Dulocare®
(Duloxetine HCl)
Gastro-Resistant Capsules

ڈیولوکیئر® کیپسولز
(ڈیولوکسی ٹین ہائیڈروکلورائیڈ)

COMPOSITION:
Each capsule contains:

Dulocare 30 mg Capsules:
Duloxetine as HCl (Enteric Coated Pellets) ..... 30 mg

Dulocare 60 mg Capsules:
Duloxetine as HCl (Enteric Coated Pellets) ..... 60 mg

PHARMACEUTICAL FORM:
Hard Gelatin gastro-resistant capsules.

INDICATIONS:
Treatment of major depressive episodes.
Treatment of diabetic peripheral neuropathic pain in adults.
Treatment of generalized anxiety disorder.

CONTRAINDICATIONS:
Hypersensitivity to the active substance or to any of the excipients.
Concomitant use of Duloxetine with non-selective, irreversible monoamine oxidase inhibitors(MAOIs) is contra-indicated.
Liver disease resulting in hepatic impairment.
Duloxetine should not be used in combination with fluvoxamine, ciprofloxacin or enoxacin (i.e., potent CYP1A2 inhibitors) since the combination results in elevated plasma concentrations of Duloxetine. Severe renal impairment (creatinine clearance <30ml/min). The initiation of treatment with Duloxetine is contra-indicated in patients with uncontrolled hypertension that could expose patients to a potential risk of hypertensive crisis.

SIDE EFFECTS:
The most commonly reported adverse reactions in patients treated with Duloxetine were nausea, headache, dry mouth, somnolence, fatigue, insomnia, dizziness and constipation. However, the majority of common adverse reactions were mild to moderate; they usually started early in therapy, and most tended to subside even as therapy was continued.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Mania and Seizures:
Duloxetine should be used with caution in patients with a history of mania or a diagnosis of bipolar disorder, and/ or seizures.

Mydriasis:
Mydriasis has been reported in association with Duloxetine, therefore, caution should be taken when prescribing Duloxetine to patients with increased intra-ocular pressure or those at risk of acute narrow-angle glaucoma.

Blood Pressure and Heart Rate:
Duloxetine has been associated with an increase in blood pressure and clinically significant hypertension in some patients. This may be due to the noradrenergic effect of Duloxetine. Therefore,in patients with known hypertension and/or other cardiac disease, blood pressure monitoring is recommended.

Renal Impairment:
Increased plasma concentrations of Duloxetine occur in patients with severe renal impairment on haemodialysis (creatinine clearance <30ml/min).

Use With Antidepressants:
Caution should be exercised when using Duloxetine in combination with antidepressants. In particular the combination with selective reversible MAOIs is not recommended.

St John's Wort:
Undesirable effects may be more common during concomitant use of Duloxetine and herbal preparations containing St John's Wort (Hypericum perforatum).

Suicide:
Major Depressive Episodes and Generalised Anxiety Disorder: Depression is associated with an increased risk of suicidal thoughts, self-harm, and suicide (suicide-related events). This risk persists until significant remission occurs. As improvement may not occur during the first few weeks or more of treatment, patients should be closely monitored until such improvement occurs.

Diabetic Peripheral Neuropathic Pain:
As with other medicinal products with similar pharmacological action (antidepressants), isolated cases of suicidal ideation /behaviors have been reported during Duloxetine therapy or early after treatment discontinuation.

Use in Children and Adolescents Under 18 Years of Age:
No clinical trials have been conducted with Duloxetine in paediatric populations. Duloxetine should not be used in the treatment of children and adolescents under the age of 18 years.

Haemorrhage:
There have been reports of bleeding abnormalities. such as ecchymosis, purpura, and gastrointestinal haemorrhage, with selective serotonin reuptake inhibitors (SSRIs) and serotonin/noradrenaline reuptake inhibitors (SNRIs) Caution is advised in patients taking anticoagulants and/or medicinal products known to affect platelet function, and in patients with known bleeding tendencies.

Hyponatremia:
Hyponatremia has been reported rarely, predominantly in the elderly, when administering Duloxetine Caution is required in patients at increased risk for hyponatremia such as elderly, cirrhotic, or dehydrated patients or patients treated with diuretics.

Discontinuation of Treatment:
Withdrawal Symptoms when treatment is discontinued are common, particularly if discontinuation is abrupt. In clinical trials adverse events are seen on abrupt treatment discontinuation coourred in approximately 45% of patients treated with Duloxetine and 23% of patients taking placebo.

