

Abridged Prescribing Information:

Active Ingredient: Tynept 12.5 mg Tablets contains Tianeptine 12.5 mg; Tynept OD 37.5 mg Extended Release Tablets contains Tianeptine 37.5 mg.

Indication: Neurotic or reactive states of depression Anxiodepressive states with somatic complaints such as digestive problems Anxiodepressive states observed in the alcoholic undergoing detoxification. **Dosage & Administration:** Recommended dosage is one tablet containing 12.5 mg, three times a day (morning, midday and evening) at the beginning of the main meals. **Contraindications:** Hypersensitivity to the drug substance or to any of the excipients mentioned in Description. Children and adolescents under 15 years old, Association with MAO inhibitors- There should be an interval of two weeks between the end of treatment with a MAO inhibitor and the beginning of treatment with tianeptine, and at least 24 hours is required when replacing tianeptine with a MAOI. **Warnings & Precautions:** Suicide/suicidal thoughts or clinical worsening, Abuse/dependence and withdrawal syndrome, Hyponatraemia, Effects on ability to drive and use machines. **Pregnancy & Lactation:** It is preferable not to use tianeptine during pregnancy whatever the term. If initiation or continuation of treatment with tianeptine proves to be vital during pregnancy, the pharmacological profile of the molecule should be taken into account when monitoring the newborn baby. Tricyclic antidepressants are excreted in the breast milk, and thus breast feeding is not recommended during treatment. **Interaction:** Irreversible MAOIs (iproniazide): due to risk of cardiovascular collapse or paroxysmal hypertension, hyperthermia, convulsions, death. **Adverse Reactions:** The undesirable effects observed with tianeptine during clinical trials are moderate in intensity. They consist primarily of nausea, constipation, abdominal pain, drowsiness, headaches, dry mouth and vertigo. **Overdose:** Symptoms: The experience concerning cases of acute tianeptine intoxication (maximum quantity: 2250 mg, ingested in a single dose) primarily reveals alertness disorders which can lead to coma, especially in case of multiple intoxications. Recommended procedure: Tianeptine has no known specific antidote. In case of acute intoxication, a symptomatic treatment and routine monitoring must be started. Medical monitoring in a specialized setting is recommended. *(For details, please refer full prescribing information)*

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