Product Monograph

Including Patient Medication Information

PRQULIPTA®

atogepant tablets

for oral use

10 mg, 30 mg, and 60 mg of atogepant

Calcitonin gene-related peptide (CGRP) receptor antagonist

AbbVie Corporation
8401 Trans-Canada Highway
Saint-Laurent, Quebec
H4S 1Z1

Date of Authorization:
2026-04-22

Control Number: 305622

Recent Major Label Changes

1. Indications	2024-04
4. Dosage and Administration, 4.2. Recommended Dose and Dosage Adjustment	2024-04
7. Warnings and Precautions, 7.1.2 Breastfeeding	2025-06
Immune	2026-04
7. Warnings and Precautions, 7.2.1. Pregnancy	2026-04

Table of Contents

Certain sections or subsections that are not applicable at the time of the preparation of the most recent authorized product monograph are not listed.

Part 1: Healthcare Professional Information

1. Indications

QULIPTA (atogepant tablets) is indicated for:

- the prevention of migraine in adults who have at least 4 migraine days per month.

1.1. Pediatrics

Pediatrics (< 18 years of age): The safety and efficacy of QULIPTA in pediatric patients has not been studied. No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

1.2. Geriatrics

Geriatrics (≥ 65 years of age): Clinical studies of QULIPTA did not include sufficient number of patients aged 65 years and over (N=80) to determine whether they respond differently compared to younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range and maintained at the lowest effective dose, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy (see 7.1.4. Geriatrics; 10.3. Pharmacokinetics).

2. Contraindications

QULIPTA is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container. For a complete listing, see 6. Dosage Forms, Strengths, Composition, and Packaging. Reported cases of hypersensitivity included anaphylaxis, and dyspnea (see 7. Warnings and Precautions - Immune; 8.5. Post-Market Adverse Reactions).

4. Dosage and Administration

4.1. Dosing Considerations

- QULIPTA is available in 10 mg, 30 mg, and 60 mg tablets.
- Dosing modifications should be considered for concomitant use of specific drugs and for patients with hepatic or renal impairment. See Table 1.

4.2. Recommended Dose and Dosage Adjustment

- Episodic migraine: The recommended dose is 10 mg, 30 mg or 60 mg orally once daily. The maximum recommended daily dose is 60 mg.
- Chronic migraine: The recommended dose is 60 mg orally once daily.

Table 1 Dose Modifications for Special Populations and for Drug Interactions

Special Populations/Drug Interactions	Recommended Daily Dose
Patients with Hepatic Impairment. See 7. Warnings and Precautions - Hepatic; 8.4. Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data and 10.3. Pharmacokinetics**.**	
Severe hepatic impairment (Child-Pugh Class C)	Should Avoid Use
Mild or moderate hepatic impairment (Child-Pugh Class A or B)	10, 30, or 60 mg
Patients with Renal Impairment. See 10.3. Pharmacokinetics.	
Severe Renal Impairment and end stage renal disease (CLcr <30 mL/min) only if the benefit of treatment with QULIPTA is deemed to outweigh the risk.	10 mg
Mild or moderate (CLcr 30-89 mL/min) renal impairment	10, 30, or 60 mg
Concomitant Drug. See 9.4. Drug-Drug Interactions.	
Strong CYP3A4 Inhibitors (e.g., itraconazole, ketoconazole, clarithromycin)	10 mg
Moderate and weak CYP3A4 Inhibitors (e.g., ciprofloxacin, fluconazole, fluvoxamine, grapefruit juice, cimetidine, esomeprazole)	10, 30, or 60 mg
Strong and moderate CYP3A4 Inducers (e.g., multiple dose rifampicin, carbamazepine, phenytoin, St. John's wort, efavirenz, etravirine)	30 or 60 mg
Weak CYP3A4 Inducers (e.g., topiramate, armodafinil, rufinamide)	10, 30, or 60 mg
OATP Inhibitors (e.g., cyclosporine, single dose rifampicin)	10 or 30 mg

4.4. Administration

QULIPTA is administered orally once daily **with or without food**.

4.5. Missed Dose

A missed dose should be taken right away. If it is almost time for the next dose, patients should be instructed to skip the missed dose and take the next dose as scheduled.

5. Overdose

Treatment of an overdose of QULIPTA should consist of general supportive measures including monitoring of vital signs and observation of the clinical status of the patient. No specific antidote for the treatment of QULIPTA overdose is available.

For the most recent information in the management of a suspected drug overdose, contact your regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669).

6. Dosage Forms, Strengths, Composition, and Packaging

Table 2 – Dosage Forms, Strengths, and Composition

Route of Administration	Dosage Form/ Strength/Composition	Non-Medicinal Ingredients
oral	tablet, 10, 30 and 60 mg atogepant	colloidal silicon dioxide, croscarmellose sodium, mannitol, microcrystalline cellulose, polyvinylpyrrolidone vinyl acetate copolymer, sodium chloride, sodium stearyl fumarate, and vitamin E polyethylene glycol succinate.

Description

QULIPTA 10 mg is supplied as white to off-white, round biconvex tablet with “A” and “10” debossed on one side.

QULIPTA 30 mg is supplied as white to off-white, oval biconvex tablet with “A30” debossed on one side.

QULIPTA 60 mg is supplied as white to off-white, oval biconvex tablet with “A60” debossed on one side.

7. Warnings and Precautions

Carcinogenesis and Genotoxicity

There was no evidence of genotoxic or carcinogenic potential in the non-clinical toxicology studies. For animal data (see 16. Non-Clinical Toxicology).

Cardiovascular

See 10.2. Pharmacodynamics.

Dependence, Tolerance and/or Abuse Liability

No studies on the abuse liability of QULIPTA have been performed in humans. See 10.2. Pharmacodynamics.

Driving and Operating Machinery

QULIPTA may cause fatigue and somnolence in some patients. Patients should be advised not to perform skilled tasks (e.g., driving, operating machinery) until they are reasonably certain that QULIPTA does not affect them adversely (see 8.2. Clinical Trial Adverse Reactions).

Hepatic/Biliary/Pancreatic

Since atogepant is mainly metabolized by the liver through oxidation, use of this drug in patients with severe hepatic impairment should be avoided. In a small number of cases in clinical studies, a temporal association was noted between atogepant treatment and transaminase elevations greater than 3 times the upper limit of normal. In such circumstances, re-challenge is not recommended. See 4.2. Recommended Dose and Dosage Adjustment and 8.4. Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data.

