For the Use of a Registered Medical Practitioner Only

1. GENERIC NAME AND BRAND NAME

Tramadol Dispersible Tablets BP 50 mg
Contramal® DT

Tramadol Prolonged-Release Tablets I.P. 100 mg
Contramal® SR 100

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Contramal® DT:
Each uncoated dispersible tablet contains:
Tramadol Hydrochloride I.P. 50 mg
Excipients q.s.

Contramal® SR 100:
Each sustained release (film coated) tablet contains:
Tramadol Hydrochloride I.P. 100 mg
Excipients q.s.
Colour: Titanium Dioxide I.P.

3. DOSAGE FORM AND STRENGTH

Kindly refer to section 1 & 2

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATION

Indicated for severe acute pain only for a period not exceeding 5 days.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

Recommended for patients above 12 years of age.
The dose should be adjusted to the intensity of the pain and the sensitivity of the individual patient.

Acute Pain: An initial dose of 100mg is usually necessary. This can be followed by doses of 50 or 100mg not more frequently than 4 hourly, and duration of therapy should be matched to clinical need.

Pain Associated with Chronic Conditions: Use an initial dose of 50mg and then titrate dose according to pain severity. The need for continued treatment should be assessed at regular intervals as withdrawal symptoms and dependence have been reported.
The lowest analgesically effective dose should generally be selected. Daily doses of 400 mg active substance should not be exceeded, except in special clinical circumstances.

Contramal capsules
To be taken whole, not divided or chewed, with sufficient liquid, independent of meals.

Contramal soluble tablets
Should be dissolved in at least 50 ml water before administration, independent of meals.

Contramal SR
The usual initial dose is 100 mg Tramadol hydrochloride twice daily, morning and evening. If pain relief is insufficient, the dose may be titrated upwards to 150 mg or 200 mg Tramadol hydrochloride twice daily.

Elderly
The usual dosage may be used although it should be noted that in very old patients (>75 years old), the elimination half-life of Tramadol was reported to be increased. Therefore, if necessary, the dosage interval is to be extended according to the patients requirements.

Renal Insufficiency / Renal Dialysis
The elimination of Tramadol may be prolonged. The usual initial dosage should be used. For patients with creatinine clearance <30ml/min, the dosage interval should be increased to 12 hours. Tramadol is not recommended for patients with severe renal impairment (creatinine clearance <10ml/min). As Tramadol is only removed very slowly by hemodialysis or hemofiltration, post-dialysis administration to maintain analgesia is not usually necessary.

Hepatic impairment
The elimination of Tramadol may be prolonged. The usual initial dosage should be used but in severe hepatic impairment the dosage interval should be increased to 12 hours. Contramal SR is not recommended in cases of severe hepatic impairment.
Children under 12 years: Not recommended.

4.3 CONTRAINDICATIONS

Tramadol is contraindicated in:

- Patients with known hypersensitivity to tramadol or any excipients.
- Acute intoxication with alcohol, analgesics, hypnotics, opioids or psychotropic drugs.
- Subjects who are receiving MAO inhibitors or who have taken them within the last 14 days.
- Known hypersensitivity to opioids.
- Patients with uncontrolled epilepsy or epilepsy not adequately controlled by treatment.
- Tramadol must not be used for narcotic withdrawal treatment

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Keep out of reach of children.

Not for veterinary use.

Tramadol:

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should consult a physician prior to use.

Acute abdominal conditions

The administration of tramadol may complicate the assessment of patients with acute abdominal conditions.

Respiratory depression

When large doses of tramadol are administered with anaesthetic medications or alcohol, respiratory depression may result. Tramadol should be administered cautiously in patients at risk of respiratory depression.

Increased intracranial pressure, head trauma, shock or reduced levels of consciousness

Tramadol should be used with caution in patients with increased intracranial pressure, shock, head injury or a reduced level of consciousness of uncertain origin.

Renal and hepatic disease

With the prolonged half-life in these conditions, steady state achievement is delayed, so that it may take several days for elevated plasma concentrations to develop.

