
Now available in Canada
whole
SEIZE THE DAY
WITH A 1600 mg 5-ASA
PrOCTASA® is indicated for the induction of remission of moderate active ulcerative colitis (UC).
THE HIGHEST-STRENGTH*
DELAYED-RELEASE 5-ASA
AVAILABLE
PrOCTASA®
mesalamine
1600 mg
OPTICORE®
WITH OPTICORE® TECHNOLOGY:
A MULTI-LAYER COATING SYSTEM FOR TARGETED RELEASE*
5-ASA: 5-aminosalicylic acid
*Clinical significance has not been established.

Induce remission in moderately active UC

Get patients back to making each day count

Highest-strength tablet on the market*

Canada's only 1600 mg delayed-release 5-ASA tablet

Cutting-edge technology*

OPTICORE®: Two trigger release mechanisms facilitate targeted mesalamine release

Clinically proven efficacy and safety

Demonstrated short- and long-term efficacy†,‡,§ in an induction trial and open-label extension and has an established safety profile

*Clinical significance has not been established.
†The TP0503 study was a randomized, double-blind, active-controlled, multicentre non-inferiority trial that compared the safety and efficacy of 3.2 g/day of OCTASA® 1600 mg (n=409) to 3.2 g/day of ASACOL 400 mg (n=408) over an 8-week period. An open-label extension to assess the long-term safety and tolerability of OCTASA® 1600 mg continued based on induction response. Clinical and endoscopic remission at Week 8 was considered as the primary measure of efficacy for the induction phase, while clinical remission at Week 38 was considered as the primary measure of efficacy in the open-label extension.
‡At Week 8, clinical and endoscopic remission occurred in 22.4% and 24.6% of patients receiving 2 x 1600 mg tablets once daily and 4 x 400 mg tablets twice daily, respectively (non-inferiority p=0.005).
§33.9% (95% CI [confidence interval]: 28.4%–39.9%) of responders but non-remitters after 12 weeks of induction, who received 3.2 g/day following induction, and 30.7% (95% CI: 24.3%–37.6%) of non-responders after 8 weeks of induction at 3.2 g/day, who received 4.8 g/day following induction, achieved clinical remission at Week 38.

PENDOPHARM | PROUDLY CANADIAN

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Pr OCTASA® mesalamine 1600 mg OPTICORE®

Reducing pill burden for UC patients

Simplicity in dosing

To induce remission:

3.2 g	2 x	1 x
Daily dose (1600 mg x 2)	With 2 tablets	Once daily (or in divided doses)

Similar size as other high-strength mesalamine tablets

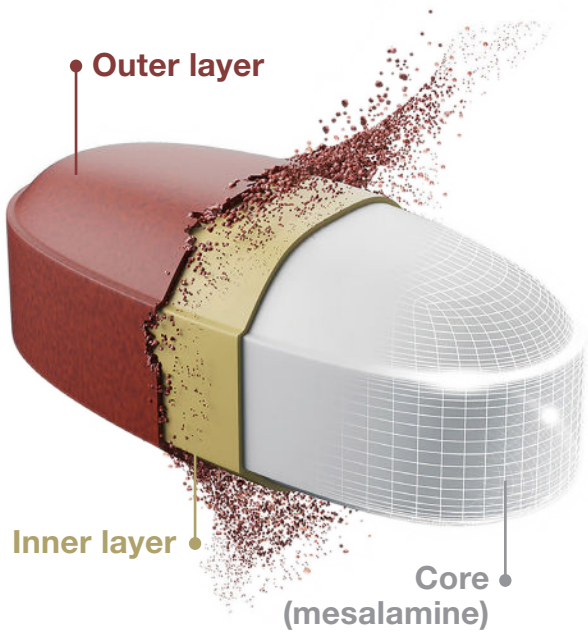
REDUCE

PILL BURDEN WITH A HIGH-STRENGTH FORMULATION

Pr OCTASA® mesalamine 1600 mg OPTICORE

Two trigger mechanisms for targeted release

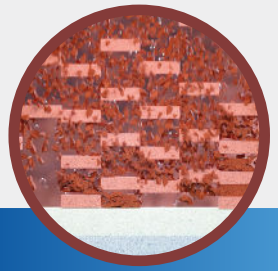
Ensures mesalamine release throughout the entire colon*



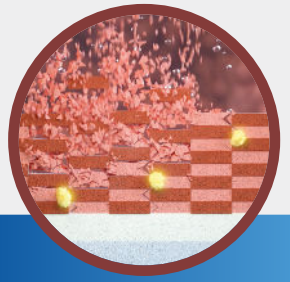
*Clinical significance has not been established.

