DATA INTERPRETATION

Patient Information

Sumatriptan succinate injection is indicated for the acute treatment of migraine headache with or without Quebec experienced by adults 18 years and older that are not responsive to other preventive therapies, such as beta-blockers or anticonvulsants. Sumatriptan succinate injection is contraindicated in patients with: a history of sensitivity to sumatriptan or any components of sumatriptan succinate injection; a history of a seizure disorder or history of prolonged QT interval; a history of uncontrolled hypertension; a history of a recent coronary event (including myocardial infarction, unstable angina, or Prinzmetal's angina); or a history of a recent stroke or transient ischemic attack.

In adults, sumatriptan succinate injection is administered by subcutaneous injection and has been shown to be effective in the treatment of migraine headache. The usual dose is 6 mg given as a single dose. The response to subcutaneous administration of sumatriptan injection is generally apparent within 15 to 30 minutes, and the headache usually begins to subside within 1 to 2 hours. The maximum number of doses per day should be no more than 2 doses, with a minimum interval of 2 hours between doses. The maximum number of doses per week should be no more than 4 doses.

ADVERSE REACTIONS

The most common adverse reactions associated with the use of sumatriptan injection are chest pain, nausea, and vomiting. Other possible reactions include feeling of tightness, pain, pressure, or heaviness in the chest, throat, neck, or jaw, breaking out in a cold sweat, uncontrolled high blood pressure (hypertension), and serotonin syndrome. These reactions should be observed for a few hours following administration of sumatriptan injection. If any of these reactions occur, the patient should be instructed to seek medical attention immediately.

CONTRAINdications

Sumatriptan injection is contraindicated in patients with: a history of a seizure disorder or history of prolonged QT interval; a history of uncontrolled hypertension; a history of a recent coronary event (including myocardial infarction, unstable angina, or Prinzmetal's angina); or a history of a recent stroke or transient ischemic attack.

WARNINGS

Serotonin syndrome is a potentially fatal reaction caused by the excessive release of serotonin in the central nervous system. Serotonin syndrome may occur with sumatriptan injection, particularly during co-administration with serotonin reuptake inhibitors (SSRIs). The signs and symptoms of serotonin syndrome include mental status changes, agitation, confusion, hyperreflexia, and hypotension. If serotonin syndrome is suspected, the patient should be immediately withdrawn from the treatment and appropriate medical attention should be sought.

CLINICAL PHARMACOLOGY

Sumatriptan injection is a selective 5-HT1B/1D receptor agonist that acts on the vascular smooth muscles of the cerebral, cranial, and spinal arteries to cause vasoconstriction and relieve the symptoms of migraine headache.

PHARMACOKINETICS

Sumatriptan injection is rapidly absorbed after subcutaneous administration and reaches peak plasma concentrations in about 30 minutes. The elimination half-life of sumatriptan is about 4 hours. The plasma clearance of sumatriptan is reduced in patients with renal impairment.

DOSE AND ADMINISTRATION

Sumatriptan injection is administered subcutaneously as a single 6-mg dose. The dose should be administered as soon as possible after the onset of migrainous symptoms. If the headache is not controlled after the first dose, a second dose may be administered after a minimum interval of 2 hours. If the headache is not controlled after the second dose, additional sumatriptan injections should not be used until further evaluation has been performed.

SUMMARY

Sumatriptan injection is an effective and well-tolerated treatment for the acute treatment of migraine headache. It is administered subcutaneously and is available in a single 6-mg dose. The dose should be administered as soon as possible after the onset of migrainous symptoms. If the headache is not controlled after the first dose, a second dose may be administered after a minimum interval of 2 hours. If the headache is not controlled after the second dose, additional sumatriptan injections should not be used until further evaluation has been performed.

ARTWORK DETAIL LABEL

Product: Sumatriptan, 6 mg Single-dose Vial

SuperDry

Unit: 2 mg x 1 or 5 mg per vial

Dimension: 400 x 400 mm

New Item Code: 092927

Colour Shown: Black

Change Control No.: 092927

Regulatory Authority: Health Canada

CRediT: W. M. L. D. Z.

ificant other. For your records, please provide the following at your next medical check-up, including:

- Date of your last treatment
- Total number of treatments
- Any adverse reactions or experiences associated with the treatment

We hope this information is helpful and wish you a successful treatment for your headache. Thank you for choosing Sumatriptan for your healthcare.

For more information or if you have any questions, please contact your healthcare provider.
You should give an injection only if the symptoms of your headache start, but it may be given at any time during a migraine or cluster headache attack.

If you give an injection any time after the first injection, do not give a second injection without first talking with your healthcare provider.

If your headache comes back or you only get some relief after your first injection, you can take a second injection 1 hour after the first injection, but do not take more than 2 mg/kg/day (the highest dose in rat was reduced from 360 mg/kg/day during the carcinogenicity studies, which were performed at 160 mg/kg/day).

If you use too much sumatriptan, call your healthcare provider or go to the nearest hospital emergency room right away.

You should write down when you have headaches and when you take sumatriptan so you can talk with your healthcare provider about how sumatriptan is working for you.

What should I avoid while taking sumatriptan?

Sumatriptan 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 the possible side effects of sumatriptan?

Sumatriptan may cause serious side effects. See "What is the most important information I should know about sumatriptan?" These serious side effects include:

- Changes in color or sensation of your fingers and toes (Raynaud's syndrome)
- Pain and throbbing problems (marginal and median ischemic events). Symptoms of gastrointestinal and colon ischemic events include:
  - Sudden or severe stomach pain
  - Stomach pain after meals
  - Weight loss
  - Nausea or vomiting
  - Constipation or diarrhea
  - Bloody diarrhea
- Headaches
- Problems with blood circulation to your legs and feet (peripheral vascular ischemia). Symptoms of peripheral vascular ischemia include:
  - Crushing pain or stiffness in your legs or hips
  - Feeling of heaviness or tightness in your leg muscles
  - Burning or achiness in your feet or toes while resting
  - Numbness, tingling, or weakness in your legs
  - Cold feeling or color changes in 1 or both legs or feet
  - Hair, (dhlb, buttocks,) swelling of your tongue, mouth, or throat
- Medication overuse headache. Some people who use too many sumatriptan injections may have worsening headaches and medication overuse headache. If your headaches get worse, your healthcare provider may decide to stop your treatment with sumatriptan.
- Vascular headache. Sudden severe headache is a rare but serious problem that can happen in people using sumatriptan, especially if sumatriptan is used with anti-depressant medicines called SSRIs or SNRIs.
- 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 heart beat
  - Changes in blood pressure
  - High body temperature
  - Cold sweat
  - Nausea, diarrhea, or vomiting
  - Irritability, anxiety, or depression
  - Your healthcare provider can tell you what to do if you have signs of serotonin syndrome.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of sumatriptan. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Sumatriptan Injection (USP)?

Store sumatriptan between 20° to 25°C (68° to 77°F).

Keep sumatriptan and all medicines out of the reach of children.