DESKTOP

<Variable Subject Line Options>

01 [Have you seen the latest Rx VELSIPITY® (etrasimod) TV commercial?]

02 [Hear the latest news about Rx VELSIPITY® (etrasimod)]

03 [Introducing a new TV commercial about Rx VELSIPITY® (etrasimod)]

04 [Rx VELSIPITY® (etrasimod), now seen on TV]

<Variable Greeting Options>

01 <[Dear]>

02 <[Dr]>

03 <[Nurse]>

04 <[Greetings]>

05 <[Hello]>

06 <[Mr]>

07 <[Mrs]>

450px fold height

TO: <<variable HCP email address>>
FROM: <[firstname.lastname>]@pfizercustomerrepresentatives.com[p>
SUBJECT: Have you seen the latest Rx VELSIPITY® (etrasimod) TV commercial?
PREHEADER: Learn more about this treatment option for your patients

Please see full Prescribing Information, including Medication Guide.

Velsipity® (etrasimod) 2mg tablets | Pfizer

<Variable Greeting – [Dear]> [<First Name> <Last Name>],

<Drop-down #1 – [I hope this email finds you well.]> <Drop-down #2 – [Have you seen the new TV commercial promoting **VELSIPITY® (etrasimod)** for adults with moderate to severe UC who are ready for first-line advanced therapy*?]>

*Advanced therapies include S1P receptor modulators, biologics, and JAKi.[1]

IMPORTANT SAFETY INFORMATION

Contraindications

- Patients in the last 6 months who experienced myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure
- Patients with a history or presence of Mobitz type II second-degree or third-degree AV block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker

Infections

VELSIPITY may increase the susceptibility to infections. Life-threatening and rare fatal infections have been reported in association with other sphingosine 1-phosphate (S1P) receptor modulators. Before starting VELSIPITY, obtain a recent (i.e., within 6 months) CBC, including lymphocyte count. Delay initiation of VELSIPITY in patients with an active infection until the infection is resolved. Consider interruption of treatment with VELSIPITY if a patient develops a serious infection. Continue monitoring for infections up to 5 weeks after discontinuing VELSIPITY.

Important Safety Information continued below.

Watch the TV ad to learn more, and see data below.

Watch Now

For adults with moderate to severe UC[1]

UC can cause CHAOS for your patients[3]

Help CALM the chaos of UC[1]

A proportion of patients achieved clinical remission,[1] including improvements in stool frequency and rectal bleeding.[1]

Velsipity® (etrasimod) 2mg tablets

*Colonoscopy endpoints. Clinical remission at week 12 and at week 52. Clinical remission was defined as a stool frequency (SF) subscore of 0 or 1, a rectal bleeding (RB) subscore of 0, and an endoscopic subscore (ES) of 1 (excluding friability). Clinical remission: UC-1: At week 12, 27% (74/274) vs 7% (9/134) with placebo; At week 52, 32% (88/274) vs 7% (9/134) with placebo. UC-2: At week 12, 29% (87/221) vs 16% (17/112) with placebo. See Trial Design below.[1]

VELSIPITY is an Rx treatment option for patients who prefer:

A **first-line** advanced treatment*

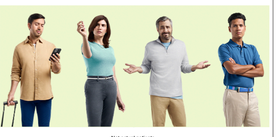
*Advanced therapies include S1P receptor modulators, biologics, and JAKi.[1]

One pill, once daily, same dose[1]

No boxed warning[1]

Contraindicated in patients with specific cardiovascular conditions. Select Warnings & Precautions: Infections, Bradyarrhythmia & AV Conduction Delays, Liver Injury. See USPI.[1]

AV=atrioventricular.



Not actual patients.

Which of your patients may be ready for VELSIPITY?

See Patient Profiles

INDICATION

VELSIPITY is indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd)