OPTICORE® – *OPTImized COlonic RElease*

Outer layer

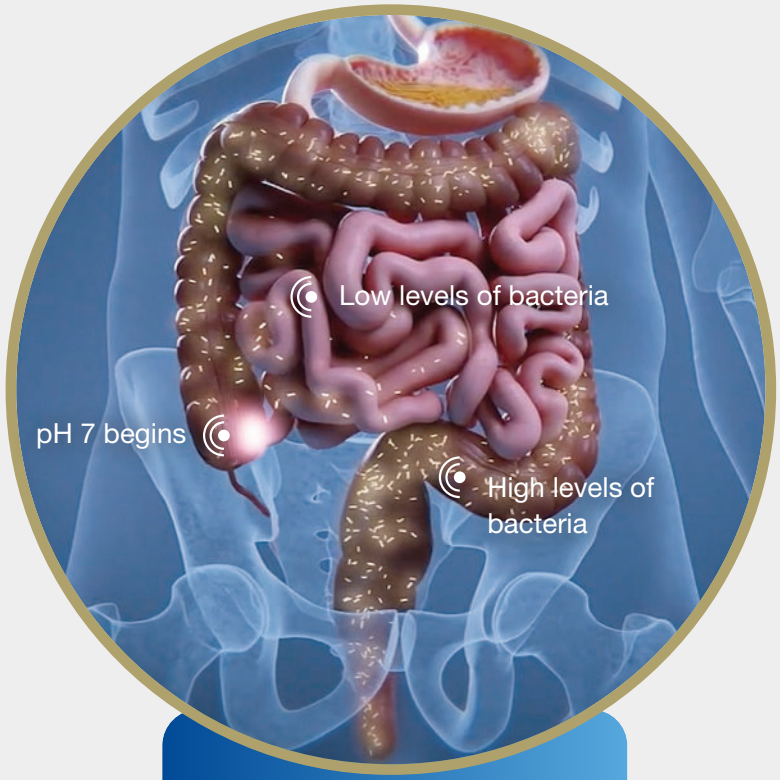


Trigger 1
pH-responsive polymer begins dissolving at pH ≥ 7



Trigger 2
Enzyme-sensitive polymer digested by colonic bacterial enzymes

Inner layer

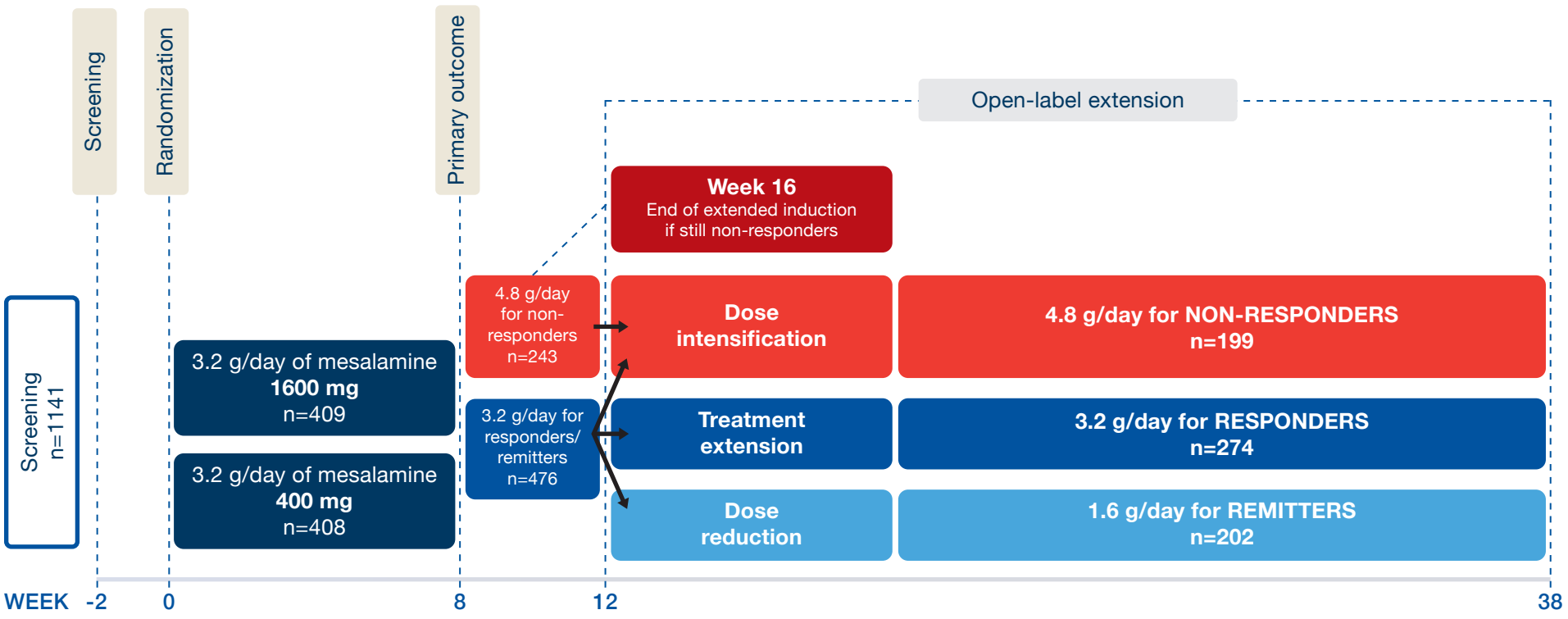


Accelerator
Middle alkaline buffer layer accelerates drug release

Pr OCTASA® mesalamine 1600 mg OPTICORE

OCTASA® 1600 mg was part of the largest induction clinical trial with mesalamine in UC†

Design of the mesalamine 1600 mg clinical trial (D'Haens)†



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OCTASA® 1600 mg demonstrated short- and long-term efficacy†,‡,§ in an induction trial and open-label extension

Clinical data from the largest published induction clinical trial with mesalamine in UC

Induction phase

Efficacy endpoint at Week 8: Clinical and endoscopic remission