Serotonin syndrome

Serotonin syndrome, a potentially life-threatening condition, has been reported in patients receiving tramadol in combination with other serotonergic agents or tramadol alone (see sections 4.5, 4.8 and 4.9).

If concomitant treatment with other serotonergic agents is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose escalations.

Symptoms of serotonin syndrome may include mental status changes, autonomic instability, neuromuscular abnormalities and/or gastrointestinal symptoms.

If serotonin syndrome is suspected, a dose reduction or discontinuation of therapy should be considered depending on the severity of the symptoms. Withdrawal of the serotonergic drugs usually brings about a rapid improvement.

Renal disease

In patients with renal insufficiency the tramadol elimination is delayed. In cases of severe renal insufficiency tramadol is not recommended.

Hepatic disease

Metabolism of tramadol and M1 is reduced in patients with advanced liver cirrhosis. In cirrhotic patients, dosage reduction is recommended.

Patients physically dependent on opioids

Tramadol is not recommended as a substitute in opioid-dependent patients. In patients with a tendency for drug abuse or dependence, treatment with tramadol should only be carried out for short periods under strict medical supervision.

Seizure risk

Convulsions are reported in patients receiving tramadol. The risk is increased when doses of tramadol exceed the recommended upper daily dose limit Patients with epilepsy or the ones susceptible to seizures should only be treated with tramadol if there are compelling circumstances.

Anaphylactoid reactions

Serious and rarely fatal anaphylactoid reactions have been reported in patients taking tramadol. These reactions often occur after the first dose. Other reported reactions include pruritus, bronchospasm, hives and angioedema.

Long-term use

When long term tramadol treatment is required, careful and regular monitoring should be carried out to establish whether, and to what extent, ongoing treatment is necessary.

Labour and delivery

The use of tramadol in pregnant women prior to or during labour is not recommended unless the potential benefits outweigh the risks, because safe use in pregnancy has not been established. Chronic use during pregnancy may cause neonatal withdrawal symptoms. If tramadol were to be used during labour, it may lead to respiratory depression in the new-born.

Sleep-related breathing disorders:

Opioids can cause sleep-related breathing disorders including central sleep apnoea (CSA) and sleep-related hypoxemia. Opioid use increases the risk of CSA in a dose-dependent fashion. In patients who present with CSA, consider decreasing the total opioid dosage.

Adrenal insufficiency

Opioid analgesics may occasionally cause reversible adrenal insufficiency requiring monitoring and glucocorticoid replacement therapy. Symptoms of acute or chronic adrenal insufficiency may include e.g. severe abdominal pain, nausea and vomiting, low blood pressure, extreme fatigue, decreased appetite, and weight loss.

4.5 DRUGS INTERACTIONS

Drug	Drug Interaction	Remarks
CNS depressants	The combination of tramadol with mixed opiate agonists/antagonists (eg. Buprenorphine, pentazocine) is not advisable because the analgesic effect of a pure agonist may be theoretically reduced in such circumstances.	Tramadol should be used with caution and in reduced dosages when administered to patients receiving CNS depressants such as alcohol, opioids, anaesthetic agents, phenothiazines, tranquillisers or sedative hypnotics.
Serotonergic agents	Concomitant therapeutic use of tramadol and serotonergic medicines such as selective serotonin re-uptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), MAO inhibitors, tricyclics antidepressants and mirtazapine may cause serotonin toxicity.	-
Coumarin derivatives	Concomitant use may increase international normalised ratio (INR) with major bleeding and ecchymoses in some patients.	Caution should be exercised during concomitant treatment with tramadol and coumarin derivatives (eg. Warfarin)
Drugs which reduce the seizure threshold	tramadol can induce convulsions and increase the potential for selective serotonin re-uptake inhibitors (SSRIs), serotonin norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants, antipsychotics and other seizure-threshold-lowering drugs (such as bupropion, mirtazapine, tetrahydrocannabinol) to cause convulsions.	-
MAO inhibitors	Tramadol inhibits the uptake of noradrenaline and serotonin.	Tramadol should not be used in patients who are taking MAO inhibitors or who have taken them within the last fourteen days.

