedronate/calcium (Actonel Plus Calcium) not be listed on the Ontario Drug Benefit (ODB) Formulary, on the basis that it is more expensive than products with similar benefits already listed on the Formulary.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer has decided not to list risedronate/calcium (Actonel Plus Calcium).

Status

No funding through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Risedronate/calcium (Actonel Plus Calcium) is a combination kit containing risedronate and calcium. The risedronate is taken once weekly, and the calcium is taken once daily on the other six days of the week. Each calcium tablet provides the equivalent of 500mg of elemental calcium.
- ◆ Risedronate/calcium (Actonel Plus Calcium) is used to treat osteoporosis.
- ◆ Among other strategies, adequate intake of calcium and Vitamin D is considered first-line treatment for osteoporosis, and may prevent its onset.
- ◆ Alendronate, etidronate/calcium, and risedronate are alternatives that are all available on the Ontario Drug Benefit Formulary.
- ◆ The manufacturer provided clinical data for risedronate in its submission for risedronate/calcium (Actonel Plus Calcium). The manufacturer did not provide any new data for the combination products.
- ◆ Risedronate/calcium (Actonel Plus Calcium) costs approximately the same as risedronate (Actonel), but is more expensive than products with similar benefits such as alendronate and etidronate/calcium. Calcium supplements are inexpensive and may be purchased over the counter.
- ◆ **Overall, in light of the fact that risedronate/calcium (Actonel Plus Calcium) is no more effective but is more expensive than alternatives currently listed on the Formulary, the Committee recommended that risedronate/calcium (Actonel Plus Calcium) not be listed on the ODB Formulary.**

Background:

Osteoporosis is the loss of bone mineral density, and is a disease of aging. More common in women than in men, osteoporosis may lead to fractures of the spine and hip in advanced cases.

Primary treatment (and prevention) of osteoporosis includes making sure patients consume enough calcium and Vitamin D and strengthen their muscles through weight-bearing exercise. Patients should also stop smoking, consume little or no alcohol, and try to prevent falls.

Secondary treatment involves a class of drugs called, bisphosphonates, which inhibit the reabsorption of bone. This class includes etidronate/calcium, alendronate and risedronate. All are currently listed on the ODB Formulary.

Third-line treatments (in women only) are raloxifene and hormone replacement therapy. Both are listed in the ODB Formulary.

Risedronate/calcium (Actonel Plus Calcium) contains risedronate 35mg and six calcium carbonate 1250mg tablets (each providing 500mg of elemental calcium). It is indicated for the treatment of osteoporosis in postmenopausal women. Actonel Plus Calcium is provided in a "compliance package" kit.

Detailed Discussion:

- ◆ The manufacturer, Procter & Gamble Pharmaceuticals Canada, asked the Ontario Ministry of Health and Long-Term Care to reimburse risedronate/calcium (Actonel Plus Calcium) on the ODB Formulary.
- ◆ The manufacturer's submission did not provide any new clinical trial data, beyond that previously reviewed for risedronate (Actonel) alone.

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- ◆ Risedronate/calcium (Actonel Plus Calcium) is available at approximately the same price as risedronate 35mg (i.e. the manufacturer is providing the calcium component free of charge). Calcium is not a benefit on the Formulary, is inexpensive, and customers may purchase it over the counter.
- ◆ The Committee noted that risedronate and risedronate/calcium (Actonel Plus Calcium) are more expensive than generic alendronate (approximately \$37.44 monthly for risedronate versus \$17.70 monthly for alendronate), while both risedronate and alendronate have demonstrated comparable efficacy in the treatment of osteoporosis.
- ◆ Since alendronate is now a generic product and is available at a lower cost, using risedronate may not be as cost-effective when compared to using alendronate.
- ◆ Common side effects of risedronate/calcium (Actonel Plus Calcium) include joint pain, infection and back pain.
- ◆ Overall, in light of the fact that that risedronate/calcium (Actonel Plus Calcium) provides no therapeutic benefit over existing bisphosphonate alternatives on the formulary and is more expensive, the Committee recommended that this product not be funded.
- ◆ The CED expressed a willingness to reconsider this recommendation if risedronate/calcium (Actonel Plus Calcium) is 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 risedronate/calcium (Actonel Plus Calcium).



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