Immune

Hypersensitivity reactions, including anaphylaxis, rash, pruritus, urticaria, facial edema, and dyspnea, have been reported during treatment with QULIPTA. QULIPTA may cause serious hypersensitivity reactions, which can be life-threatening. Although no fatal cases were reported in clinical trials, a fatal case of anaphylaxis was reported during post-market use of QULIPTA. Such reactions can occur within hours to days following drug administration. If a hypersensitivity reaction occurs, QULIPTA should be discontinued and appropriate therapy instituted (see 2. Contraindications; 8.5. Post-Market Adverse Reactions).

Reproductive Health

See 7.1.1. Pregnancy and 16. Non-Clinical Toxicology.

7.1. Special Populations

7.1.1. Pregnancy

QULIPTA should not be used by pregnant women unless the expected benefit to the mother outweighs the potential risk to the fetus.

There are no adequate human data on the developmental risk associated with the use of QULIPTA in pregnant women. In animal studies, oral administration of atogepant during organogenesis resulted in adverse effects on development in rats at exposures greater than those used clinically, and which were associated with maternal toxicity (see 16. Non-Clinical Toxicology).

Pregnancy Registry

A registry has been established to collect information about the effect of QULIPTA exposure during pregnancy. Patients who become pregnant while taking QULIPTA should be encouraged to enroll in the EMPRESS Pregnancy Registry at www.empresspregnancyregistry.ca, or call 1-844-467-0844 to speak to a registry representative. This registry is collecting information about the effect of QULIPTA exposure during pregnancy.

7.1.2. Breastfeeding

Data from a human lactation study shows minimal transfer of atogepant into breastmilk following a single dose (see 10.3. Pharmacokinetics).

There are no data on the effects of atogepant on the breastfed infant or on milk production (see 16. Non-Clinical Toxicology).

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for QULIPTA and any potential adverse effects on the breastfed infant from QULIPTA or from the underlying maternal condition.

7.1.3. Pediatrics

Pediatrics (<18 Years of age): No data are available to Health Canada; therefore, Health Canada has not authorized an indication for pediatric use.

7.1.4. Geriatrics

Population pharmacokinetic modeling suggests no clinically significant pharmacokinetic differences between elderly and younger subjects. Based on these findings, no dose adjustment of QULIPTA is needed in elderly patients. However, the three placebo-controlled clinical studies of QULIPTA did not include adequate number of patients aged 65 years and over (N=80) to determine whether they respond differently compared to younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range (see 4.2. Recommended Dose and Dosage Adjustment).

8. Adverse Reactions

8.1. Adverse Reaction Overview

A total of 2626 patients with episodic and chronic migraine were exposed to QULIPTA who received at least one dose, representing 1450 patient-years of exposure. Of these, 1225 were exposed to QULIPTA daily for at least 6 months and 826 patients received QULIPTA for 12 months.

In pooled placebo-controlled studies (Studies 1, 2 and 3), 2500 patients with episodic and chronic migraine received various doses of QULIPTA (N=1837) and Placebo (N=663). In these studies, 57.6% of patients treated with QULIPTA and 51.9% of patients treated with placebo experienced adverse events.

In the three placebo-controlled studies, the frequently reported adverse reactions (>1%) with QULIPTA were constipation, nausea, fatigue/somnolence, and decreased appetite, and most were mild to moderate in intensity (see table 3). No serious adverse reactions were identified with atogepant.

In these studies, 4.1%, 3.4%, and 3.1% of the patients receiving atogepant 10 mg once daily (QD), 30 mg QD, and 60 mg QD, respectively, discontinued the study (Placebo: 3.2%).

The most common adverse events that led to discontinuation in QULIPTA arms of the three placebo-controlled studies included nausea (0.5%; Placebo: 0.3%), constipation (0.4%; Placebo: 0.3%), fatigue/somnolence (0.2%; Placebo: 0%), and dizziness (0.2%; Placebo: 0.2%). The most common adverse events resulting in discontinuation in the long-term safety studies were nausea (0.5%) and dizziness (0.3%).

8.2. Clinical Trial Adverse Reactions

Clinical trials are conducted under very specific conditions. The adverse reaction rates observed in the clinical trials, therefore, may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse reaction information from clinical trials may be useful in identifying and approximating rates of adverse drug reactions in real-world use.

In the 12-week, placebo-controlled studies of the 2500 patients, approximately 88% were female, 74% were White, 13% were Black, 12% were Asian, and 9% were of Hispanic or Latino ethnicity.

In the three placebo-controlled studies, the following adverse events in Table 3 were observed to occur at or above 2%.

Table 3 – Treatment Emergent Adverse Events Occurring with an Incidence of ≥2% in any treatment group in the Placebo-Controlled Studies of episodic and chronic migraine

	Placebo (N= 663) %	QULIPTA 10 mg QD (N=314) %	QULIPTA 30 mg QD (N=411) %	QULIPTA 60 mg QD (N=678) %
Gastrointestinal disorders				
Nausea	3	5	6	9
Constipation	2	6	6	8
Diarrhea	2	1	1	2
General disorders and administration site conditions				
Fatigue	3	1	2	3
Infections and infestations				
Upper respiratory tract infection	5	5	7	3
Nasopharyngitis	3	2	5	5
Urinary tract infection	2	2	5	3
Sinusitis	1	3	1	2
Gastroenteritis	1	1	2	1
Investigations				
Blood creatine phosphokinase increased	<1	3	1	2
Metabolism and nutrition disorders				
Decreased appetite	<1	2	1	3
Nervous system disorders				
Dizziness	2	2	2	3
Somnolence	1	3	2	2

The overall safety profile in the open-label, long-term safety studies was consistent with the placebo-controlled studies.

8.3. Less Common Clinical Trial Adverse Reactions

Adverse events reported by <2% of patients in controlled clinical studies of QULIPTA in adult patients with episodic or chronic migraine that occurred in more than 2 patients in any QULIPTA treatment arm and twice more frequently than in the placebo group are listed below. Causality to QULIPTA has not been established in every case.

