Do not break the tablets. They should be swallowed whole.

Tears, abnormal vision, dizziness, emotional disturbances, headaches, and nightmares, among other things, are possible side effects of ramelteon tablets. Contact your doctor if any of these symptoms persist or worsen.

5.3.3 Other Information

Ramelteon tablets are a hypothesized medicine used to treat insomnia. Study has shown that people who take ramelteon tablets are more likely to fall asleep faster and stay asleep longer than those who take placebo. Additionally, ramelteon tablets may improve sleep quality, including the number of awakenings and the latency to sleep, as well as the duration of sleep. However, it is important to note that the effectiveness of these effects may vary from person to person.

5.4.1.1 Consumer Information

Ramelteon tablets may cause severe allergic reactions, including swelling of the tongue or throat, trouble breathing, and other symptoms of anaphylaxis. If you experience any of these symptoms, stop taking ramelteon tablets and seek medical attention immediately.

5.4.1.2 Drug Interactions

Ramelteon tablets should be avoided in patients who are taking other medications that may cause euphoria or hallucinations. Additionally, ramelteon tablets should be used with caution in patients who are taking other medications that cause drowsiness or other CNS-acting effects.

5.4.1.3 Other Conditions

Ramelteon tablets may cause sleep-related disorders such as sleepwalking or sleep-related eating disorder. Contact your doctor if you experience any of these symptoms while taking ramelteon tablets.

5.4.1.4 Antidotes

There is no specific antidote for ramelteon tablets. However, if you experience severe adverse reactions to ramelteon tablets, discontinue the medication and seek medical attention immediately.

5.4.1.5 Overdose

In the event of an overdose, contact your doctor or local poison control center immediately. The recommended treatment for overdose is supportive care, such as intubation and ventilation, as needed.

5.4.1.6 Known Uses

Ramelteon tablets are indicated for the treatment of insomnia in adults 18 years of age and older. It is important to note that this medication is not recommended for use in children.

5.4.1.7 Pregnancy and Breastfeeding

Ramelteon tablets may cause harm to the fetus if taken during pregnancy. If you are pregnant, please consult your doctor before taking this medication. Additionally, breastfeeding is not recommended while taking ramelteon tablets.

5.4.1.8 Other Conditions

Ramelteon tablets may cause changes in mood, behavior, or sleep patterns. Contact your doctor if you experience any of these symptoms while taking ramelteon tablets.

5.4.1.9 Other Medications

Ramelteon tablets may interact with other medications, such as medications that cause drowsiness or other CNS-acting effects. Contact your doctor before taking any new medications while taking ramelteon tablets.

5.4.1.10 Common Reactions

Common reactions to ramelteon tablets include drowsiness, dizziness, emotional disturbances, headaches, and nightmares. Contact your doctor if any of these symptoms persist or worsen.

5.4.1.11 Rare Reactions

Rare reactions to ramelteon tablets include severe allergic reactions, such as swelling of the tongue or throat, trouble breathing, and other symptoms of anaphylaxis. Contact your doctor if you experience any of these symptoms while taking ramelteon tablets.

5.4.1.12 Adverse Reactions

Adverse reactions to ramelteon tablets include drowsiness, dizziness, emotional disturbances, headaches, and nightmares. Contact your doctor if any of these symptoms persist or worsen.

5.4.1.13 Precautions

Ramelteon tablets should be used with caution in patients with severe hepatic impairment. Additionally, ramelteon tablets should be used with caution in patients with severe renal impairment.

5.4.1.14 Contraindications

Ramelteon tablets should be avoided in patients with severe hepatic impairment. Additionally, ramelteon tablets should be avoided in patients with severe renal impairment.

5.4.1.15 Dosage

Ramelteon tablets are available in 8 mg and 16 mg strengths. The recommended dosage is 8 mg taken 30 minutes before bedtime. In some cases, a dosage of 16 mg may be prescribed.

5.4.1.16 Storage

Store ramelteon tablets at room temperature and away from heat and moisture. Do not store in the bathroom or kitchen.

5.4.1.17 Disposition

This Medication Guide is intended for use by consumers and health care professionals who are responsible for the safe and effective use of ramelteon tablets. It is important to consult your doctor before taking ramelteon tablets or any other medication.
Ramelteon Tablets

**Active Ingredient:**
- ramelteon

**Inactive Ingredients:**
- lactose monohydrate, corn starch, hydroxypropyl cellulose, magnesium stearate, hypromellose, titanium dioxide, FD&C yellow No. 6, FD&C yellow No. 1, FD&C blue No. 1, and polysorbate 80.

**Recommended Usage:**
- Take ramelteon tablets prior to bedtime. Do not drive or do any other dangerous activities after taking ramelteon tablets until you feel fully awake.

**Side Effects:**
- The most common side effects of ramelteon tablets are:
  - drowsiness
  - headaches
  - nausea
  - nightmares
  - hallucinations

**Possible Serious Side Effects:**
- These are not all the side effects of ramelteon tablets. Ask your doctor or pharmacist for more information.

**Contraindications:**
- Do not use ramelteon tablets for a condition for which it is not prescribed.
- Do not use ramelteon tablets with other people, even if they have the same symptoms that you have.
- Do not use ramelteon tablets longer than recommended.
- Do not use ramelteon tablets with other medications that are similar to ramelteon tablets.

**Drug Interactions:**
- Patients should be advised to take ramelteon tablets within 30 minutes prior to going to bed and not to drive or do any other dangerous activities after taking ramelteon tablets until you feel fully awake.

**Precautions:**
- Patients should be advised to talk to their doctor before taking ramelteon tablets if they have a history of severe allergic reactions, hormone effects, blood clots, or any other medical condition.

**Other Information:**
- Patients should be advised to talk to their doctor about ramelteon tablets if they would like more information about ramelteon tablets.

**Legal Information:**
- All brand names listed are the registered trademarks of the manufacturers.

**Company Information:**
- Teva Pharmaceuticals USA, Inc.
- 1070 Horsham Road, North Wales, PA, 19454
- Phone: 215-591-3000

**References:**

**Additional Information:**
- This Medication Guide summarizes the most important information about ramelteon tablets. If you or your doctor have any questions about the use of ramelteon tablets, call Teva Pharmaceuticals USA, Inc. at 1-800-328-7777 or visit www.teva.com.

**Important Information:**
- Please talk to your doctor or pharmacist for more information about ramelteon tablets.

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