Abridged Prescribing Information:

Active Ingredient: TIAPREX 25 / 50 / 100- Each tablet contains tiapride hydrochloride ph. Eur. Eq.to tiapride-25mg, 50mg, 100mg **Indication:** For the treatments of agitation and aggressiveness in adult patients with cognitive impairment, neuroleptic-induced tardive dyskinesia, mainly oro-bucco-lingual type **Dosage & Administration:** Irritability agitation, and aggressiveness in the adults and elderly:200-300 mg/day in divided doses for 1-2 months, or longer under medical supervision, Neuroleptic-induced tardive dyskinesia: 100-200 mg three times a day **Contraindications:** Hypersensitivity to the active substance or to any of the excipients, Concomitant Prolactin-dependent tumours, e.g. pituitary gland prolactinoma and breast cancer, Phaeochromocytoma, association with levodopa or other dopaminergic medicines, Neuroleptic malignant syndrome. **Warnings & Precautions:** As with other neuroleptics, Neuroleptic Malignant Syndrome, a potentially fatal complication, which is characterised by hyperthermia, muscle rigidity and autonomic dysfunction may occur. In case of hyperthermia of undiagnosed origin, tiapride should be discontinued, Prolongation of the QT interval Tiapride may induce a prolongation of the QT interval, Venous thromboembolism Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs, Increased Mortality in Elderly people with dementia Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death, Stroke - elderly patients with dementia and treated with certain atypical antipsychotic drugs, a 3-fold increase of the risk of cerebrovascular events has been observed, Children-tiapirde is not intended for treatment in children **Pregnancy & Lactation:** Pregnancy-There are limited amount of data from the use of tiapride in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development. Breastfeeding-It is not known whether tiapride is excreted in breast milk. Breast-feeding during treatment with tiapride is not recommended. **Interactions:** Combinations which are contraindicated - Dopaminergic agonists, excluding patients with Parkinson's disease (cabergoline, quinagolide), due to reciprocal antagonism between dopaminergic agonists and neuroleptics, Combinations which are not recommended- Class Ia (quinidine, hydroquinidine, disopyramide), and class III antiarrhythmic agents (amiodarone, sotalol, dofetilide, ibutilide), certain neuroleptics (sultopride, pipothiazine, sertindole, veralipide, chlorpromazine, levomepromazine, trifluoperazine, cyamemazine, sulpiride, pimozide, haloperidol, droperidol, fluphenazine, pipamperone, flupentixol, zuclopentixol), some antiparasitic drugs (halofantrine, lumefrantine, pentamidine), other medications: IV erythromycin, IV spiramycin, moxifloxacin, bepridil, cisapride, diphemanil, mizolastine, IV vincamine,alcohol, Levodopa, Methadone **Adverse Reactions:**Hyperprolactinemia, drowsiness/sleepiness, insomnia, agitation, impassivity. Dizziness/vertigo, headache. Parkinsonism and symptoms related symptoms: tremor, hypertonia, hypokinesia, hypersalivation, Asthenia/fatigue **Overdose:** Signs and symptoms .Experience regarding the overdose of tiapride is limited. Drowsiness, sedation, coma, hypotension and extrapyramidal symptoms may be observed. Treatment -Hemodialysis should not be used in overdose to remove the active substance, because tiapride is moderately dialysed. There is no specific antidote to tiapride. Appropriate supportive measures (monitoring vital and cardiac functions) should therefore be instituted. In case of severe extrapyramidal symptoms, anticholinergic medicines should be administered. *(For details, please refer full prescribing information)*

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