Blood and lymphatic system disorders: anaemia

Cardiac disorders: palpitations, tachycardia

Gastrointestinal disorders: abdominal discomfort, dyspepsia, food poisoning, gastroesophageal reflux disease, toothache

General disorders and administration site conditions: asthenia, non-cardiac chest pain, pyrexia

Infections and infestations: bronchitis, cellulitis, gastroenteritis viral, herpes zoster, pharyngitis streptococcal, pneumonia, viral upper respiratory tract infection

Injury, poisoning and procedural complications: foot fracture, muscle strain, skin laceration

Investigations: weight decreased

Musculoskeletal and connective tissue disorders: back pain, muscle spasms, neck pain, tendonitis

Nervous system disorders: hypoesthesia, mental impairment

Psychiatric disorders: abnormal dreams, irritability

Renal and urinary disorders: proteinuria

Respiratory, thoracic and mediastinal disorders: nasal congestion

Skin and subcutaneous tissue disorders: dermatitis contact, pruritus

Vascular disorders: hypertension

8.4. Abnormal Laboratory Findings: Hematologic, Clinical Chemistry, and Other Quantitative Data

Clinical Trial Findings

Hepatic:

Atogepant is mainly metabolized by the liver through oxidation. In the placebo-controlled studies, similar proportion of patients in atogepant (0.9%) and placebo (1.2%) groups experienced transaminase elevations 3 times the upper limit of normal. However, there was a temporal association between atogepant treatment and reported transaminase elevations. In the majority of cases, patients had normal transaminase levels at baseline and none of the patients had a history of pre-existing liver disease. Transaminase elevations were mostly asymptomatic and resolved within 2 to 9 weeks following atogepant discontinuation. There were no reported cases of severe liver injury or jaundice. Atogepant use should be avoided in patients with severe hepatic impairment. See 4.2. Recommended Dose and Dosage Adjustment and 7. Warnings and Precautions - Hepatic.

Gastrointestinal:

One of the most common adverse events in placebo-controlled clinical studies of atogepant was constipation, reported by 7% (96/1403) of patients (Placebo: 2% [13/663]). Constipation also led to the discontinuation in 0.4% (6/1403) of patients in the combined atogepant arms (Placebo: 0.3%, 2/663). There were no serious cases of constipation in controlled studies. Approximately 5% of patients had previous history of constipation. In a 52-week long-term safety study, constipation was reported in 7% (39/543) of patients who received atogepant 60 mg/day compared to 3% (6/196) of patients who received standard of care. In a 40-week long-term safety study, constipation was reported in 3.4%**.** (23/685) of patients who received atogepant 60 mg/day. There were no serious cases. Two patients receiving atogepant discontinued the long-term safety studies. There were 2 cases of severe constipation (one in a patient with history of constipation) that did not result in discontinuation of atogepant. See 9.4. Drug-Drug Interactions.

Decrease in Body Weight:

In the placebo-controlled studies, patients had a mean weight of 79.3 kg and mean BMI of 28.86 kg/m^2. In these studies, there was a dose-dependent decrease in mean body weight of patients who received QULIPTA 30 mg (-0.40 kg) and 60 mg (-0.90 kg). Patients receiving placebo gained a mean body weight of 0.23 kg during the course of these studies. The proportion of patients with a weight decrease ≥7% at any point during the studies was 2.5% for placebo, 3.8% for QULIPTA 10 mg, 3.2% for QULIPTA 30 mg,

and 5.3% for QULIPTA 60 mg. No patients in the placebo-controlled studies discontinued treatment due to an adverse event of decreased weight.

In a 52-week open-label long-term safety study, patients had a mean weight of 83.9 kg and mean BMI of 30.55 kg/m^2. In this study, patients who were treated with QULIPTA 60 mg had a mean decrease in body weight of 1.42 kg versus those who received oral migraine preventive standard of care who had a mean body weight increase of 0.20 kg. The proportion of patients with a weight decrease ≥7% at any point during the study was 14.7% for the oral migraine preventive standard of care group and 24.1% for the QULIPTA 60 mg once daily group. Maximum weight loss of approximately 1.7 kg was also reported at 6 and 9 months. In a 40-week long-term safety study, patients had a mean weight of 84.2 kg and mean BMI of 30.58 kg/m^2; at the end of treatment with QULIPTA 60 mg, there was a mean decrease from baseline in body weight of 1.77 kg, and 23.9% had a weight decrease ≥7% during the study. In these long-term safety studies, two QULIPTA-treated patients discontinued atogepant due to an adverse event of weight decreased.

8.5. Post-Market Adverse Reactions

The following adverse reactions have been identified during post-approval use of QULIPTA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or establish a causal relationship to drug exposure.

Immune System Disorders*:* Hypersensitivity (e.g., anaphylaxis, dyspnea, rash, pruritus, urticaria, facial edema). A fatal case of anaphylaxis was reported.

9. Drug Interactions

9.2. Drug Interactions Overview

Atogepant is metabolized primarily by cytochrome P450 3A4 (CYP3A4). Drug-drug interactions with medications that are inducers or inhibitors of CYP3A4 have been demonstrated. Dose adjustments are recommended for patients concomitantly using strong CYP3A4 inhibitors or inducers (see Table 4).

Atogepant is not an inhibitor of CYP3A4, 2B6, 2C8, 1A2, 2C9, 2C19, or 2D6 at clinically relevant concentrations. Atogepant is not an inducer of CYP1A2, 2B6 or 3A4 at clinically relevant concentrations.

Atogepant is not a potent inhibitor of MAO-A or UGT1A1.

Atogepant is a substrate of P-gp, BCRP, OATP1B1, OATP1B3 and OAT1. Atogepant is not a substrate of OAT3, OCT2, or MATE1. Drug interactions with medications that are strong inhibitors of OATP have been demonstrated. Dose adjustments are recommended for patients concomitantly using strong OATP inhibitors (see Table 4). No atogepant dose adjustment is anticipated with other transporter inhibitors.

There are no clinically significant pharmacokinetic interactions with ubrogepant. Potential pharmacodynamic interactions may increase the risk of adverse reactions. Atogepant should be used with care when other gepants, such as ubrogepant, are used concurrently.

See 10.3. Pharmacokinetics; 9.4. Drug-Drug Interactions and Table 1 in 4.2. Recommended Dose and Dosage Adjustment.

9.3. Drug-Behaviour Interactions

The interaction of QULIPTA with individual behavioural risks (e.g. cigarette smoking, cannabis use, and/or alcohol consumption) has not been studied.