- **Progressive multifocal leukoencephalopathy (PML)** is an opportunistic viral infection of the brain that typically occurs in patients who are immunocompromised, and usually leads to death or severe disability. PML has been reported in multiple sclerosis (MS) patients treated with S1P receptor modulators. If PML is suspected, suspend VELSIPITY and discontinue if PML is confirmed by appropriate diagnostic evaluation. Immune reconstitution inflammatory syndrome (IRIS) has been reported in patients with MS treated with S1P receptor modulators who developed PML and discontinued treatment. Clinical decline may be rapid, can lead to serious neurological complications or death, and is often associated with characteristic MRI changes. Onset was generally within a few months after S1P receptor modulator discontinuation. Monitoring for IRIS should be undertaken.
- **Herpes simplex encephalitis, varicella zoster meningitis, and localized herpes viral infections** have been reported with S1P receptor modulators. In UC-1, herpes zoster was reported in 0.7% of subjects treated with VELSIPITY and in none of the subjects who received placebo. Patients without a healthcare professional-confirmed history of varicella (chickenpox), or without documentation of a full course of vaccination against varicella zoster virus (VZV), should be tested for antibodies to VZV before initiating VELSIPITY. A full course of VZV vaccination for antibody-negative patients is recommended prior to commencing treatment with VELSIPITY.
- Cases of fatal **cryptococcal meningitis (CM) and disseminated cryptococcal infections** have been reported with S1P receptor modulators. VELSIPITY treatment should be suspended until a cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated.
- VELSIPITY has not been studied in combination with anti-neoplastic, immune-modulating, or non-corticosteroid immunosuppressive therapies. Avoid concomitant administration of these therapies with VELSIPITY.
- Update immunizations according to current guidelines prior to VELSIPITY treatment. Avoid the use of live attenuated vaccines during and for 5 weeks after treatment with VELSIPITY. If live attenuated vaccine immunizations are required, administer at least 4 weeks prior to initiation of VELSIPITY.

Bradyarrhythmia and Atrioventricular (AV) Conduction Delays

Initiation of VELSIPITY may result in a transient decrease in heart rate and AV conduction delays. Before starting VELSIPITY, obtain an ECG to assess for preexisting cardiac conduction abnormalities. Seek advice of a cardiologist for patients with: significant QT prolongation; arrhythmia requiring treatment with Class Ia or Class III anti-arrhythmic drugs or QT prolonging drugs; unstable ischemic heart disease, Class I or Class II heart failure, history of cardiac arrest, cerebrovascular disease, or uncontrolled hypertension; resting HR<50bpm; history of symptomatic bradycardia, recurrent cardiogenic syncope, or severe untreated sleep apnea; history of Mobitz type I second-degree AV block in the absence of a functioning pacemaker.

Liver Injury

Elevations of aminotransferases may occur in patients receiving VELSIPITY. Obtain transaminase and bilirubin levels, if not recently available (i.e., within the last 6 months), before initiation of VELSIPITY or in patients who develop symptoms suggestive of hepatic dysfunction. Discontinue VELSIPITY if significant liver injury is confirmed. Use of VELSIPITY in patients with severe hepatic impairment is not recommended.

Macular Edema

S1P receptor modulators have been associated with an increased risk of macular edema. Obtain baseline evaluation of the fundus, including the macula near the start of VELSIPITY treatment. Periodically assess the fundus, including the macula, during treatment or if there is a change in vision. Consider discontinuing VELSIPITY if macular edema develops.

Increased Blood Pressure

VELSIPITY patients in clinical trials had average increases of 1 to 4 mm Hg systolic and 1 to 2 mm Hg diastolic blood pressure (BP). Increases were first detected after 2 weeks of treatment and remained within the specified average range of BP increases throughout treatment. Monitor BP during treatment with VELSIPITY and manage appropriately.

Fetal Risk

Based on animal studies, VELSIPITY may cause fetal harm. Advise pregnant females and females of reproductive potential of the potential risk to a fetus and to use effective contraception to avoid pregnancy during and for one week after stopping VELSIPITY. Pregnant females exposed to VELSIPITY are encouraged to contact the pregnancy registry by calling 1-800-616-3791.

Malignancies

Cases of malignancies (including skin) have been reported in patients treated with S1P receptor modulators. Skin examinations are recommended prior to or shortly after the start of treatment and periodically thereafter for all patients, particularly those with risk factors for skin cancer. Monitor for suspicious skin lesions.

Posterior Reversible Encephalopathy Syndrome

Rare cases of posterior reversible encephalopathy syndrome (PRES) have been reported in patients receiving S1P receptor modulators. If a patient develops neurological or psychiatric symptoms/signs or any symptom/sign suggestive of an increase of intracranial pressure, or accelerated neurological deterioration, complete a physical and neurological examination promptly and consider an MRI. Symptoms of PRES are usually reversible but may evolve into ischemic stroke or cerebral hemorrhage. Delay in diagnosis and treatment may lead to permanent neurological sequelae. If PRES is suspected, discontinue treatment with VELSIPITY.

Respiratory Effects

VELSIPITY may cause a decline in pulmonary function. Spirometric evaluation should be conducted during therapy if clinically indicated.

Unintended Additive Immune System Effects from Prior Treatment with Immunosuppressive or Immune-Modulating Drugs

When switching to VELSIPITY from drugs with prolonged immune effects, consider the half-life and mode of action of these drugs to avoid unintended additive immunosuppressive effects.

