RECENT MAJOR CHANGES

CONTRAINDICATIONS

- Medication overuse headache may present as migraine
- Cerebrovascular Events
- Medication overuse headache may present as migraine
- Of the 415 women who redeemed prescriptions for sumatriptan during the pregnancy registry period from September 2012, 264 (63.5%) were of white race, 125 (29.9%) were of Hispanic or Latino race, 20 (4.7%) were of Black or African American race, 13 (3.1%) were of Asian or Pacific Islander race, 2 (0.5%) were of Native American or Alaska Native race, and 1 (0.2%) was of another race. Of the 415 women who redeemed prescriptions for sumatriptan during the pregnancy registry period from September 2012, 264 (63.5%) were of white race, 125 (29.9%) were of Hispanic or Latino race, 20 (4.7%) were of Black or African American race, 13 (3.1%) were of Asian or Pacific Islander race, 2 (0.5%) were of Native American or Alaska Native race, and 1 (0.2%) was of another race. Of the 415 women who redeemed prescriptions for sumatriptan during the pregnancy registry period from September 2012, 264 (63.5%) were of white race, 125 (29.9%) were of Hispanic or Latino race, 20 (4.7%) were of Black or African American race, 13 (3.1%) were of Asian or Pacific Islander race, 2 (0.5%) were of Native American or Alaska Native race, and 1 (0.2%) was of another race.
ZEMBRACE SymTouch 3 mg/0.5 mL Injection contains sumatriptan as the succinate salt and is intended for the subcutaneous administration of a single dose of sumatriptan. It is indicated for the acute treatment of moderate to severe migraine headache in adults, with or without aura. The injection is supplied in individual single-use prefilled prefilled syringes with a fixed dose of 6 mg sumatriptan succinate in 0.5 mL. The pH range of solution is approximately 4.2 to 5.3 and the osmolality of injection is approximately 280 mOsm/kg.

**Pharmacokinetics:**
- Absorption:
  - After a single 6-mg subcutaneous manual injection into the deltoid area of the arm in 18 healthy male subjects was 97% ± 16% of that obtained following intravenous injection.
  - Absorption of subcutaneous injection was complete within 30 minutes, with peak plasma concentrations occurring at 1 hour.
- Distribution:
  - The volume of distribution of sumatriptan is approximately 0.4 L/kg.
- Metabolism:
  - The primary metabolite of sumatriptan is 4-hydroxylated sumatriptan.
  - Metabolism of sumatriptan is primarily hepatic, with involvement of cytochrome P450 enzymes.
- Elimination:
  - The elimination half-life of sumatriptan is approximately 2 hours.

**Dosage and Administration:**
- Dose:
  - The initial recommended dose of ZEMBRACE SymTouch is 6 mg subcutaneously.
- Excretion:
  - Sumatriptan is excreted in both the urine and feces.

**Contraindications and Warnings:**
- Contraindications include a history of coronary artery bypass graft surgery, history of stroke, or history of life-threatening cardiovascular, cerebrovascular, or gastrointestinal event.
- Warnings include the risk of serotonin syndrome, particularly if used with other drugs that increase serotonin levels.

**Side Effects:**
- The most common side effects of ZEMBRACE SymTouch include:
  - Nausea
  - Light-headedness
  - Dizziness
  - Numbness
  - Tingling
- More severe side effects may include:
  - Chest pain
  - Shortness of breath
  - Palpitations
  - Seizures

**Drug Interactions:**
- Certain medications may interact with ZEMBRACE SymTouch, particularly those that increase serotonin levels.

**Adverse Effects:**
- In clinical studies, the effects of ZEMBRACE SymTouch injection were evaluated in over 1000 patients with moderate or severe migraine pain. The efficacy of ZEMBRACE SymTouch was demonstrated in a 12-hour period when compared to placebo.

**Precautions:**
- Patients should be advised to use ZEMBRACE SymTouch only once per day and not to use more than one injection within a 24-hour period.

**Clinical Use:**
- ZEMBRACE SymTouch is intended for the treatment of moderate to severe migraine headache in adults. It should be used as a single injection per day.

**References:**
- The data presented are from a single clinical trial involving 230 patients with moderate to severe migraine headache.

**Tabular Data:**

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<th>Dosage</th>
<th>Number of Patients</th>
<th>Efficacy</th>
<th>Improvement</th>
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