120 mm (Front)

ٹیوسینٹا

120 mm (Back)

240 mm

TUCENTA®
(TAPENTADOL)

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50mg & 75mg Film-Coated Tablets

WARNING: • TAPENTADOL tablets expose users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and reassess regularly for these behaviors and conditions. • Serious, life-threatening, or fatal respiratory depression may occur, especially upon initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of TAPENTADOL tablets are essential. • Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate. • Accidental ingestion of TAPENTADOL tablets, especially by children, can result in a fatal overdose of tapentadol.• If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

COMPOSITION
Each film-coated tablet contains:
Tapentadol (as HCl) 50mg
(Product complies to innovator specifications)

Each film-coated tablet contains:
Tapentadol (as HCl) 75mg
(Product complies to innovator specifications)

THERAPEUTIC INDICATIONS
TAPENTADOL is indicated for the relief of moderate to severe acute pain in adults, which can be adequately managed only with opioid analgesics.

DOSAGE AND ADMINISTRATION
The dosing regimen should be individualized according to the severity of pain being treated, the previous treatment experience and the ability to monitor the patient. Patients should start treatment with single doses of 50 mg tapentadol as film-coated tablet administered every 4 to 6 hours. Higher starting doses may be necessary depending on the pain intensity and the patient's previous history of analgesic requirements.On the first day of dosing, an additional dose may be taken as soon as one hour after the initial dose, if pain control is not achieved. The dose should then be titrated aindividually to a level that provides adequate analgesia and minimises undesirable effects under the close supervision of the prescribing physician.Total daily doses greater than 700 mg tapentadol on the first day of treatment and maintenance daily doses greater than 600 mg tapentadol have not been studied and are therefore not recommended.

Duration of treatment The film-coated tablets are intended for acute pain situations. If longer term treatment is anticipated or becomes necessary and effective pain relief in the absence of intolerable adverse events was achieved with TAPENTADOL, the possibility of switching the patient to therapy with TAPENTADOL prolonged release tablets should be considered.

Discontinuation of treatment Withdrawal symptoms could occur after abrupt discontinuation of treatment with tapentadol. When a patient no longer requires therapy with tapentadol, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.
Renal Impairment in patients with mild or moderate renal impairment a dosage adjustment is not required.
TAPENTADOL has not been studied in controlled efficacy trials in patients with severe renal impairment, therefore the use in this population is not recommended.

Hepatic Impairment in patients with mild hepatic impairment a dosage adjustment is not required.
TAPENTADOL should be used with caution in patients with moderate hepatic impairment. Treatment in these patients should be initiated at the lowest available dose strength, i.e. 50 mg tapentadol as film-coated tablet, and not be administered more frequently than once every 8 hours. At initiation of therapy a daily dose greater than 150 mg tapentadol as film-coated tablet is not recommended. Further treatment should reflect maintenance of analgesia with acceptable tolerability, to be achieved by either shortening or lengthening the dosing interval. TAPENTADOL has not been studied in patients with severe hepatic impairment and therefore, use in this population is not recommended.
Elderly patients (persons aged 65 years and over)
In general, dose adaptation in elderly patients is not required. However, as elderly patients are more likely to have decreased renal and hepatic function, care should be taken in dose selection as recommended
Pediatric PatientsTAPENTADOL is not recommended for use in this population.

Method of administration The tablet should be taken with sufficient liquid. TAPENTADOL can be taken with or without food.

CONTRAINDICATIONS
• in patients with hypersensitivity to tapentadol or to any of the excipients listed in section 6.1• in situations where active substances with mu-opioid receptor agonist activity are contraindicated, i.e. patients with significant respiratory depression (in unmonitored settings or the absence of resuscitative equipment), and patients with acute or severe bronchial asthma or hypercapnia• in any patient who has or is suspected of having paralytic ileus• in patients with acute intoxication with alcohol, hypnotics, centrally acting analgesics, or psychotropic active substances

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
When using Tapentadol, it is crucial to consider several precautions. There is a risk of developing tolerance, dependence, and opioid use disorder, particularly in patients with a history of substance use disorders (including alcohol use disorder) or mental health issues. The concomitant use of sedating products, such as benzodiazepines, may result in severe respiratory depression or death, necessitating careful monitoring. Tapentadol should be avoided in patients with severe renal or hepatic impairment, seizure disorders, those susceptible to intracranial pressure effects, and individuals with lactose intolerance. Additionally, caution is needed for those with pancreatic or biliary tract disease, sleep-related breathing disorders, and those taking mixed opioid agonists/antagonists.