Immune System Effects After Stopping VELSIPITY

After stopping VELSIPITY, lymphocyte counts returned to the normal range in 90% of subjects within 4 to 5 weeks. Use of immunosuppressants within this period may lead to an additive effect on the immune system, and therefore monitor patients receiving concomitant immunosuppressants for infectious complications up to 5 weeks after the last dose of VELSIPITY.

Most Common Adverse Reactions

Most common adverse reactions reported in ≥ 2% of subjects and at a higher rate than placebo included: headache, elevated liver tests, dizziness, arthralgia, nausea, hypertension, bradycardia, UTI, hypercholesterolemia, and herpes viral infection.

TRIAL DESIGN[1,2]

Adult patients with moderately to severely active UC (an mMS of 5 to 9) were randomized to VELSIPITY or placebo in 2 randomized, multi-center, double-blind, placebo-controlled, phase 3 trials after an inadequate response, a loss of response, or an intolerance to ≥1 predefined UC therapies (oral aminosalicylates [5-ASAs], corticosteroids, thiopurines, JAKi, and biologics) (N=741). A modified Mayo score (an mMS of 0 to 9) consists of stool frequency (0 to 3), rectal bleeding (0 to 3), and findings on a centrally read endoscopy score (0 to 3). Primary analyses were conducted at week 12 and at week 52 in UC-1 and at week 12 in UC-2. Concomitant use of stable doses of oral aminosalicylates and/or oral corticosteroids (≤20 mg/day prednisone, ≤9 mg/day budesonide, or equivalent steroid) was permitted. Concomitant therapies not permitted were immunomodulators, biologic therapies, JAKi, rectal 5-ASAs, or rectal corticosteroids.

Please see full **Prescribing Information**, including **Medication Guide**.

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<Variable Closing Options>

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[<Variable Closing – [Please let me know when you would like to schedule a meeting to discuss further.]>

<Variable Sign-off Options>

01 [Sincerely,]

02 [Best regards,]

03 [Many thanks,]

<Variable Sign-off – [Sincerely,]>

[Rep photo]

[Rep first name and rep last name]
[Rep email address]
[Rep phone number]

References: 1. VELSIPITY [prescribing information]. New York, NY: Pfizer Inc.; November 2023. 2. Sandborn WJ, Vermeire S, Peyrin-Biroulet L, et al. Etrasimod as induction and maintenance therapy for ulcerative colitis (ELEVATE): two randomised, double-blind, placebo-controlled, phase 3 studies [published correction appears in *Lancet*. 2023;401(10381):1000]. *Lancet*. 2023;401(10383):1159-1171. 3. Kaplan GG, Ng SC. Epidemiology, pathogenesis, and diagnosis of inflammatory bowel diseases. In: Feldman M, Friedman LS, Brandt LJ, Chung RT, Rubin DT, Wilcox CM, eds. *Sleisenger and Fordtran's Gastrointestinal and Liver Disease: Pathophysiology, Diagnosis, Management*. 11th ed. Philadelphia, PA: Elsevier; 2021:1865-1897.

Connecticut price disclosure information for prescribers available here.
Colorado price disclosure information for prescribers available here.
Vermont price disclosure information for prescribers available here.

If you no longer wish to receive marketing emails about VELSIPITY directly from Pfizer Customer Representatives, please unsubscribe here.

Please do not reply, as this email address cannot accept replies. If you wish to contact Pfizer, click here.
View the Pfizer Privacy Policy here.

Pfizer, Attn: VELSIPITY
P.O. Box 23909
Messot, KS 66201

MOBILE

TO: <variable HCP email address>

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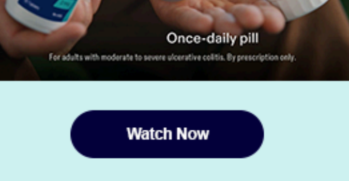

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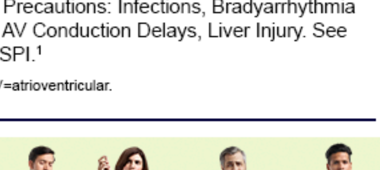

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<Variable Closing Options>

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[Rep photo]

[Rep first name and rep last name]

[Rep email address]

[Rep phone number]

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Pfizer, Attn: VELSIPITY
P.O. Box 29309
Mission, KS 66201

You are encouraged to report adverse events related to Pfizer products by calling 1-800-438-1985 (U.S. only). If you prefer, you may contact the U.S. Food and Drug Administration (FDA) directly. Visit www.fda.gov/MedWatch or call 1-800-FDA-1088.

Pfizer

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VELSIPITY

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Cancel Confirmation

Your changes have been canceled.