Carbamazepine	Concomitant administration of tramadol with carbamazepine causes a significant increase in tramadol metabolism, presumably through metabolic induction by carbamazepine.	Patients receiving chronic carbamazepine doses of up to 800 mg daily may require up to twice the recommended dose of tramadol.
Quinidine, phenothiazines, antipsychotic agents	Drugs that selectively inhibit that isoenzyme may cause increased concentrations of tramadol and decreased concentrations of M1.	-
Add ondansetron/ 5HT3 antagonists		
Serotonergic agents such as selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), MAO inhibitors, tricyclic antidepressants and mirtazapine	Serotonin syndrome, a potentially life-threatening condition, has been reported in patients receiving tramadol in combination with other serotonergic agents or tramadol alone.	If concomitant treatment with other serotonergic agents is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose escalations. If serotonin syndrome is suspected, a dose reduction or discontinuation of therapy should be considered depending on the severity of the symptoms. Withdrawal of the serotonergic drugs usually brings about a rapid improvement.

4.6 USE IN SPECIAL POPULATIONS (SUCH AS PREGNANT WOMEN, LACTATING WOMEN, PAEDIATRIC PATIENTS, GERIATRIC PATIENTS ETC.)

Pregnancy

Animal studies with tramadol revealed at very high doses effects on organ development, ossification and neonatal mortality. Teratogenic effects were not observed. Tramadol crosses the placenta. There is inadequate evidence available on the safety of tramadol in human pregnancy. Therefore tramadol should not be used in pregnant women.

Tramadol - administered before or during birth - does not affect uterine contractility. In new-born infants it may induce changes in the respiratory rate which are usually

not clinically relevant. Chronic use during pregnancy may lead to neonatal withdrawal symptoms.

Breast-feeding:
Approximately 0.1% of the maternal dose of tramadol is excreted in breast milk. In the immediate post-partum period, for maternal oral daily dosage up to 400 mg, this corresponds to a mean amount of tramadol ingested by breast-fed infants of 3% of the maternal weight-adjusted dosage. For this reason, tramadol should not be used during lactation or alternatively, breast-feeding should be discontinued during treatment with tramadol. Discontinuation of breast-feeding is generally not necessary following a single dose of tramadol.

Children:
Tramadol capsules are not suitable for children below the age of 12 years.

Geriatric patients:
A dose adjustment is not usually necessary in patients up to 75 years without clinically manifest hepatic or renal insufficiency. In elderly patients over 75 years elimination may be prolonged. Therefore, if necessary, the dosage interval is to be extended according to the patient's requirements.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

Even when taken according to instructions, Tramadol may cause effects such as somnolence and dizziness and therefore may impair the reactions of drivers and machine operators. This applies particularly in conjunction with alcohol and other psychotropic substances.

4.8 UNDESIRABLE EFFECTS

Immune system disorders	Rare: Anaphylaxis, allergic reactions, shock reactions
Endocrine disorders	Very rare: Syndrome of inappropriate antidiuretic hormone secretion characterised by hyponatraemia secondary to decreased free-water excretion
Metabolism and nutrition disorders	Rare: Changes in appetite
Psychiatric disorders	Rare: Hallucinations, confusional state, sleep disturbance, anxiety, nightmares, delirium, changes in mood (usually euphoric mood, occasionally dysphoria), changes in activity (usually suppression, occasionally increase), changes in cognitive and sensorial capacity (eg. decision behaviour, perception disorders)
Nervous system disorders	Very common: Dizziness