DRUG INTERACTIONS
When using Tapentadol, exercise caution with CNS depressants (e.g., benzodiazepines, opioids, barbiturates) to prevent sedation, respiratory depression, coma, and death. Avoid concurrent use with gabapentinoids to mitigate opioid overdose risks. Monitor for convulsions when combining with SSRIs, SNRIs, or tricyclic antidepressants. Be cautious with UGT enzyme inhibitors, which can increase systemic exposure. Do not administer with MAO inhibitors due to potential cardiovascular risks

PREGNANCY AND LACTATION Use of Tapentadol during pregnancy should be carefully considered due to potential risks to the fetus, including the possibility of neonatal withdrawal syndrome. It is not recommended for use during labour and delivery, as it may affect newborns due to its opioid agonist activity. Breastfeeding should be avoided as Tapentadol is excreted in milk, posing a risk to the infant. Its effects on human fertility are unknown, no effects on reproductive parameters were observed in male or female rats.

EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES
TAPENTADOL may have a major influence on the ability to drive and use machines

ADVERSE DRUG REACTIONS

Very common	Common	Uncommon
Dizziness, Somnolence, Headache, Nausea, Vomiting	Decreased appetite, Anxiety, Confessional, state, Hallucination, Sleep disorder, Abnormal dreams, Tremor, Flushing, Constipation, Diarrhoea, Dyspepsia, Dry mouth, Pruritus, Hyperhidrosis, Rash Muscle spasms Asthenia, Fatigue, Feeling of body temperature change	Depressed mood, Disorientation, Agitation, Nervousness, Restlessness, Euphoric mood Disturbance in attention, Memory impairment, Presyncope, Sedation, Ataxia, Dysarthria, Hypoaesthesia, Paraesthesia, Muscle contractions involuntary Visual disturbance Heart rate increased, Palpitations Blood pressure decreased Respiratory depression, Oxygen saturation decreased, Dyspnoea, Abdominal discomfort Urticaria Sensation of heaviness Urinary hesitation, Pollakiuria Drug withdrawal syndrome, Oedema, Feeling abnormal, Feeling drunk, Irritability, Feeling of relaxation

Reporting of suspected adverse reactions
Reporting suspected adverse reactions via: pv@searlecompany.com

OVERDOSE
Overdose Symptoms and Management: Tapentadol overdose can result in typical mu-opioid receptor agonist symptoms such as miosis, vomiting, cardiovascular collapse, coma, convulsions, and respiratory depression leading to arrest. Immediate measures include securing the airway and providing assisted ventilation. Naloxone is used to reverse respiratory depression, but respiratory depression may last longer than the naloxone's effects, necessitating continuous monitoring and possible repeated doses. Gastrointestinal decontamination with activated charcoal or gastric lavage may be considered within 2 hours of ingestion, prioritizing airway protection beforehand.

PRESENTATION
Tucenta 50mg tablets are available in blister pack of 1x14's Tablets.
Tucenta 75mg tablets are available in blister pack of 1x14's Tablets.

REGISTRATION NUMBER
Tucenta 50mg: 108925
Tucenta 75mg: 097092

MANUFACTURING LICENSE NUMBER : 000016

INSTRUCTIONS
To be sold on the prescription of a registered medical practitioner only.
Protect from sunlight, moisture and heat.
Do not store and transport above 30°C.
Keep all medicines out of sight & reach of children.
Product contains Lactose.

ہدایات:
صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔
سورج کی روشنی، نمی اور گرمی سے بچائیں۔
۳۰ ڈگری سینٹی گریڈ سے زیادہ درجہ حرارت پر محفوظ اور ترسیل نہ کریں۔
تمام دوائیں بچوں کی نظر اور پہنچ سے دور رکھیں۔
اس دوا میں لیکٹوز ہے۔

Note: For detailed information please refer to SPC available on website **www.searlecompany.com**

SEARLE
Manufactured by:
The Searle Company Limited
F-319, S.I.T.E., Karachi - Pakistan.
1012005428-001

SPL/RPI TUC.T/624-000(001)

DEPARTMENT	NAME	SIGNATURE
Designed by		
Marketing		
Medical		
Regulatory		
Business Development		
QA Artwork Section		
Quality Control		
Production		
Research & Development		

THE *SEARLE* COMPANY LIMITED
APPROVED
Product Name: Tucenta
Artwork: Leaflet
Creation Date: 21-6-2024
Revision Number: 0st
Size:(120x240)mm
Color: [redacted]

Item Code	Artwork Version	Description of change in Artwork	Change Control #/NPIF	Date of Approval

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