Pregnancy and lactation:
Pregnancy:
There are no adequate data on the use of Duloxetine in pregnant women. Studies in animals have shown reproductive toxicity at systemic exposure level (AUC) of duloxetine lower than the maximum clinical exposure.

The potential risk for humans is unknown. As with other serotonergic medicinal products, discontinuation symptoms may occur in the neonate after maternal Duloxetine use near term. Duloxetine should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus. Women should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy.

Breast-Feeding:
Duloxetine is very weakly excreted into human milk based on a study of 6 lactating patients who did not breast-feed their children. The estimated daily infant dose on a mg/kg basis is approximately 0.14% of the maternal dose. As the safety of Duloxetine in infants is not known, the use of Duloxetine while breast-feeding is not recommended.

Effects on ability to drive and use machines:
No studies on the effects on the ability to drive and use machines have been performed. Duloxetine may be associated with sedation and dizziness. Patients should be instructed that if they experience sedation or dizziness they should avoid potentially hazardous tasks such as driving or operating machinery.

DOSAGE AND ADMINISTRATION:
For oral use.
Adults:
Major Depressive Episodes:
Administer Duloxetine at a dose 60mg daily with or without food. However, there is no clinical evidence suggesting that patients not responding to the initial recommended dose may benefit from dose up-titrations. Therapeutic response is usually seen after 2-4 weeks of treatment. After consolidation of the anti- depressive response, it is recommended to continue treatment for several months, in order to avoid relapse.
Generalized Anxiety Disorder: The recommended starting dose in patients with Generalized Anxiety Disorder is 30mg once daily with or without food. In patients with insufficient response the dose should be increased to 60mg, which is the usual maintenance dose in most patients.
In patients with co-morbid Major Depressive Episodes, the starting and maintenance dose is 60mg once daily. Doses up to 120mg per day have been shown to be efficacious and have been evaluated from a safety perspective in clinical trials. In patients with insufficient response to 60mg, escalation up to 90mg or 120mg may therefore be considered. Dose escalation should be based upon clinical response and tolerability. After consolidation of the response, it is recommended to continue treatment for several months, in order to avoid relapse.
Diabetic Peripheral Neuropathic Pain: The starting and recommended maintenance dose is 60mg daily with or without food. Dosages above 60mg once daily, up to a maximum dose of 120mg per day administered in evenly divided doses, have been evaluated from a safety perspective in clinical trials. The plasma concentration of Duloxetine displays large inter- individual variability. Hence, some patients that respond insufficiently to 60mg may benefit from a higher dose.
Response to treatment should be evaluated after 2 months. In patients with inadequate initial response, additional response after this time is unlikely. The therapeutic benefit should be reassessed regularly (at least every three months).
Elderly: Major Depressive Episodes: No dosage adjustment is recommended for elderly patients solely on the basis of age However, as with any medicine, caution should be exercised when treating the elderly, especially with Duloxetine 120mg per day for which data are limited.
Other Indications: No dosage adjustment is recommended for elderly patients solely on the basis of age. However, caution should be exercised when treating the elderly.

Children and Adolescents:
The safety and efficacy of Duloxetine in these age groups have not been studied. Therefore, administration of Duloxetine to children and adolescents is not recommended.

Hepatic Impairment:
Duloxetine should not be used in patients with liver disease resulting in hepatic impairment.

Renal Insufficiency:
No dosage adjustment is necessary for patients with mild or moderate renal dysfunction (creatinine clearance 30 to 80ml/min).

Discontinuation of Treatment:
Abrupt discontinuation should be avoided. When stopping treatment with Duloxetine the dose should be gradually reduced over a period of at least one to two weeks in order to reduce the risk of withdrawal reactions. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, the physician may continue decreasing the dose, but at a more gradual rate.

STORAGE:
Dulocare capsules should be stored dry place below 30 C.
Protect from sun light, moisture and heat.
Keep all medicines out of reach of children.

HOW SUPPLIED:
Dulocare 30 mg Capsules: Alu. Alu blister pack of 1 x 10 capsules
Dulocare 60 mg Capsules: Alu. Alu blister pack of 2 x 7 capsules

To be sold on the prescription of a registered medical practitioner only.

خوراک:
ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات:
خشک جگہ پر ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
بچوں کی دسترس سے دور رکھیں۔
سورج کی روشنی سے بچائیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

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