

# Emijoy®

Chlordiazepoxide & Amitriptyline

Tablet

## Description

Emijoy® tablet is combination of chlordiazepoxide 5 mg & amitriptyline 12.5 mg. Chlordiazepoxide is an agent for the relief of anxiety and tension, and amitriptyline is an antidepressant.

Chlordiazepoxide exerts its action in the limbic system. Recent evidence indicates that the limbic system is involved in emotional response. Taming action was observed in some species. Amitriptyline interfere with the reuptake of norepinephrine into adrenergic nerve endings.

## Indications

Emijoy® is indicated for the treatment of patients with moderate to severe depression associated with moderate to severe anxiety. The therapeutic response to Emijoy® occurs earlier and with fewer treatment failures than when either amitriptyline or chlordiazepoxide is used alone. Symptoms likely to respond in the first week of treatment include: insomnia, feelings of guilt or worthlessness, agitation, psychic and somatic anxiety, suicidal ideation and anorexia.

## Dosage and Administration

Emijoy® tablets are recommended in an initial dosage of 3 or 4 tablets daily; this may be increased to 6 tablets daily as required. Some patients respond to smaller doses and can be maintained on 2 tablets daily.

Optimum dosage varies with the severity of the symptoms and the response of the individual patient. When a satisfactory response is obtained, dosage should be reduced to the smallest amount needed to maintain the remission. The larger portion of

the total daily dose may be taken at bedtime. In some patients, a single dose at bedtime may be sufficient. In general, lower dosages are recommended for elderly patients.

## Contraindications

Emijoy® is contraindicated in patients with hypersensitivity to either benzodiazepines or tricyclic antidepressants. It should not be given concomitantly with a monoamine oxidase inhibitor. When it is desired to replace a monoamine oxidase inhibitor with Emijoy®, a minimum of 14 days should be allowed to elapse after the former is discontinued. Emijoy® should then be initiated cautiously with gradual increase in dosage until optimum response is achieved.

This drug is contraindicated during the acute recovery phase following myocardial infarction.

## Warnings & Precautions

Antidepressants may have a role in inducing worsening of depression and the emergence of suicidality in certain patients (especially in teenager & children) during initial few months of a course of drug therapy, or at times of dose changes.

Some people may have a particularly high risk of having suicidal thoughts or actions. These include people who have (or have a family history of) bipolar illness (also called manic-depressive illness) or suicidal thoughts or actions.

Use with caution in patients with history of seizures, hyperthyroidism or those taking thyroid medication and patients with impaired renal or hepatic function.

Patients on prolonged treatment should have

periodic liver function test and blood count.

## Drug Interactions

Emijoy® may block the antihypertensive action of guanethidine or compounds with a similar mechanism of action. Caution is indicated in the coadministration of TCAs with any of the SSRIs and also in switching from one class to the other, particularly patient being withdrawn from fluoxetine (at least 5 weeks may be necessary for switch therapy to TCA).

Concomitant use of tricyclic antidepressants with drugs that can inhibit cytochrome P450 2D6 may require lower doses than usually prescribed for either the tricyclic antidepressant. Furthermore, whenever one of these drugs is withdrawn from cotherapy, an increased dose of tricyclic antidepressant may be required.

Cimetidine is reported to reduce hepatic metabolism of certain tricyclic antidepressants and benzodiazepines, thereby delaying elimination and increasing steady-state concentrations of these drugs. Emijoy® should be discontinued several days before elective surgery.

## Usage in Special Patients

**Pregnancy and Lactation:** Emijoy® should preferably not be given during pregnancy and lactation.

**Pediatric use:** Safety profile is not established over pediatric population.

**Geriatric use:** Emijoy® are excreted by kidney and the risk of toxic reaction is greater in patient with impaired renal function. dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

## Adverse Reactions

Drowsiness, dry mouth, constipation, blurred vision, dizziness and bloating were most frequently reported. Other side effects occurring less commonly included vivid dreams, impotence, tremor, confusion and nasal congestion. Many symptoms common to the depressive state, such as anorexia, fatigue, weakness, restlessness and lethargy, have been reported as side effects.

## Overdosage

Deaths may occur from overdosage with this class of drugs. Multiple drug ingestion (including alcohol) is common in deliberate tricyclic antidepressant overdose. Common clinical manifestations are cardiac dysrhythmias, severe hypotension, convulsions, CNS depression, including coma and changes in the electrocardiogram, particularly in QRS axis or width.

## Pharmaceutical Precautions

Keep in a dry place, below 30° C. Protect from light. Keep out of the reach of children.

## Commercial Pack

Emijoy® Tablet: Box containing 50 tablets in 5x10's Alu-Alu form packs. Each tablet contains Chlordiazepoxide USP 5 mg & Amitriptyline Hydrochloride BP equivalent to Amitriptyline 12.5 mg



Manufactured by  
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