	Common: autonomic nervous effects (mainly dry mouth, perspiration), sedation, asthenia, headache Uncommon: trembling Not known: Serotonin syndrome Rare: speech disorders, paraesthesia, coordination disturbance, seizures, involuntary muscle contractions, syncope, tremor
Eye disorders	Rare: Mydriasis, visual disturbance (blurred vision), miosis
Cardiac disorders	Uncommon: Flushing, tachycardia Rare: bradycardia
Vascular disorders	Uncommon: Orthostatic dysregulation (tendency to collapse and cardiovascular collapse)
Respiratory, thoracic and mediastinal disorders	Rare: Dyspnoea, respiratory depression (when the recommended doses are considerably exceeded, and other respiratory depressant substances are administered concomitantly) Very rare: Worsening of asthma (causality not established). Frequency not known: Tramadol associated Hiccups
Gastrointestinal disorders	Very common: nausea Common: constipation,vomiting Uncommon: diarrhoea, abdominal pain, flatulence, urge to vomit, dyspepsia
Hepatobiliary disorders	Very rare: Elevated liver enzymes
Skin and subcutaneous tissue disorders	Common: Sweating Uncommon: rash, skin reactions, pruritus
Musculoskeletal and connective tissue disorders	Rare: motor system weakness
Renal and urinary disorders	Rare: dysuria, micturition disorders (difficulty in passing urine and urinary retention)
General disorders and administration site conditions	Common: fatigue

4.9 OVERDOSAGE

Symptoms of overdosage with tramadol are similar to those of other centrally acting analgesics (opioids) and include vomiting, miosis, cardiovascular collapse, consciousness disorders including coma, convulsions, respiratory depression and respiratory arrest. Serotonin syndrome has also been reported.

- If overdosage occurs, general emergency measures should be implemented.
- Keep the respiratory airways open and maintain respiration and circulation.
- If overdosage is due to ingestion, emptying the stomach by gastric lavage should be considered because of the possibility of ongoing release in the stomach. Activated charcoal may reduce absorption of the drug if given within 1-2 hours after ingestion.
- In patients who are not fully conscious or have impaired gag reflex, consideration should be given to administering activated charcoal via a nasogastric tube, once the airway is protected.
- Naloxone will reverse respiratory depression, but not all symptoms caused by overdosage with tramadol.
- Tramadol is minimally eliminated from the serum by hemodialysis or hemofiltration. Therefore, treatment of overdosage with tramadol with hemodialysis or hemofiltration alone is not suitable for detoxification.

5. PHARMACOLOGICAL PROPERTIES

5.1 MECHANISM OF ACTION

Tramadol, an opioid agonist and inhibitor of norepinephrine and serotonin reuptake. Although the mode of action is not completely understood, the analgesic effect of tramadol is believed to be due to both binding to μ-opioid receptors and weak inhibition of reuptake of norepinephrine and serotonin. Opioid activity is due to both low affinity binding of the parent compound and higher affinity binding of the O-demethylated metabolite M1 to μ-opioid receptors. In animal models, M1 is up to 6 times more potent than tramadol in producing analgesia and 200 times more potent in μopioid binding.

Tramadol-induced analgesia is only partially antagonized by the opioid antagonist naloxone in several animal tests. The relative contribution of both tramadol and M1 to human analgesia is dependent upon the plasma concentrations of each compound. Analgesia in humans begins approximately within one hour after administration and reaches a peak in approximately two to three hours.

5.2 PHARMACODYNAMIC PROPERTIES

Effects on the Central Nervous System

Tramadol produces respiratory depression by direct action on brain stem respiratory centers. The respiratory depression involves a reduction in the responsiveness of the brain stem respiratory centers to both increases in carbon dioxide tension and electrical stimulation. Tramadol causes miosis, even in total darkness. Pinpoint pupils are a sign of

opioid overdose but are not pathognomonic (e.g., pontine lesions of hemorrhagic or ischemic origins may produce similar findings). Marked mydriasis rather than miosis may be seen due to hypoxia in overdose situations.

Effects on the Gastrointestinal Tract and Other Smooth Muscle
Tramadol causes a reduction in motility associated with an increase in smooth muscle tone in the antrum of the stomach and duodenum. Digestion of food in the small intestine is delayed and propulsive contractions are decreased. Propulsive peristaltic waves in the colon are decreased, while tone may be increased to the point of spasm resulting in constipation. Other opioid induced effects may include a reduction in biliary and pancreatic secretions, spasm of sphincter of Oddi, and transient elevations in serum amylase.