9.4. Drug-Drug Interactions

CYP3A4 Inhibitors

Co-administration of 60 mg QULIPTA with itraconazole, a strong CYP3A4 inhibitor, resulted in a 5.5-fold increase in the exposure of atogepant in healthy subjects (see 10.3. Pharmacokinetics). Maximum dose of QULIPTA 10 mg is recommended with concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, clarithromycin). Data from physiologically based pharmacokinetic (PBPK) modeling suggest that co-administration of QULIPTA with moderate CYP3A4 inhibitors (e.g., ciprofloxacin, fluconazole, fluvoxamine, grapefruit juice) increases atogepant exposure by 1.7-fold. No dose adjustment is required when QULIPTA is co-administered with moderate or weak CYP3A4 inhibitors (e.g., cimetidine, esomeprazole). See 4.2. Recommended Dose and Dosage Adjustment and Table 1.

CYP3A4 Inducers

Co-administration of QULIPTA with **multiple 600 mg doses** of rifampicin, a strong CYP3A4 inducer, resulted in a significant decrease in exposure of atogepant in healthy subjects (see 10.3. Pharmacokinetics). QULIPTA 30 or 60 mg is recommended when co-administered with strong and moderate CYP3A4 inducers (e.g., rifampicin, carbamazepine, phenytoin, St. John's wort, efavirenz, etravirine). No dose adjustment is required when QULIPTA is co-administered with weak CYP3A4 inducers (e.g., topiramate). See 4.2. Recommended Dose and Dosage Adjustment and Table 1.

OATP Inhibitors

Single doses of rifampicin affect atogepant pharmacokinetics mainly by inhibition of organic anion transporter polypeptide (OATP). In a drug interaction study in healthy adult subjects, co-administration of QULIPTA with a **single 600 mg dose** of rifampicin resulted in a 2-fold and 3-fold increase in atogepant C_{max} and AUC, respectively (see 10.3. Pharmacokinetics). When co-administered with OATP inhibitors (e.g., cyclosporin), maximum recommended daily dose of QULIPTA is 30 mg. See 4.2. Recommended Dose and Dosage Adjustment and Table 1.

Pharmacodynamic Interactions

There is potential for pharmacodynamic interactions when QULIPTA is co-administered with other CGRP receptor antagonists. In a drug interaction study involving adult participants with a history of migraine, atogepant and ubrogepant combination usage led to an increased rate in reported cases of constipation, compared to atogepant alone. The increased rate of constipation was not observed in a subsequent, open-label safety study in patients on daily atogepant therapy when ubrogepant was added to treat breakthrough migraine. Caution is warranted in patients receiving both QULIPTA and another gepant, such as ubrogepant, as the risk for adverse reactions may increase when these drugs are administered concomitantly. Monitor for adverse reactions. See 8.2. Clinical Trial Adverse Reactions and 8.4. Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data.

Table 4 – Established or Potential Drug-Drug Interactions

Drug Product	Source of evidence	Effect	Clinical comment
itraconazole (strong CYP3A4 inhibitor)	CT	Increased atogepant exposure. C_{max} ↑2.15-fold AUC ↑5.5-fold	Patients concomitantly using strong CYP3A4 inhibitors (e.g. itraconazole, ketoconazole, clarithromycin) should limit the dose of atogepant to 10 mg.
rifampicin (strong CYP3A4 inducer)	CT	Decreased atogepant exposure. C_{max} ↓30% AUC ↓60%	In patients taking strong CYP3A4 inducers (e.g. phenytoin, rifampin, St. John's Wort), the recommended dose of atogepant is 30 mg or 60 mg.
rifampicin (strong OATP inhibitor)	CT	Increased atogepant exposure. C_{max} ↑2.23-fold AUC ↑2.85-fold	Patients concomitantly using strong OATP inhibitors should limit their atogepant dose to a maximum of 30 mg.
ubrogepant (CGRP receptor antagonist)	CT, T	Increased atogepant exposure[1]: C_{max} ↑4% AUC ↑4% Increased ubrogepant exposure[1]: C_{max} ↑26% AUC ↑19%	No dose adjustment is anticipated. Potential pharmacodynamic interactions may increase the risk of adverse reactions. Caution is warranted in patients taking both atogepant and other CGRP receptor antagonists, such as ubrogepant. Monitor for adverse reactions (see 8.2. Clinical Trial Adverse Reactions).

Legend: CT = Clinical Trial; T = Theoretical.
[1] Not considered clinically significant.

No clinically significant pharmacokinetic interactions were observed when atogepant was co-administered with acetaminophen, naproxen, sumatriptan, esomeprazole (proton pump inhibitor), P-gp inhibitors, famotidine, topiramate, or the oral contraceptive components, ethinyl estradiol and levonorgestrel.

9.5. Drug-Food Interactions

Grapefruit juice is a moderate CYP34A inhibitor and may increase atogepant exposure (see 9.4. Drug-Drug Interactions; 10.3. Pharmacokinetics).

9.6. Drug-Herb Interactions

Interactions of QULIPTA with herbal products have not been studied.

St. John's wort (Hypericum perforatum) is a strong inducer of CYP3A4 and has the potential to significantly reduce atogepant exposure. If used concomitantly, the recommended dose of atogepant is 30 mg or 60 mg.

Curcumin is an inhibitor of P-gp efflux transporters and CYP3A4 enzymes and has the potential to increase atogepant exposure (see Table 1).

Feverfew (Tanacetum parthenium) may inhibit CYP3A4 enzyme activity, potentially increasing atogepant exposure (see Table 1).

Green tea catechins can inhibit the activity of CYP3A4. The ingestion of green tea extract or its associated catechins is not expected to result in clinically significant influences on atogepant exposure. However, some caution is advised in the consumption of significant amounts of green tea beverages or green tea extract in patients prescribed QULIPTA.

See 10.3. Pharmacokinetics.

9.7. Drug-Laboratory Test Interactions

Interactions with laboratory tests have not been studied.

10. Clinical Pharmacology

10.1. Mechanism of Action

Atogepant is an orally administered, small molecule, selective calcitonin gene-related peptide (CGRP) receptor antagonist that blocks the binding of the CGRP to its receptor. CGRP is a neuropeptide that may play a role in migraine pathophysiology.

