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GEROZAC: (fluoxetine HCL) Abbreviated prescribing information: Presentation: Each capsule contains fluoxetine hydrochloride equivalent to 20 mg of fluoxetine. **Indication:** GEROZAC is indicated for the treatment of major depressive episodes. **Dose:** A dose of 20 mg/day is recommended and a maximum daily dose should not exceed 80 mg/day which can be administered as single or divided dose, during or between meals. **Patients with renal or liver disease:** In cases of liver dysfunction or renal failure (GFR 10-80 ml/min), the dose should be reduced, e.g. to 20 mg every second day. **Children:** Fluoxetine capsules are not indicated for use in children and adolescents below the age of 18.

Elderly: Caution is recommended when increasing the dose, which should rarely exceed 40 mg and should not exceed 60 mg. **Method of administration:** For oral administration. **Contraindications:** Concurrent treatment with MAOIs (monoamine oxidase inhibitors). Cautionary use with other antidepressants. Not to be used where there is severe renal failure (GFR < 10ml/min). Unstable or uncontrolled epilepsy. Not to be used by nursing mothers. Hypersensitivity to any of the ingredients. **Precautions:** As with all antidepressants risk of suicide particularly at the beginning of treatment due to the delay between treatment and clinical improvement. Concomitant use of tryptophan. Epilepsy, electroconvulsive therapy, cardiovascular disease, recent myocardial infarction, diabetes, alcohol, hepatic and renal insufficiency, and overdose. **Side-effects:** rash and allergic reaction, psychosis and mood shift towards manic phase, serotonin syndrome, inappropriate secretion of antidiuretic hormone, anorexia, weight loss, appetite loss, nausea, vomiting, diarrhoea, dry mouth, dyspepsia, constipation, headache, restlessness, insomnia, anxiety, dizziness, visual disturbance, drowsiness, confusion, tremor, sweating, sedation. Small increases in diastolic blood pressure and tachycardia as well as bradycardia. Hyperprolactinemia with galactorrhea, hyponatremias. Rare cases of increased ALTs and exceptional cytolytic or mixed hepatitis. **Product authorisation holder:** Generics (UK) Ltd, Station Close, Potters Bar, Herts, EN6 1TL, England. **Product authorisation number:** PA/405/36/1. Available only on prescription. **Date of preparation or last review:** December 1999. For full prescribing information please see the Summary of Product Characteristics. Further information is available from: Gerard Laboratories, 2004A Orchard Avenue, CityWest Business Campus, Naas Rd, Dublin 24. **FREEPHONE 1800 272 272.** Fax: 01 4661912 **Reference:** 1. MIMS December 1999

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EFEXOR[®] XL / EFEXOR[®] venlafaxine – Prescribing information.

Presentation: **Efexor XL:** capsules containing 75mg or 150mg venlafaxine (as hydrochloride) in an extended release formulation. **Efexor:** tablets containing 37.5mg or 75mg venlafaxine (as hydrochloride). **Use:** Treatment of depressive illness, including depression accompanied by anxiety. **Dosage:** *Adults (including the elderly):* **Efexor XL:** Usually 75mg, given once daily with food, increasing to 150mg once daily if necessary. The dose can be increased further to 225mg once a day. Dose increments should be made at intervals of approximately 2 weeks or more, but not less than 4 days. **Efexor:** Usually 75mg/day (37.5mg b.d.) with food, increasing to 150mg/day (75mg b.d.) if necessary. In more severely depressed patients, 150mg/day (75mg b.d.) increasing every 2 or 3 days in up to 75mg/day increments to a maximum of 375mg/day, then reducing to usual dose consistent with patient response. Discontinue gradually to reduce the possibility of withdrawal reactions. *Children:* Contra-indicated below 18 years of age. *Elderly:* Use normal adult dose with caution. *Moderate renal or moderate hepatic impairment:* Doses should be reduced by 50%. Not recommended in severe renal or severe hepatic impairment. **Contra-indications:** Pregnancy, lactation, concomitant use with MAOIs or monoamine oxidase inhibitors.

to venlafaxine or other components, patients aged below 18 years. **Precautions:** Use with caution in patients with myocardial infarction, unstable heart disease, renal or hepatic impairment, or a history of epilepsy (discontinue in event of seizure). Patients should not drive or operate machinery if their ability to do so is impaired. Possibility of postural hypotension (especially in the elderly). Women of child-bearing potential should use contraception. Prescribe smallest quantity of capsules or tablets according to good patient management. Monitor blood pressure with doses > 200mg/day. Advise patients to notify their doctor should a rash or allergy develop or if they become or intend to become pregnant. Patients with a history of drug abuse should be monitored carefully. **Interactions:** MAOIs: do not use venlafaxine in combination with MAOIs or within 14 days of stopping MAOI treatment. Allow 7 days after stopping venlafaxine before starting an MAOI. Use with caution in elderly or hepatically-impaired patients taking cimetidine, in patients taking other CNS-active drugs, and in patients taking drugs which inhibit both CYP2D6 and CYP3A4 hepatic enzymes. **Side-effects:** Nausea, insomnia, dry mouth, somnolence, dizziness, headache, constipation, sweating, nervousness, asthenia, abnormal ejaculation/orgasm, anorexia, dyspepsia, abnormal brain anxiety, abnormal vision/accommodation, impotence,

vomiting, tremor, abnormal dreams, chills, vasodilatation, hypertension, palpitation, rash, agitation, decreased libido, hypertonia, paraesthesia, postural hypotension, reversible increases in liver enzymes, slight increase in serum cholesterol, weight gain or loss, hyponatraemia. Symptoms reported on discontinuation of venlafaxine were mostly non serious and self-limiting and included dizziness, insomnia, nausea and nervousness. **Product Authorisation Numbers:** Efexor XL 75mg capsules: PA 22/65/5. 150mg capsules: PA 22/65/6. Efexor 37.5mg tablets: PA 22/65/2. 75mg tablets: PA 22/65/4. **Legal category:** S1A. For full prescribing information please refer to the Summary of Product Characteristics. **Product Authorisation Holder:** Wyeth Laboratories, Taplow, Maidenhead, Berkshire SL6 0PH, UK. Further information may be obtained from: Wyeth Laboratories, 765 South Circular Road, Islandbridge, Dublin 8. **References:** 1. Poirier M, Boyer P. Br J Psychiatry 1999; 175: 12-16 [122844]. 2. Rudolph RL, Feiger AD. J Affect Dis 1999; 56: 171-181 [124486]. 3. Entsuah R, Rudolph RL. Poster presented at the annual meeting of the American Psychiatric Association, Washington DC, May 1999 [122607]. 4. Ferrier IN. J Clin Psychiatry 1999; 60 (Suppl 6): 10-14 [122559]. **Date of preparation:** February 2000. * trade mark. Code no. Z783300/0200