Effects on the Cardiovascular System
Tramadol produces peripheral vasodilation which may result in orthostatic hypotension or syncope. Manifestations of histamine release and/or peripheral vasodilation may include pruritus, flushing, red eyes, sweating, and/or orthostatic hypotension. The effect of oral tramadol on the QTcF interval was evaluated in a double-blind, randomized, four-way crossover, placebo- and positive- (moxifloxacin) controlled study in 68 adult male and female healthy subjects. At a 600 mg/day dose (1.5-fold the maximum immediate-release daily dose), the study demonstrated no significant effect on the QTcF interval.

Effects on the Endocrine System
Opioids inhibit the secretion of adrenocorticotropic hormone (ACTH), cortisol, and luteinizing hormone (LH) in humans. They also stimulate prolactin, growth hormone (GH) secretion, and pancreatic secretion of insulin and glucagon.
Chronic use of opioids may influence the hypothalamic-pituitary-gonadal axis, leading to androgen deficiency that may manifest as low libido, impotence, erectile dysfunction, amenorrhea, or infertility. The causal role of opioids in the clinical syndrome of hypogonadism is unknown because the various medical, physical, lifestyle, and psychological stressors that may influence gonadal hormone levels have not been adequately controlled for in studies conducted to date.

Effects on the Immune System
Opioids have been shown to have a variety of effects on components of the immune system in invitro and animal models. The clinical significance of these findings is unknown. Overall, the effects of opioids appear to be modestly immunosuppressive.

Concentration–Efficacy Relationships
The minimum effective analgesic concentration will vary widely among patients, especially among patients who have been previously treated with potent opioid agonists. The minimum effective analgesic concentration of tramadol for any individual patient may increase over time due to an increase in pain, the development of a new pain syndrome and/or the development of analgesic tolerance.

Concentration–Adverse Reaction Relationships

There is a relationship between increasing tramadol plasma concentration and increasing frequency of dose-related opioid adverse reactions such as nausea, vomiting, CNS effects, and respiratory depression. In opioid-tolerant patients, the situation may be altered by the development of tolerance to opioid-related adverse reactions.

5.3 PHARMACOKINETIC PROPERTIES

Absorption	Mention about the differences of the 3 formulations. Tramadol is rapidly and completely absorbed after oral administration of 50 mg capsules following a mean absorption delay (t0) of approximately 30 minutes. The absorption half-life (t½) is 23 ± 11 minutes.
Distribution	Tramadol is rapidly distributed in the body, with a volume of distribution of 2 – 3 L/kg in young adults.
Metabolism	Tramadol is extensively metabolised after oral administration. The major metabolic pathways appear to be *N*- and *O*-demethylation and glucuronidation or sulfation in the liver. CYP2D6 should come here.
Elimination	Tramadol and its metabolites are excreted mainly by the kidneys, with a cumulative renal excretion (tramadol and metabolites) of approximately 95%.

6. NONCLINICAL PROPERTIES

6.1 ANIMAL TOXICOLOGY OR PHARMACOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Carcinogenesis

A slight, but statistically significant, increase in two common murine tumors, pulmonary and hepatic, was observed in an NMRI mouse carcinogenicity study, particularly in aged mice. Mice were dosed orally up to 30 mg/kg in the drinking water (0.36 times the MRHD) for approximately two years, although the study was not done with the Maximum Tolerated Dose. This finding is not believed to suggest risk in humans. No evidence of carcinogenicity was noted in a rat 2-year carcinogenicity study testing oral doses of up to 30 mg/kg in the drinking water, 0.73 times the MRHD.

Mutagenesis

Tramadol was mutagenic in the presence of metabolic activation in the mouse lymphoma assay. Tramadol was not mutagenic in the in vitro bacterial reverse mutation assay using Salmonella and E. coli (Ames), the mouse lymphoma assay in the absence of metabolic activation, the in vitro chromosomal aberration assay, or the in vivo micronucleus assay in bone marrow.

