





Co-pay assistance for **ZEMBRACE SymTouch** may be available for eligible patients. For more information about eligibility, visit [www.zembrace.com](http://www.zembrace.com).

### **ZEMBRACE™ SymTouch™ (sumatriptan injection) 3 mg – Use and Important Safety Information**

#### **What is ZEMBRACE SymTouch used for?**

ZEMBRACE SymTouch is a prescription medicine used to treat acute migraine headaches with or without aura in adults who have been diagnosed with migraine. ZEMBRACE SymTouch is not used to prevent or decrease the number of migraines you have. It is not known if ZEMBRACE SymTouch is safe and effective in children under 18 years of age.

#### **What important information should I know about ZEMBRACE SymTouch?**

**ZEMBRACE SymTouch can cause serious side effects, including: heart attack and other heart problems, which may lead to death. Stop using ZEMBRACE SymTouch and get emergency medical help right away if you have any of the following symptoms of a heart attack:**

chest pain or chest discomfort that feels like an uncomfortable heavy pressure, tightness or heaviness, or pain that lasts for more than a few minutes, or that goes away and comes back

- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded

ZEMBRACE SymTouch is not for people with risk factors for heart disease (high blood pressure, high cholesterol levels, smoking, overweight, diabetes, family history of heart disease) unless a heart exam is done and shows no problem.

### **Who should not use ZEMBRACE SymTouch?**

Do not use ZEMBRACE SymTouch if you have:

- heart problems or a history of heart problems
- had a stroke, transient ischemic attacks (TIAs), or problems with your blood circulation
- narrowing of blood vessels to your legs or arms (peripheral vascular disease), stomach, or kidney
- uncontrolled high blood pressure
- hemiplegic migraines (that make you unable to move on one side of your body) or basilar (rare form of migraine with aura) migraines. If you are not sure if you have these, ask your healthcare provider
- taken any of the following medicines in the last 24 hours: sumatriptan, almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan, sumatriptan and naproxen, ergotamines, or dihydroergotamine. Ask your healthcare provider if you are not sure if your medicine is listed above
- severe liver problems
- an allergy to sumatriptan or any of the components in ZEMBRACE SymTouch

### **What should I tell my healthcare provider before taking ZEMBRACE SymTouch?**

Tell your healthcare provider about all of your medical conditions, and about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

### **What should I avoid while using ZEMBRACE SymTouch?**

ZEMBRACE SymTouch can cause dizziness, weakness, or drowsiness. If you have these symptoms, do not drive a car, use machinery, or do anything where you need to be alert.

### **What are possible side effects of ZEMBRACE SymTouch?**

ZEMBRACE SymTouch may cause serious side effects including:

- changes in color or sensation in your fingers and toes (Raynaud's syndrome)
- stomach and intestinal problems (gastrointestinal and colonic ischemic events)
- problems with blood circulation to your legs and feet (peripheral vascular ischemia)
- hives (itchy bumps); swelling of your tongue, mouth, or throat
- medication overuse headaches. Some people who use too many ZEMBRACE SymTouch injections may have worse headaches (medication overuse headache)
- serotonin syndrome. Serotonin syndrome is a rare but serious problem that can happen in people using ZEMBRACE SymTouch, especially if used with antidepressant medicines
  - **Call your healthcare provider right away if you have any of the following:** symptoms of serotonin syndrome: mental changes such as seeing things that are not there (hallucinations), agitation, or coma; fast heartbeat; changes in blood pressure; high body temperature; tight muscles; trouble walking; or nausea, vomiting, or diarrhea
- serious allergic reactions. Get medical help right away if you have any of these symptoms of a serious allergic reaction: swelling of your face, lips, mouth, or tongue;

- trouble breathing; wheezing; severe itching; skin rash, redness, or swelling; dizziness or fainting; fast heartbeat or pounding in your chest; or sweating
- Seizures have happened in people taking sumatriptan who have never had seizures before

**The most common side effects of ZEMBRACE SymTouch include** pain and redness at your injection site; tingling or numbness in your fingers or toes; dizziness; warm hot burning feeling to your face (flushing); discomfort or stiffness in your neck; feeling weak, drowsy, or tired.

These are not all the possible side effects of ZEMBRACE SymTouch. For more information, ask your healthcare provider or pharmacist. **You are encouraged to report negative side effects of prescription drugs. To report SUSPECTED SIDE EFFECTS, call Promius Pharma at 1-888-966-8766 or contact the FDA at 1-800-FDA-1088 (1-800-332-1088) or online at <http://www.fda.gov/Safety/MedWatch>**

Please see [Patient Information](#), [Instructions For Use](#) and [Full Prescribing Information](#) for ZEMBRACE SymTouch or visit [www.zembrace.com](http://www.zembrace.com).

### **About migraine**

Migraine affects millions of patients. Rapid pain relief is important to help them manage through their daily routines. Multiple factors such as nausea, vomiting, and/or other gastric disturbances may impact the response to oral medications and make these patients potential candidates for other modes of medication delivery including injectables.

### **About Promius Pharma LLC**

Promius Pharma is a wholly owned subsidiary of Dr. Reddy's Laboratories, one of largest and most respected pharmaceutical companies in the world. With a robust commercial infrastructure and extensive research and development capabilities through its parent company, Promius Pharma is committed to bringing new products to market that meet patients' needs in dermatology and neurology. For more information, visit [www.promiuspharma.com](http://www.promiuspharma.com).

### **Contact information (USA):**

Promius Pharma, LLC  
107 College Rd East  
Princeton, NJ 08540  
[www.promiuspharma.com](http://www.promiuspharma.com)

#### Investor Relations:

Ashish Girotra (USA)  
[ashishg@drreddys.com](mailto:ashishg@drreddys.com) Phone: +1 (609) 375-9805

#### Media Relations:

Lori McCreary (USA)  
[lmccreary@drreddys.com](mailto:lmccreary@drreddys.com) Phone +1 (609) 375-2955

ZEMBRACE and SymTouch are registered trademarks of Dr. Reddy's Laboratories Limited