10.2. Pharmacodynamics

Cardiac Electrophysiology

In a randomized, double-blind, placebo- and positive-controlled, 3 period crossover ECG assessment study in healthy subjects (N=60), atogepant at a single supratherapeutic dose of 300 mg (5X multiple of maximum recommended daily dose), was not observed to have any noteworthy effect on the QTcF interval, the QRS duration, or the PR interval.

Dependence Liability

Atogepant has not been studied in humans for its dependence liability. In a self-administration study conducted in male rats, atogepant was not reinforcing at the highest dose tested (C_{max} 0.7 times the maximum human recommended dose). In a physical dependence study, no new behaviors were observed in male rats following cessation of a 28 day repeat dosing period.

10.3. Pharmacokinetics

Absorption

Following oral administration of QULIPTA, atogepant is rapidly absorbed with plasma concentrations >14 nM (EC_{90} based on capsaicin induced dermal vasodilation model [CIDV]) within 0.5 hours and median T_{max} values ranging from 1 to 2 hours. Atogepant displays dose-proportional pharmacokinetics through 300 mg single dose with little to no accumulation upon once daily dosing.

Effect of Food

When QULIPTA was administered with a high-fat meal, AUC and C_{max} were reduced by approximately 18% and 22%, respectively with no effect on median time to maximum atogepant plasma concentration. QULIPTA was administered without regard to food in clinical efficacy studies.

Distribution

Plasma protein binding of atogepant was not concentration-dependent in the range of 0.1 to 10 µM; the unbound fraction of atogepant was 4.7% in human plasma. Following oral administration, the mean apparent volume of distribution of atogepant (Vz/F) is approximately 292 L.

Metabolism

Atogepant is eliminated mainly through metabolism, primarily by CYP3A4. The parent compound (atogepant), and a metabolite tentatively characterized as dioxygenated methylated glucuronide of atogepant, metabolite M23, (approximately 15% of radioactivity exposure and not a long-lasting metabolite) were the most prevalent circulating components in human plasma. Metabolite M23 is a glucuronide conjugate, and therefore unlikely to be pharmacologically active. It is found at low levels in human plasma below the threshold that would indicate concern for drug-drug interactions.

Elimination

The elimination half-life of atogepant is approximately 11 hours. The mean apparent oral clearance (CL/F) of atogepant for healthy volunteers and patients with episodic migraine were approximately 19 L/h and 17.4 L/h, respectively. Atogepant is excreted mostly via the biliary/fecal route, while the renal route is a minor route of elimination. Following single oral dose of 50 mg ^{14}C-atogepant dose to healthy male subjects, 42% and 5% of the dose was recovered as unchanged atogepant in feces and urine, respectively.

Special populations and conditions

- **Pediatrics**

  Safety and efficacy of QULIPTA in pediatric patients have not been studied.

- **Geriatrics**

  Clinical studies of QULIPTA included only 80 elderly patients, which is insufficient to determine whether the elderly respond differently to QULIPTA compared to younger individuals. Population pharmacokinetic modeling suggests no clinically significant pharmacokinetic differences between elderly and younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range and maintained at the lowest effective dose. See 1.2. Geriatrics.

- **Sex**

  Based on population PK analysis, no clinically significant differences in the pharmacokinetics of atogepant were noted between men and women.

- **Pregnancy and breastfeeding**

  It is not known whether atogepant crosses the placenta in humans (see 16. Non-Clinical Toxicology).

  In a study of 12 breast-feeding women administered a single oral dose of atogepant 60 mg, transfer of atogepant into breast milk was minimal. The relative infant dose was approximately 0.19% of the

maternal weight-adjusted dose with a milk-to-plasma ratio of 0.08. The cumulative amount of atogepant excreted in breast milk over 24 hours was minimal, at less than 0.01 mg (see 7.1.2. Breastfeeding; 16. Non-Clinical Toxicology).

- **Ethnic origin**

As assessed by population PK analysis, no clinically significant differences in the pharmacokinetics of atogepant based on ethnic origin were observed.

- **Hepatic Insufficiency**

In patients with pre-existing mild (Child-Pugh Class A), moderate (Child-Pugh Class B), or severe (Child-Pugh Class C) hepatic impairment, atogepant exposure was increased by 24%, 15% and 38%, respectively. No dose adjustment of QULIPTA is recommended for patients with mild or moderate hepatic impairment. QULIPTA is not recommended for patients with severe hepatic impairment. See 8.4. Abnormal Laboratory Findings: Hematologic, Clinical Chemistry and Other Quantitative Data and 4.2. Recommended Dose and Dosage Adjustment.

- **Renal Insufficiency**

Population pharmacokinetic analysis based on pooled data from clinical studies was used to evaluate the effect of renal impairment. Atogepant pharmacokinetics were similar between patients with normal renal function (CLcr >90 mL/min) and those with mild (CLcr 60-89 mL/min) or moderate (CLcr 30-59 mL/min) renal impairment. Patients with severe renal impairment (CLcr 15-29 mL/min) or End Stage Renal Disease (ESRD; CLcr <15 mL/min) have not been studied. A Physiologically-Based Pharmacokinetic model predicted that atogepant exposures increase by about 2.3-fold in patients with severe renal impairment. Based on ADME information, in patients with ESRD, atogepant exposure is unlikely to increase beyond 6-fold. Therefore, the maximum recommended daily dose of atogepant in patients with severe renal impairment and ESRD is 10 mg. For patients with ESRD undergoing intermittent dialysis, QULIPTA should be taken after dialysis. No dose adjustment is recommended for patients with mild or moderate renal impairment. See 4.2. Recommended Dose and Dosage Adjustment.

- **Obesity**

Based on population PK analysis, body weight did not have a clinically significant effect on the pharmacokinetics of atogepant.

11. Storage, Stability, and Disposal

Store between 15°– 30°C.

Part 2: Scientific Information

13. Pharmaceutical Information

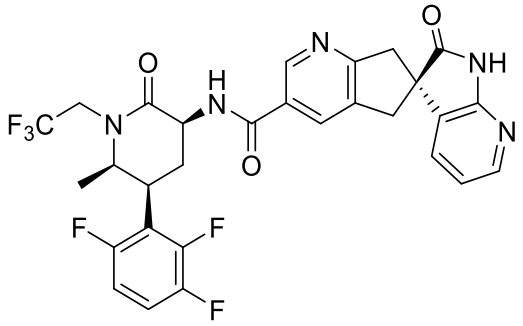
Drug Substance

Non-proprietary name of the drug substance(s): atogepant

Chemical name: (3'*S*)-*N*-[(3*S*,5*S*,6*R*)-6-methyl-2-oxo-1-(2,2,2-trifluoroethyl)-5-(2,3,6-trifluorophenyl)piperidin-3-yl]-2'-oxo-1',2',5,7-tetrahydrospiro[cyclopenta[*b*]pyridine-6,3'-pyrrolo[2,3-*b*]pyridine]-3-carboxamide

Molecular formula and molecular mass: $C_{29}H_{23}F_6N_5O_3$ and molecular weight is 603.5 g/mol.