Patients receiving 2 x 1600 mg tablets once daily	22.4% (non-inferiority p=0.005)
Patients receiving 4 x 400 mg tablets twice daily	24.6%

Open-label extension

Proportion of patients who achieved clinical remission for the duration of the extension (Week 38)

33.9%	(95% CI: 28.4%–39.9%) of responders but non-remitters after 12 weeks of induction, who received 3.2 g/day following induction
30.7%	(95% CI: 24.3%–37.6%) of non-responders after 8 weeks of induction at 3.2 g/day, who received 4.8 g/day following induction

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Pr OCTASA® mesalamine 1600 mg OPTICORE

An established safety profile

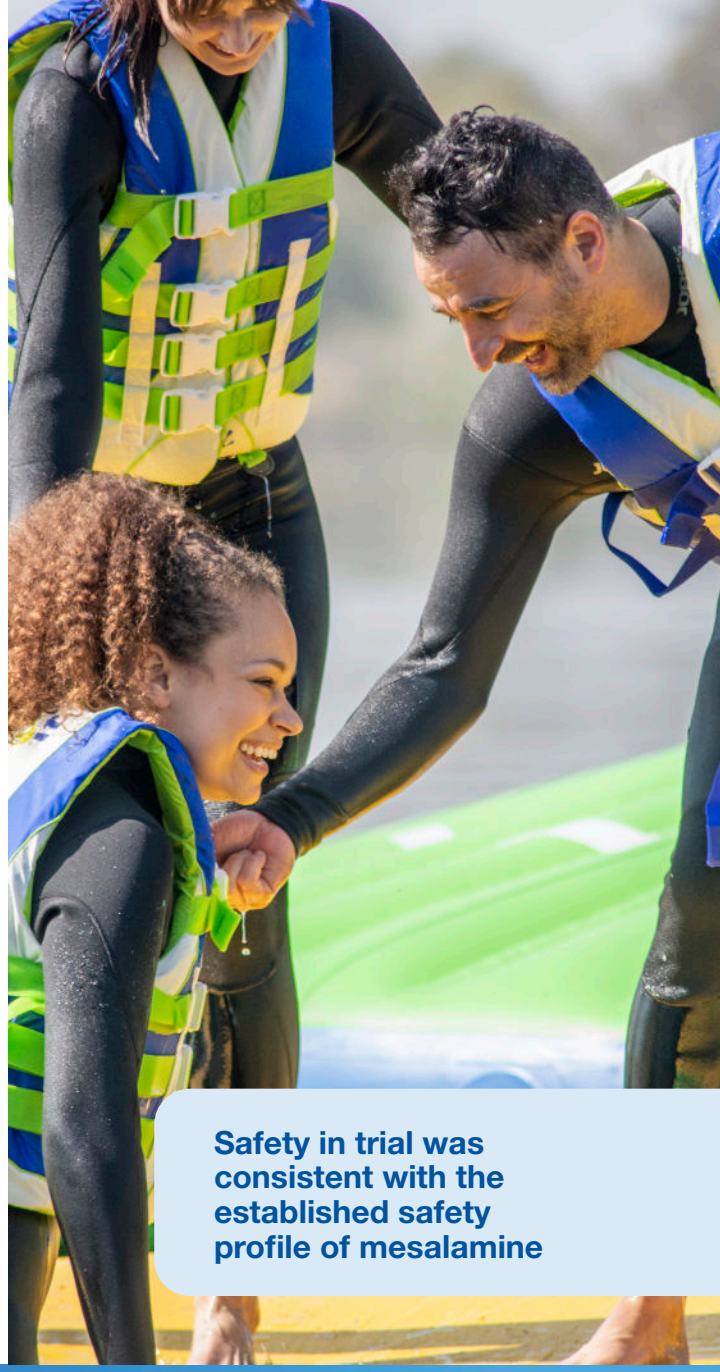
Generally well tolerated,
with a low incidence of serious adverse events in both treatment groups (2.0% of patients in the OCTASA® group vs. 1.7% of patients in the ASACOL group)

