

Akums Drugs & Pharmaceuticals Ltd. (Plant-I) Software use : CorelDraw X8
 Country/Customer **Uganda (Unosource)** Layout No. N/A
 Substrate **60 ± 15% Gsm Maplitho paper with 2 horizontal & 1 vertical fold**
 at equal distance, packing leaflet **120x150 mm ± 2mm**

Artwork SAP code	XXXXXXXX	Product name	Proposed size	60x37.5 mm
Reason for change	New export Commercial RO			
Pantone No./CMYK	BLACK	No. of colours	1 colour	
Customer/Market ng	DRA Pkg Dev Product on	QC QA	Remark f any	
Note: (1) Please ensure that the artwork provided to you in CDR format is exactly as per approved signature artwork copy. In case of any changes, please do not proceed without written confirmation. (2) Folded in two / three folds, (3) Bundled to 50 nos. or 100 nos., (4) Outer packing wt not more than 5 kg.				

FRONT PAGE

Artwork SAP code	XXXXXXXX	Product name	Proposed size	60x37.5 mm
Reason for change	New export Commercial RO			
Pantone No./CMYK	BLACK	No. of colours	1 colour	
Customer/Market ng	DRA Pkg Dev Product on	QC QA	Remark f any	
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BACK PAGE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

TRADMIN



Tramadol Capsules BP

COMPOSITION

Each hard gelatin capsule contains:
 Tramadol Hydrochloride BP 50mg

PHARMACOLOGICAL CLASSIFICATION

Opioid

MECHANISM OF ACTION

Tramadol is a centrally acting synthetic opioid analgesic. Although its mode of action is not completely understood, from animal tests, at least two complementary mechanisms appear applicable: binding of parent and M1 metabolite to μ -opioid receptors and weak inhibition of reuptake of norepinephrine and serotonin.

Tramadol has been shown to inhibit reuptake of norepinephrine and serotonin in vitro, as have some other opioid analgesics. These mechanisms may contribute independently to the overall analgesic profile of tramadol.

PHARMACOKINETICS

Absorption: Readily absorbed from the GI tract (oral).
 Distribution: Widely distributed. Crosses the placenta and enters breast milk.
 Metabolism: Extensive hepatic first-pass metabolism; converted to O-desmethyltramadol (active) by N- and O-demethylation via the cytochrome P450 isoenzymes CYP3A4 and CYP2D6 and glucuronidation or sulfation.

Excretion: Via urine (as metabolites); 6 hr (elimination half-life).
 Pregnancy: This medication should be used only when clearly needed. It may slightly increase the risk of birth defects if used during the first two months of pregnancy. Also, using it for a long time or in high doses near the expected delivery date may harm the unborn baby. To lessen the risk, take the smallest effective dose for the shortest possible time. Tell the doctor right away if notice any symptoms in newborn baby such as slow/shallow breathing, irritability, abnormal/persistent crying, vomiting, or diarrhea.

SIDE EFFECTS

Dizziness, GI upset, constipation, headache, somnolence, pruritus, CNS stimulation, asthenia, sweating, dry mouth, seizures, anaphylaxis.

INDICATIONS

Indicated for the management of moderate to moderately severe chronic pain.

DOSAGE & ADMINISTRATION: One capsule three times a day or as directed by the physician.

CONTRAINDICATIONS

Acute intoxication with alcohol, hypnotics, narcotics, centrally-acting analgesics, other opioids, or psychotropic drugs.

DRUG INTERACTIONS

Concomitant MAOIs, carbamazepine, alcohol, or other forms of tramadol: not recommended. Increased risk of seizures and/or serotonin syndrome with SSRIs, SNRIs, tricyclics, cyclobenzaprine, promethazine, opioids, MAOIs, naloxone, triptans, linezolid, lithium, neuroleptics, others that lower seizure threshold. Potentiation with alcohol, other CNS depressants; reduce dose. May be potentiated by CYP2D6 inhibitors (eg, quinidine, fluoxetine, paroxetine, amitriptyline). May potentiate digoxin, warfarin. May be affected by CYP3A4 inhibitors (eg, ketoconazole, erythromycin) or CYP3A4 inducers (eg, rifampin, St. John's Wort).

WARNINGS & PRECAUTIONS

Do not give to opioid-dependent patients. Respiratory depression. Increased intracranial pressure. Head injury. Seizure disorders. Acute abdomen. Renal or hepatic impairment. Suicidal ideation. Drug abusers. Avoid abrupt cessation. Elderly (esp. >75 years). Labor & delivery, pregnancy (Cat.C), nursing mothers: not recommended. Tramadol capsule contains lactose and therefore should not be used by patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

OVERDOSE

Symptoms: Miosis, vomiting, cold and clammy skin, respiratory depression, lethargy, flaccid skeletal muscle, coma, seizures, bradycardia, hypotension, cardiac arrest, cardiac collapse and death. Management: Treatment is supportive and ensure adequate ventilation. Although naloxone will reverse some, but not all, symptoms of tramadol overdosage, there is an increased risk of seizures which has to be taken into consideration. Haemodialysis is unlikely to be helpful.

STORAGE

Store below 30°C, protected from light & moisture.
 Keep all medicines out of reach of children.

PRESENTATION

10 capsules pack in a Blister and such 10 Blisters pack in a carton along with pack insert.



Product from
Unosource Pharma Ltd.

Manufactured by:
Akums Drugs & Pharmaceuticals Ltd.
 19, 20, 21, Sector-6A, I.I.E., SIDCUL,
 Ranipur, Haridwar-249 403, INDIA.

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150 mm

150 mm

120 mm

120 mm