Structural formula:



Physicochemical properties: Atogepant (as atogepant monohydrate) is a white to off-white powder. It is freely soluble in ethanol, soluble in methanol, sparingly soluble in acetone, slightly soluble in acetonitrile and practically insoluble in water.

14. Clinical Trials

14.1. Clinical Trials by Indication

Episodic Migraine

Table 5 Summary of Patient Demographics for Clinical Trials in Episodic Migraine

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
3101-301-002	Phase 3, randomized, double-blind, placebo-controlled	QULIPTA 10 mg, 30 mg, or 60 mg orally once daily for 12 weeks	QULIPTA 10 mg (N = 222) 30 mg (N = 230) 60 mg (N = 235) Placebo (N = 223)	42 years (18-73)	89% Female 11% Male

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
CGP-MD-01	Phase 2/3, randomized, double-blind, placebo-controlled	QULIPTA 10 mg, 30 mg, or 60 mg orally once daily for 12 weeks	QULIPTA 10 mg (N = 94) 30 mg (N = 185) 60 mg (N = 187) Placebo (N = 186)	40 years (18-74)	86% Female 14% Male

The efficacy of QULIPTA for the preventive treatment of episodic migraine in adults was demonstrated in two randomized, multicenter, double-blind, placebo-controlled studies (Study 3101-301-002 and Study CGP-MD-01). The studies enrolled patients with at least a 1-year history of migraine with or without aura, according to the International Classification of Headache Disorders (ICHD-3) diagnostic criteria. In both studies, patients were allowed to use acute headache treatments (i.e., triptans, ergotamine derivatives, NSAIDs, acetaminophen, and opioids) as needed. The studies excluded patients with clinically significant liver disease at screening and myocardial infarction, stroke, or transient ischemic attacks within six months prior to screening.

In Study 3101-301-002, after a 28-day baseline period, a total of 910 patients were randomized 1:1:1:1 to receive either QULIPTA 10 mg (N = 222), QULIPTA 30 mg (N = 230), QULIPTA 60 mg (N = 235) or placebo (N = 223) once daily for 12 weeks. In Study CGP-MD-01, after a 28-day baseline period, a total of 652 patients were randomized 1:2:2:2 to receive either QULIPTA 10 mg (N = 94), QULIPTA 30 mg (N = 185), QULIPTA 60 mg (N = 187), or placebo (N = 186) once daily for 12 weeks.

The primary efficacy endpoint in Study 3101-301-002 was the change from baseline in mean monthly migraine days across the 12-week treatment period. Secondary endpoints included the change from baseline in mean monthly headache days, change from baseline in mean monthly acute medication use days, and proportion of patients achieving a ≥ 50% reduction from baseline in mean monthly migraine days (average over 12 weeks).

Likewise, in Study CGP-MD-01, the primary efficacy endpoint was the change from baseline in mean monthly migraine days across the 12-week treatment period. Secondary endpoints were monthly headache days, ≥ 50% reduction from baseline in mean monthly migraine days across the 12-week treatment period, and change from baseline in mean monthly acute medication use days.

In Study 3101-301-002, nearly 83% of the patients were White, 14% were Black and 9% were of Hispanic or Latino ethnicity. The mean migraine frequency at baseline was approximately 8 migraine days per month (range: 4-16) and was similar across treatment groups. In Study CGP-MD-01, nearly 76% of the patients were White, 20% were Black, and 16% were of Hispanic of Latino ethnicity. The mean migraine frequency at baseline was approximately 8 migraine days per month (range: 4-16) and was similar across treatment groups.

A total of 88% (604/687) of patients randomized to once-daily atogepant doses in Study 3101-301-002 completed the 12-week double-blind study (placebo: 90% or 201/223 patients). In Study CGP-MD-01, a total of 84% (393/466) of patients randomized to once-daily atogepant doses completed the 12-week double-blind study (placebo: 80% or 148/186 patients).

Table 6 Results of Primary and Secondary Efficacy Endpoints in Subjects with Episodic Migraine

	Placebo **N=214**	**QULIPTA** **10 mg/day** **N=214**	**QULIPTA** **30 mg/day** **N=223**	**QULIPTA** **60 mg/day** **N=222**
Study 3101-301-002				
Monthly Migraine Days (MMD) across 12 weeks				
Baseline	7.5	7.5	7.9	7.8
Mean change from baseline	-2.5	-3.7	-3.9	-4.2
Placebo-subtracted change	--	-1.2	-1.4	-1.7
p-value		<0.001	<0.001	<0.001
Monthly Headache Days across 12 weeks				
Baseline	8.4	8.4	8.8	9.0
Mean change from baseline	-2.5	-3.9	-4.0	-4.2
Placebo-subtracted change	--	-1.4	-1.5	-1.7
p-value		<0.001	<0.001	<0.001
Monthly Acute Medication Use Days across 12 weeks				
Baseline	6.5	6.6	6.7	6.9
Mean change from baseline	-2.4	-3.7	-3.7	-3.9
Placebo-subtracted change	--	-1.3	-1.3	-1.5
p-value		<0.001	<0.001	<0.001
≥ 50% MMD Responders across 12 weeks				
% Responders	29	56	59	61
Placebo-subtracted change	--	27	30	32
p-value		<0.001	<0.001	<0.001
	Placebo **N= 178**	**QULIPTA** **10 mg/day** **N= 92**	**QULIPTA** **30 mg/day** **N= 182**	**QULIPTA** **60 mg/day** **N= 177**