Treatment-emergent adverse events related to study drug occurring in ≥ 1% of subjects versus ASACOL, 8-week study (double-blind, randomized induction)

Adverse reaction	OCTASA® 1600 mg n=409 n (%)	ASACOL 400 mg* n=408 n (%)
Gastrointestinal disorders		
Abdominal pain	6 (1.5%)	3 (0.7%)
Investigations		
ALT increased	5 (1.2%)	2 (0.5%)
Renal and urinary disorders		
Hematuria	5 (1.2%)	2 (0.5%)
Leukocyturia	5 (1.2%)	2 (0.5%)
Proteinuria	4 (1.0%)	2 (0.5%)

Discontinuations due to adverse events occurred in 6.6% of patients in the OCTASA® group and in 5.6% of patients in the ASACOL 400 mg group.

ALT: alanine aminotransferase
*ASACOL (4 x 400 mg tablets).



Safety in trial was consistent with the established safety profile of mesalamine

Pr OCTASA® mesalamine 1600 mg OPTICORE

Important safety information

Clinical use:

- Health Canada has not authorized an indication for pediatric (< 18 years of age) use.

Contraindications:

- Patients with a history of sensitivity to salicylates
- Patients with severe hepatic impairment
- Patients with severe renal impairment (GFR < 30 mL/min/1.73 m^2)
- Patients with urinary tract obstruction
- Patients unable to swallow the intact tablet

Most serious warnings and precautions:

History of adverse drug reactions to sulfasalazine: Patients with a history of adverse drug reactions to sulfasalazine therapy should be kept under close medical supervision. Treatment must be stopped immediately if acute symptoms of intolerance occur, such as abdominal cramps, acute abdominal pain, fever, severe headache, and rash.

Blood system: Serious blood dyscrasia has very rarely been reported. Therapy should be stopped immediately if there is a suspicion or evidence of blood dyscrasia (signs of unexplained bleeding, bruising, purpura, anemia, persistent fever, or sore throat), and patients should seek immediate medical advice. It is recommended that hematological investigations (differential blood count) be performed prior to initiation of therapy and while on therapy, at the discretion of the treating physician.

Renal: Renal impairment, including minimal change nephropathy, acute and chronic interstitial nephritis, and renal failure, has been reported in patients taking mesalamine products. Contraindicated in patients with severe renal impairment. It is recommended that all patients have an evaluation of their renal function prior to initiation of therapy and repeatedly while on therapy.

Pulmonary: Patients with pulmonary disease, in particular asthma, should be very carefully monitored during treatment.

Other relevant warnings and precautions:

- Carcinogenesis and mutagenesis
- Mesalamine-induced cardiac hypersensitivity reactions
- Caution in patients with active gastric or duodenal ulcer
- Caution in hepatic and renal dysfunction
- Monitor hepatic and renal function and differential blood count
- Severe cutaneous adverse reactions
- Pregnant and breastfeeding women

For more information:

Please consult the Product Monograph at https://pdf.hres.ca/dpd_pm/00066914.PDF for important information relating to adverse reactions, drug interactions, and dosage and administration that has not been discussed in this piece. The Product Monograph can also be obtained by calling **1-888-550-6060**.

GFR: glomerular filtration rate

References: 1. OCTASA® Product Monograph. Tillotts Pharma AG. August 4, 2022. **2.** Tillotts Pharma AG internal data. **3.** D'Haens GR, Sandborn WJ, Zou G, et al. Randomised non-inferiority trial: 1600 mg versus 400 mg tablets of mesalazine for the treatment of mild-to-moderate ulcerative colitis. *Aliment Pharmacol Ther.* 2017;46(3):292–302.

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