

# MOLCET®

## Tramadol 37.5mg + Paracetamol 325mg

**DESCRIPTION:** MOLCET® Tablet combines two analgesics. Each tablet contain 37.5 mg Tramadol hydrochloride BP and 325 mg Paracetamol BP as active ingredients and are light yellow in color. Inactive ingredients in the tablet are powdered cellulose, pregelatinized corn starch, sodium starch glycolate, corn starch, magnesium stearate, hypromellose, polyethylene glycol, polysorbate 80, titanium dioxide, iron oxide, and carnauba wax.

**USES:** This product is used to treat moderate short-term pain (5 days or fewer). It contains 2 medications: Tramadol and Paracetamol. Tramadol is similar to narcotic pain relievers (opiate-type). It acts on certain centers in the brain to give you pain relief. Paracetamol is a non-narcotic pain reliever.

**HOW TO USE:** Take this medication by mouth with or without food as directed by your doctor. If you have nausea, it may help to take this drug with food. Consult your doctor or pharmacist about other ways to decrease nausea (such as taking anti-histamines, lying down for 1 to 2 hours with as little head movement as possible).

The dosage is based on your medical condition and response to treatment. In adults who do not have kidney disease, the maximum recommended dose for this product is 300 milligrams of tramadol a day. Do not increase your dose, take the medication more frequently, or take it for a longer time than prescribed. Properly stop the medication when so directed. This product also contains Paracetamol. Do not take more Paracetamol than recommended. (See also Side Effects and Precautions sections.) Pain medications work best if they are used when the first signs of pain occur. If you wait until the pain has worsened, the medication may not work as well.

This medication may cause dependence, especially if it has been used regularly for a long time or in high doses. In such cases, withdrawal reactions (such as anxiety, sweating, trouble sleeping, shaking) may occur if you suddenly stop this drug. To prevent withdrawal reactions, your doctor may reduce your dose gradually. Consult your doctor or pharmacist for more details, and report any withdrawal reactions immediately.

When this medication is used for a long time, it may not work as well. Your doctor may need to increase your dose or change your medication. Talk with your doctor if this medication stops working well.

Along with its benefits, this medication may rarely cause abnormal drug-seeking behavior (addiction). This risk may be increased if you have abused alcohol or drugs in the past. Take this medication exactly as prescribed to lessen the risk of addiction. Tell your doctor if your pain persists or worsens.

**SIDE EFFECTS:** Nausea, vomiting, constipation, lightheadedness, dizziness, drowsiness, increased sweating, or dry mouth may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.

To prevent constipation, maintain a diet adequate in fiber, drink plenty of water, and exercise. Consult your pharmacist for help in selecting a laxative (such as a stimulant type with stool softener).

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor immediately if any of these unlikely but serious side effects occur: vision changes, shaking (tremor).

Tell your doctor immediately if any of these rare but very serious side effects occur: change in the amount of urine, fainting, slow/shallow breathing, seizures.

This medication may rarely cause a very serious condition called serotonin syndrome. The risk increases when this medication is used with certain other drugs. Seek immediate medical attention if you develop some of the following symptoms: mental/mood changes (such as agitation, hallucinations), unusual restlessness, loss of coordination, fast heartbeat, severe dizziness, unexplained fever, severe nausea/vomiting/diarrhea, twitchy muscles.

In adults who do not have liver problems, the maximum dose of Paracetamol is 4 grams (4000 milligrams) per day. Taking more may cause serious (possibly fatal) liver disease. Seek immediate medical attention if you have any of the following symptoms of liver damage: severe stomach/abdominal pain, persistent nausea/vomiting, yellowing eyes/skin, dark urine, extreme tiredness.

A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any

symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

**PRECAUTIONS:** Before taking this product, tell your doctor or pharmacist if you are allergic to tramadol or Paracetamol; or to narcotic pain medications (such as codeine); or if you have any other allergies.

This medication should not be used if you have certain medical conditions. Before using this medicine, consult your doctor or pharmacist if you have: certain bowel diseases (paralytic ileus, infectious diarrhea).

Before using this medication, tell your doctor or pharmacist your medical history, especially of: kidney disease, liver disease, personal or family history of regular use/abuse of drugs/alcohol, brain injuries/disorders (such as seizures, head injury, tumor, increased intracranial pressure), breathing problems (such as slow/shallow breathing, sleep apnea), lung disease (such as asthma, chronic obstructive pulmonary disease-COPD), a certain spinal problem (kyphoscoliosis), certain heart problems (irregular heartbeat), under active thyroid (hypothyroidism), disease of the pancreas (such as pancreatitis), mental/mood disorders (such as toxic psychosis), gallbladder disease, adrenal gland problem (such as Addison &apos;s disease), intestinal disorders (such as colitis, blockage), difficulty urinating (for example, due to enlarged prostate or narrowed urethra).

This drug may make you dizzy or drowsy. Use caution while driving, using machinery, or doing any activity that requires alertness. Avoid alcoholic beverages because they may increase the risk of this drug &apos;s side effects.

Paracetamol may cause liver damage. Daily use of alcohol may increase your risk for liver damage, especially when combined with Paracetamol. Ask your doctor or pharmacist for more information.

Before having surgery, tell your doctor or dentist that you are using this medication.

To lower your risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position.

Older adults may be more sensitive to the effects of this drug, especially slow/shallow breathing and drowsiness.

During pregnancy, this medication should be used only when clearly needed. Using it for long periods or in high doses near the expected delivery date is not recommended because of possible harm to the unborn baby. Discuss the risks and benefits with your doctor. Infants born to mothers who have used this medication for a long time may have seizures or withdrawal symptoms such as irritability, abnormal/persistent crying, vomiting, or diarrhea. Tell your doctor immediately if you notice any of these symptoms in your newborn.

This product passes into breast milk, and the effect on a nursing infant is unknown. Discuss the risks and benefits with your doctor before breast-feeding.

**OVERDOSE:** Symptoms of overdose may include: slow/shallow breathing, seizures, persistent nausea/vomiting, yellowing eyes/skin, dark urine, severe stomach/abdominal pain, extreme tiredness.

**NOTES:** Do not share this medication with others.

This medication has been prescribed for your current condition only. Do not use it later for another condition unless told to do so by your doctor. A different medication may be necessary in that case.

**STORAGE:** Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company for more details about how to safely discard your product.

**SUPPLY:** Molcet<sup>®</sup> is packed in blisters of 10 tablets by Pharmadex S.A.L – Kahaleh, Lebanon under license from ORBUCELL PHARMA, Quebec, Canada. Manufactured by: COBALT PHARMACEUTICALS, Ontario, Canada.