Study CGP-MD-01				
Monthly Migraine Days (MMD) across 12 weeks				
Baseline	7.8	7.6	7.6	7.7
Mean change from baseline	-2.8	-4.0	-3.8	-3.6
Placebo-subtracted change	--	-1.1	-0.9	-0.7
p-value		0.024	0.039	0.039
Monthly Headache Days across 12 weeks				
Baseline	9.1	8.9	8.7	8.9
Mean change from baseline	-2.9	-4.3	-4.2	-3.9
Placebo-subtracted change	--	-1.4	-1.2	-0.9
p-value		0.024	0.039	0.039
≥ 50% MMD Responders across 12 weeks				
% Responders	40	58	53	52
Placebo-subtracted change		17	13	12
p-value		NS	NS	NS
Monthly Acute Medication Use Days across 12 weeks				
Baseline	6.6	6.2	6.6	6.8
Mean change from baseline	-2.4	-3.7	-3.9	-3.5
Placebo-subtracted change	--	-1.3	-1.4	-1.1
p-value		NS	NS	NS

Legend: NS = not statistically significant

QULIPTA treatment demonstrated clinically meaningful and statistically significant improvements for the primary and secondary efficacy endpoints compared to placebo (Table 6 Results of Primary and Secondary Efficacy Endpoints in Subjects with Episodic Migraine). The results of most other efficacy endpoints were also supportive.

The least square mean change from baseline in moderate or severe headache days for each of the treatment groups was -2.42 in the placebo group, -3.48 in QULIPTA 10 mg, -3.50 in QULIPTA 30 mg, and -3.98 in QULIPTA 60 mg. The least square mean change from baseline in severe headache days for each of the treatment groups was -1.21 in the placebo group, -1.50 in QULIPTA 10 mg, -1.58 in QULIPTA 30 mg, and -1.77 in QULIPTA 60 mg.

In Study 3101-301-002, across the 12-week treatment period, the proportions of patients with ≥ 50% reduction in monthly migraine days were 29% with placebo and between 56% and 61% across QULIPTA treatment arms. The proportions of patients with ≥ 75% reduction were 11% with placebo and between 30% and 38% across QULIPTA treatment arms. The proportions of patients with 100% reduction were 1% with placebo and between 5% and 8% across QULIPTA treatment arms.

In Study CGP-MD-01, across the 12-week treatment period, the proportions of patients with ≥ 50% reduction in monthly migraine days were 40% with placebo and between 52% and 58% across QULIPTA treatment arms. The proportions of patients with ≥ 75% reduction were 18% with placebo and between 29% and 36% across QULIPTA treatment arms. The proportions of patients with 100% reduction were 3% with placebo and approximately 11% across QULIPTA treatment arms.

Chronic Migraine

Table 7 Summary of Patient Demographics for Clinical Trials in Chronic Migraine

Study #	Study design	Dosage, route of administration and duration	Study subjects (n)	Mean age (Range)	Sex
3101-303-002	Phase 3, randomized, multicenter, double-blind, placebo-controlled study	QULIPTA 60 mg orally once daily for 12 weeks	QULIPTA 60 mg QD (N = 262) Placebo (N = 259)	42 years (18-74)	87% Female 13% Male

The efficacy of QULIPTA for the preventive treatment of chronic migraine in adults was demonstrated in a randomized, multicenter, double-blind, placebo-controlled study (Study 3101-303-002). The study enrolled patients with at least a 1-year history of chronic migraine, according to the ICHD-3 diagnostic criteria (2018).

Study 3101-303-002 randomized patients to QULIPTA 60 mg once daily (N = 262) or placebo (N = 259) for 12 weeks. Approximately 11% of the patients continued to use one concomitant migraine preventive medication (e.g., amitriptyline, propranolol, topiramate) when entering the study. However, concomitant use of other CGRP receptor antagonists was not permitted for either acute or preventive treatment of migraine. Patients were allowed to use acute headache treatments (i.e., triptans, ergotamine derivatives, NSAIDs, acetaminophen, and opioids), as needed. The study excluded patients with myocardial infarction, stroke, or transient ischemic attacks, as well as any significant liver disease, within six months prior to screening.

The primary efficacy endpoint was the change from baseline in mean monthly migraine days (MMD) across the 12-week treatment period. Secondary endpoints included the change from baseline in mean monthly headache days, the change from baseline in mean monthly acute medication use days, and the proportion of patients achieving at least a 50% reduction from baseline in mean MMD (3-month average).

In Study 3101-303-002, 60% of the patients were White, 3% were Black, 36% were Asian, and 4% were of Hispanic or Latino ethnicity. The mean migraine frequency at baseline was approximately 19 migraine days per month and was similar across treatment groups. A total of 89% (233/262) of patients

randomized to atogepant in Study 3101-303-002 completed the 12-week double-blind study (placebo: 89% or 230/259 patients).

Table 8 Results of Primary and Key Secondary Efficacy Endpoints in Subjects with Chronic Migraine

	QULIPTA 60 mg QD N=256	**Placebo N=246**
Monthly Migraine Days (MMD) across 12 weeks		
Baseline	19.2	19.0
Mean change from baseline	-6.9	-5.1
Difference from placebo	-1.8	
p-value	<0.001	
Monthly Headache Days across 12 weeks		
Baseline	21.5	21.4
Mean change from baseline	-7.0	-5.1
Difference from placebo	-1.9	
p-value	<0.001	
Monthly Acute Medication Use Days across 12 weeks		
Baseline	15.5	15.4
Mean change from baseline	-6.2	-4.1
Difference from placebo	-2.1	
p-value	<0.001	
≥ 50% MMD Responders across 12 weeks		
% Responders	41	26
Difference from placebo (%)	15	
p-value	<0.001	

Patients treated with QULIPTA 60 mg QD had greater mean decreases from baseline in MMD across the 12-week treatment period compared to patients who received placebo.

Across the 12-week treatment period, the proportions of patients with ≥ 75% reduction were 6% with placebo and 19% with QULIPTA (2 arms, 30 mg BID and 60 mg QD). Approximately 1% of QULIPTA-treated patients became migraine-free (Placebo: 0%). The results of most other efficacy endpoints were also supportive.

16. Non-Clinical Toxicology

General toxicology: The toxicity studies conducted to date have demonstrated margins of approximately 2 to 33 times that in human at the maximum recommended human dose (MRHD) of 60 mg/day. The NOAEL of 100 mg/kg/day in the 6-month rat chronic study represents an exposure multiple of approximately 33-fold. The NOAEL of 300 mg/kg/day for 9-month dosing in the monkey represents a 12-fold margin.