Impairment of Fertility

No effects on fertility were observed for tramadol at oral dose levels up to 50 mg/kg in male rats and 75 mg/kg in female rats. These dosages are 1.2 and 1.8 times the maximum recommended human daily dose based on body surface area, respectively.

7. DESCRIPTION

Contramal DT-
CONTRAMAL DT is supplied for oral administration, as a dispersible tablet of Tramadol Hydrochloride. Each uncoated dispersible tablet of CONTRAMAL DT contains Tramadol Hydrochloride 50 mg.

Contramal SR 100-
CONTRAMAL SR 100 is supplied for oral administration, as a sustained release (film coated) tablet of Tramadol Hydrochloride. Each sustained release (film coated) tablet of CONTRAMAL SR 100 contains Tramadol Hydrochloride 100 mg.

8. PHARMACEUTICAL PARTICULARS

8.1 INCOMPATIBILITIES
Not Applicable

8.2 SHELF-LIFE
Refer pack

8.3 PACKAGING INFORMATION
Refer pack

8.4 STORAGE CONDITION AND HANDING INSTRUCTIONS
Refer pack

9. PATIENT COUNSELLING INFORMATION

Contramal is:
• A strong prescription pain medicine that contains an opioid (narcotic) that is used for the management pain in adults, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
• An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about Contramal:
• Get emergency help right away if you take too much CONTRAMAL (overdose). When you first start taking CONTRAMAL, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.

• Taking CONTRAMAL with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
• Never give anyone else your CONTRAMAL. They could die from taking it. Selling or giving away CONTRAMAL is against the law.
• Store CONTRAMAL securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Important Information Guiding Use in Pediatric Patients:
• Do not give CONTRAMAL to a child younger than 12 years of age.
• Do not give CONTRAMAL to a child younger than 18 years of age after surgery to remove the tonsils and/or adenoids.
• Avoid giving CONTRAMAL to children between 12 to 18 years of age who have risk factors for breathing problems such as obstructive sleep apnea, obesity, or underlying lung problems.

Do not take Contramal if you have:
• Severe asthma, trouble breathing, or other lung problems.
• A bowel blockage or have narrowing of the stomach or intestines.
• An allergy to tramadol.
• Taken a Monoamine Oxidase Inhibitor, MAOI, (medicine used for depression) within the last 14 days.

Before taking Contramal, tell your healthcare provider if you have a history of:
• head injury, seizures
• liver, kidney, thyroid problems
• problems urinating
• pancreas or gallbladder problems
• abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems.

Tell your healthcare provider if you are:
• pregnant or planning to become pregnant. Prolonged use of CONTRAMAL during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
• breastfeeding. Not recommended; it may harm your baby. • living in a household where there are small children or someone who has abused street or prescription drugs.
• taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking CONTRAMAL with certain other medicines can cause serious side effects that could lead to death.

When taking Contramal:
• Do not change your dose. Take CONTRAMAL exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
• Take your prescribed dose as indicated by your healthcare provider. The maximum dosage is 1 or 2 tablets every 4 to 6 hours, as needed for pain relief. Do not take more than your

prescribed dose and do not take more than 8 tablets per day. If you miss a dose, take your next dose at your usual time.

- Call your healthcare provider if the dose you are taking does not control your pain. • If you have been taking CONTRAMAL regularly, do not stop taking CONTRAMAL without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused CONTRAMAL.

While taking Contramal DO NOT:

- Drive or operate heavy machinery, until you know how CONTRAMAL affects you. CONTRAMAL can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with CONTRAMAL may cause you to overdose and die.

The possible side effects of Contramal

• constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.
Get emergency medical help right away if you have:
• trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body.

10. DETAILS OF MANUFACTURER

Refer Pack for manufacturer details.

11. DETAILS OF PERMISSION OR LICENCE NUMBER

Refer Pack for Permission/License details.

12. DATE OF REVISION

Version 6.0; Dated 23-Jan-26

For Product Complaints/Adverse events or Queries please write to
webmasterindia@abbott.com