

Ontario Public Drug Programs Drug Submission Status

Generic Name: mesalazine (5-aminosalicylic acid)

Brand Name: Pentasa

Strength: 1g ER tablet

Manufacturer: Ferring Inc.

Indication: Treatment of mild to moderate active ulcerative colitis and for long-term maintenance therapy in order to maintain remission and prevent relapse of active disease and Management of mild to moderate Crohn's Disease and maintenance of Crohn's Disease in remission induced by surgery or medication

Rapid Review: Not Requested

Submission Type:	Date Submission Received:	Date Submission Deemed Complete:	Review Status:	Funding Status:
First Review: (Initial Submission)	14/03/2013	01/08/2013	EO decision rendered	Listed on the Ontario Drug Benefit Formulary as General Benefit

Rapid Review:

Details of the Rapid Review process can be found at:

[Rapid Review Process](#)

Review Status:

- Screening - Ministry is screening the manufacturer's submission to ensure all regulatory and policy requirements have been met in order to proceed with the drug review.

- Submission incomplete - Manufacturer did not meet the necessary requirements to allow review to proceed.
- Submission complete & under review - Manufacturer met all requirements to proceed with the drug review, and evaluation of the drug submission is underway.
- Committee to Evaluate Drugs (CED) review completed, manufacturer requesting reconsideration – A recommendation was made by the CED, however the manufacturer has submitted or will be submitting additional information.
- Committee to Evaluate Drugs (CED) review completed - A recommendation was made by the CED.
- Ontario Steering Committee for Cancer Drugs (OSCCD) review completed-A recommendation was made by the OSCCD.
- Executive Officer (EO) decision rendered.

Funding Status:

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision, if available, can be found at:

[The CED recommendation and the EO decision](#)

Updated: November 27, 2015