Genotoxicity: Atogepant was negative in *in vitro* (Ames, chromosomal aberration test in Chinese Hamster Ovary cells) and in vivo (rat bone marrow micronucleus) assays.

Carcinogenicity: Two-year oral carcinogenicity studies of atogepant were conducted in mice (0, 5, 20, or 75 mg/kg/day in males; 0, 5, 30, 160 mg/kg/day in females) and rats (0, 10, 20, or 100 mg/kg in males; 0, 25, 65, or 200 mg/kg in females). There was no evidence of drug-related tumors in either species. Plasma exposure (AUC) at the highest dose tested in mice was approximately 9 times that in humans at the MRHD of 60 mg/day. Similarly, in rats it was at least 23 times that in humans at the MRHD of 60 mg/day.

Reproductive and developmental toxicology: Oral administration of atogepant (0, 5, 20, or 125 mg/kg/day) to male and female rats (mated with drug-naïve females and males, respectively) resulted in no adverse effects on fertility or reproductive performance at doses corresponding to approximately 20 times the human equivalent therapeutic dose.

Oral administration of atogepant (0, 5, 15, 125, or 750 mg/kg/day) to pregnant rats during the period of organogenesis resulted in decreased fetal body weight and an increased incidence of fetal skeletal variations at 125 and 750 mg/kg which were not associated with maternal toxicity. AUC at the no-effect dose (15 mg/kg/day) for adverse effects on embryofetal development was approximately 5 times that in humans at the MRHD of 60 mg/day. Slight maternal toxicity was noted at the highest dose of atogepant administered to pregnant rabbits (130 mg/kg/day), with fetal visceral and skeletal variations. No adverse effects were observed in pregnant rabbits at oral doses of atogepant up to 90 mg/kg/day (AUC approximately 3 times that in humans at the MRHD).

No adverse effects on development were observed in rats at oral atogepant doses throughout gestation and lactation of up to 125 mg/kg/day (AUC approximately 5 times that in humans at the MRHD). Maternal transfer to the pups via lactation was demonstrated by a milk to plasma ratio of 2 to 3-fold.

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]QULIPTA®

atogepant tablets

This Patient Medication Information is written for the person who will be taking **QULIPTA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **QULIPTA**, talk to a healthcare professional.

What QULIPTA is used for:

QULIPTA is used to prevent migraine headaches in adults who have at least 4 migraine days per month.

How QULIPTA works:

QULIPTA belongs to a group of medicines known as calcitonin gene-related peptide (CGRP) receptor antagonists. It works by blocking the action of a chemical in the body called CGRP that is linked to migraine headaches.

The ingredients in QULIPTA are:

Medicinal ingredient: atogepant.

Non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, mannitol, microcrystalline cellulose, polyvinylpyrrolidone/vinyl acetate copolymer, sodium chloride, sodium stearyl fumarate, and vitamin E polyethylene glycol succinate.

QULIPTA comes in the following dosage form:

Tablets; 10 mg, 30 mg and 60 mg of atogepant.

Do not use QULIPTA if:

- you are allergic to atogepant, or any of the other ingredients in QULIPTA.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take QULIPTA. Talk about any health conditions or problems you may have, including if you:

- have kidney problems or are on dialysis;
- have heart problems;

- have liver problems;
- are pregnant, think you might be pregnant or are planning to become pregnant. It is not known if QULIPTA will harm an unborn baby. A pregnancy registry is available for women taking QULIPTA during pregnancy. This registry collects information about your health and your baby's health. If you become pregnant while taking QULIPTA, talk with your healthcare professional about taking part in this registry. You can enroll in this registry at www.empresspregnancyregistry.ca, or by calling 1-844-467-0844;
- are breastfeeding or plan to breastfeed. Very small amounts of QULIPTA pass into breast milk. Your healthcare professional will help you decide the best way to feed your baby if you take QULIPTA;
- are 65 years of age or older.

Other warnings you should know about:

Driving and using machines: QULIPTA can cause fatigue and drowsiness. Do not drive, operate machinery, or do tasks that require special attention until you are certain that QULIPTA does not affect you.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with QULIPTA:

- medicines used to treat bacterial infections (e.g., clarithromycin and rifampicin);
- medicines used to treat fungal infections (e.g., itraconazole and ketoconazole);
- medicines used to treat HIV (e.g., efavirenz and etravirine);
- medicines used to treat seizures and epilepsy (e.g., carbamazepine and phenytoin);
- cyclosporine, a medicine used to suppress the immune system following organ transplant;
- ubrogepant, a medicine used to treat migraines;
- St. John's wort, a herbal remedy commonly used to treat depression and mood disorders;
- curcumin (turmeric);
- feverfew (Tanacetum parthenium), a perennial herb.

How to take QULIPTA:

Take QULIPTA tablets by mouth exactly as your healthcare professional tells you to. QULIPTA must be taken one time each day and can be taken with or without food.

Do not use QULIPTA for a condition for which it was not prescribed. Do not give QULIPTA to anyone else, even if they have the same symptoms you have. It may harm them. You can ask your healthcare professional for information about QULIPTA.

Usual dose:

Your healthcare professional will determine the right dose of QULIPTA for you and how long you should take it. Do not stop taking QULIPTA without first speaking to your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much QULIPTA, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss a dose of your medication, you can take the missed dose as soon as you remember. If it is almost time for your next dose, skip your missed dose and take the next dose of your medication at your regularly scheduled time. Do not take 2 doses at the same time to make up for a missed dose.

Possible side effects from using QULIPTA:

These are not all the possible side effects you may have when taking QULIPTA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects of QULIPTA may include:

- common cold;
- constipation;
- decreased appetite;
- decrease in body weight;
- diarrhea;
- dizziness;
- drowsiness;
- facial swelling;
- fatigue;
- hives;
- infection of the kidneys, ureters, bladder or urethra (urinary tract infection);
- infection of the sinuses and throat (upper respiratory tract infection);
- inflammation of the sinuses (sinusitis) or stomach and intestines (gastroenteritis);
- life threatening allergic reaction;
- itching;
- nausea;

- rash;
- shortness of breath.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store QULIPTA tablets between 15°C to 30°C.

Keep out of reach and sight of children.

If you want more information about QULIPTA:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website www.abbvie.ca, or by calling 1-888-704-8271.

This leaflet was prepared by AbbVie Corporation.

Date of Authorization: 2026-04-22