ALGODOL®
Capsules

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about ALGODOL
Each capsule for oral administration of ALGODOL contains paracetamol 325 mg and tramadol HCl 37.5 mg. Other ingredients are: magnesium stearate, sodium lauryl sulfate, lactose monohydrate.
Algodol combines 2 analgesics, tramadol HCl, a centrally acting opioid analgesic, which is a pure non selective agonist of the μ, δ, and κ opioid receptors with a higher affinity for the μ receptors and paracetamol, a clinically proven analgesic / antipyretic which produces analgesia by elevation of the pain threshold.
ALGODOL is indicated for the symptomatic, short-term treatment of moderate to severe pain.
The way to take ALGODOL
Take ALGODOL as directed.
For the treatment of acute pain, the recommended dose for adults and adolescents (12 years and older) is 2 capsules every 4 to 6 hours as needed for pain relief up to a maximum of 8 capsules per day.
For patients with renal impairment (creatinine clearance 10-30 mL/min), the dosing interval should be increased not to exceed 2 capsules every 12 hours.
In case of overdose
In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.
In case of missed dose
If you miss taking a dose there is no cause for concern, since analgesics may be used only when needed. However, if your health care professional has recommended that you take this drug try to remember to take it as directed. Do not take a double dose at once.
Contraindications
This drug is contraindicated in the following conditions:
-History of hypersensitivity to any of the components
-Severe liver function impairment
-Acute intoxication with alcohol, hypnotics, centrally acting analgesics, opioids or psychotropic medicines
-Concomitant use of monoamine oxidase inhibitors
-Epilepsy not controlled by treatment
Precautions
-This drug is not recommended in patients with hepatic impairment, respiratory depression and in patients with severe renal insufficiency (creatinine clearance < 10mL/min).
- This drug should be used with caution in patients with history or a recognized risk for seizures (head trauma, metabolic disorders, alcohol and drug withdrawal, central nervous system infection), in patients taking medicines that increase the risk of seizure or drugs that reduce the seizure threshold.
-This drug should be used with caution in patients with biliary tract disorders, in a state of shock, or in patients with an increased intracranial pressure.
- Inform your doctor that you are taking this drug in case of surgery.
-Dosages in excess of those recommended may cause severe liver damage.
-Periodic monitoring of prothrombin time is needed in case of concomitant use of warfarin-like compounds.
-Caution should be taken when driving a car or operating dangerous machinery until you know how you respond to the drug.

- Consult your doctor before using this medication in case of pregnancy or lactation. Lactation should be avoided during treatment with this drug.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

This drug should not be used in combination with a MAOI, or within 14 days of discontinuing treatment with a MAOI.

The administration with central nervous system (CNS) depressants such as alcohol, opioids, barbiturates, benzodiazepines, anesthetic agents, neuroleptics, tranquilizers, sedative antidepressants, sedative antihistamines, hypnotics, baclofen and centrally-acting antihypertensive drugs is likely to intensify and prolong CNS effects.

Concomitant use of carbamazepine, buprenorphine, nalbuphine and pentazocine is not recommended.

Caution should be used with quinidine, amitriptyline, cimetidine, bupropion, digoxin, warfarin, linezolid, lithium, ketoconazole, erythromycin, antidepressants and triptans.

Adverse reactions

The most frequently reported adverse reactions were nausea, dizziness and somnolence.

Other reported adverse reactions include: headache, trembling, confusion, mood changes, sleep disorders, vomiting, constipation, dry mouth, diarrhea, abdominal pain, dyspepsia, flatulence, sweating, and pruritus.

Inform your doctor if any side effect appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don’t use this medicine after this date.

Pack Presentation

ALGODOL, paracetamol 325 mg and tramadol HCl 37.5 mg, pack of 20 capsules

Issue date: 02/2013

ALDC/001