Tramadol tablets film-coated retard, capsules, drops, suppositories,injections

Each tablets retard film-coated retard tablets contains:
Tramadol hydrochloride…….. 100 mg

Each capsule contains:
Tramadol hydrochloride……50 mg

1 ml (40 drops) of solution contains:
tramadol hydrochloride……100 mg

Each suppository contains:
Tramadol hydrochloride…….. 100 mg

1 ml of solution (1 ampoule) contains:
Tramadol hydrochloride……50 mg

2 ml solution (1 ampoule) contains:
Tramadol hydrochloride……100 mg

DRUG CLASS AND MECHANISM:

Tramadol is a man-made (synthetic) analgesic (pain reliever). Its exact mechanism of action is unknown but similar morphine. Like morphine, tramadol binds to receptors in the brain (opioid receptors) that are important for transmitting the sensation of pain from throughout the body to. Tramadol, like other narcotics used for the treatment of pain, may be abused. Tramadol is not a nonsteroidal antiinflammatory drug (NSAID) and does not have the increased risk of stomach ulceration and internal bleeding that can occur with NSAIDs.

PREPARATIONS:

Tablets (immediate release): 50 mg. Tablets (extended release): 100, 200, and 300 mg.

STORAGE:

Store at room temperature, 15-30 C (59-86 F). Store in a sealed container.

PRESCRIBED FOR:

Tramadol is used in the management of moderate to moderately severe pain. Extended release tablets are used for moderate to moderately severe chronic pain in adults who require continuous treatment for an extended period.

DOSING:

The recommended dose of tramadol is 50-100 mg (immediate release tablets) every 4-6 hours as needed for pain. The maximum dose is 400 mg/day. To improve tolerance patients should be started at 25 mg/day, and doses may be increased by 25 mg every 3 days to reach 100 mg/day (25 mg 4 times daily). Thereafter, doses can be increased by 50 mg every 3 days to reach 200 mg day (50 mg 4 times daily). Tramadol may be taken with or without food.

Recommended dose for extended release tablets is 100 mg daily which may be increased by 100 mg every 5 days but not to exceed 300 mg /day. Extended release tablets should be swallowed whole and not crushed or chewed.

DRUG INTERACTIONS:

Carbamazepine (Tegretol, Tegretol XR , Equetro, Carbatrol) reduces the effect of tramadol by increasing its inactivation in the body. Quinidine (Quinaglute, Quinidex) reduces the inactivation of tramadol, thereby increasing the concentration of tramadol by 50%-60%. Combining tramadol with monoamine oxidase inhibitors (for example, Parnate) or selective serotonin inhibitors ((SSRIs, for example, fluoxetine Prozac]) may result in severe side effects such as seizures or a condition called serotonin syndrome.

Tramadol may increase central nervous system and respiratory depression when combined with alcohol, anesthetics, narcotics, tranquilizers or sedative hypnotics.

PREGNANCY: The safety of tramadol during pregnancy has not been established.

NURSING MOTHERS: The safety of tramadol in nursing mothers has not been established.

SIDE EFFECTS:

Tramadol is generally well tolerated, and side effects are usually transient. Commonly reported side effects include nausea, constipation, dizziness, headache, drowsiness, and vomiting. Less commonly reported side effects include itching, sweating, dry mouth, diarrhea, rash, visual disturbances, and vertigo. Some patients who received tramadol have reported seizures. Abrupt withdrawal of tramadol may result in anxiety, sweating, insomnia, rigors, pain, nausea, diarrhea, tremors, and hallucinations.

For Information about Generic Medicines : **genericmedicines@tajpharma.com**

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Information for Health Care Professionals

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Taj Pharmaceuticals Limited is a pharmaceutical company founded and based in India. The company manufacturers pharmaceutical formulations and API for India and other countries of world. The company was established in 1995 as an enterprise and in 2004 became a public limited company. As per Mumbai pharmaxil and Chemixil association the company manufacturers and exports to countries like Albania, Argentina, Austria, Chile and Iraq. In 1995 pharmaceuticals wing only has a schedule M certification for pharmaceuticals products manufacturing in India. Taj Pharmaceuticals established its manufacturing unit in Gujarat because of government policies in 1999 with WHO / GMP licence. The company in 2003 revived all the old manufacturing units and approached the FDA Gujarat for 4000 new pharmaceuticals drug permissions for the first time in India.

According to the Indian Trade Mark the company owns about 450 brands and 4600 generic manufacturing permissions in India. According to the export data analysis the company was the largest exporter of generic medicines to the Europe and Middle East countries.
www.tajpharma.com

The company medicines are present in France, Georgia, Egypt and CIF countries.

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