Canadian Agency for Drugs and Technologies in Health

Agence canadienne des médicaments et des technologies de la santé

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

QUINAGOLIDE
(Norprolac – Ferring Pharmaceuticals Inc.)

Description:
Quinagolide is a selective dopamine-2 receptor agonist indicated for the treatment of hyperprolactinemia (idiopathic or originating from a prolactin-secreting pituitary microadenoma or macroadenoma).

Dosage Forms:
0.075 and 0.15 mg tablets

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that quinagolide be listed in patients with hyperprolactinemia who have failed or are intolerant to bromocriptine.

Reasons for the Recommendation:

1. In four randomized controlled trials (RCTs), quinagolide was similar in efficacy compared with bromocriptine with respect to lowering/normalizing serum prolactin, resolution of amenorrhea/oligomenorrhea and resolution of galactorrhea. Limited evidence from direct comparisons of quinagolide and cabergoline (2 small RCTs) suggest similar efficacy.

2. A meta-analysis of three RCTs comparing quinagolide with bromocriptine found fewer withdrawals due to adverse effects in quinagolide treated patients, although the interpretation of this information is difficult as many of the patients in these trials had been previously treated with bromocriptine.

3. Women wishing to conceive may be treated with quinagolide, but its risk to the fetus is not known because there are limited published data to support its safety in pregnancy.

4. Since the initial submission reviewed by the Committee, the cost of quinagolide has been significantly reduced and is now equivalent in cost to bromocriptine and less costly than cabergoline.

Of Note:

1. There are no RCTs of newly diagnosed patients with hyperprolactinemia that compare quinagolide to bromocriptine or cabergoline.

2. Both published and unpublished data were used and taken into consideration in making this recommendation.