**Trade name:** No Deprine tablets.

**Generic name:** Tolcapone.

**Composition:**
1. **Active ingredients:** Each tablet contains: Tolcapone 50 mg.

**Contraindications:**
- Severe Liver disease
- Liver failure
- Starch, Lactose, Talc, Avicol & Magnesium Stearate.

**Pharmaceutical form:** Scored tablets.

**Pharmacological actions:**
- Tolcapone belongs to an anti-tremor group of medications known as homobenzazepines (e.g. griseofulvin, neroisoprop, tolcapone), which show strong antianxiety potential with insignificant muscle relaxant and antispasmodic effects to differ from ordinary benzodiazepines. They are formerly called 2,3 benzodiazepine derivatives.
- In clinical investigation, the administration of tolcapone (10-150 mg) causes a statistically significant increase in plasma concentration of dopamine, in particular of dopamine radiolabeled with GABA/Benzodiazepine receptors. These data indicate that tolcapone has a stimulant psychophysical and behavioral profile, clearly distinct from classical benzodiazepines.
- Tolcapone, in contrast to clinically effective 1,4 benzodiazepines, does not bind to the benzodiazepine receptors in vitro or in vivo. It enhances the binding of GABA agonists to GABA receptors (GABA binding site on GABA receptors).
- A further potential site of action of tolcapone is the B2E peripheral-binding site.

**Pharmacokinetics:**
- The pharmacokinetics and metabolism of tolcapone were studied in animals and humans. The pharmacokinetics profile of the compound can be described as follows: Tolcapone is a liposoluble compound with a half-life of about 4 hours in normal subjects and 2-3 hours in patients with cirrhosis. The major route of elimination is excretion in the feces of the deconjugated metabolite in humans and/or by glomerular filtration. The major metabolite of tolcapone is mono, d- and tri-octyl phosphorylation in the various degrees and positions of aromatic ring.

**Indications:**
1. No Deprine (tolcapone) has demonstrated efficacy in a wide range of therapeutic applications, including anxiety, functional gastrointestinal (GI) disorders, premature symptoms, hypotension, depression, and disorders of autonomic function.
2. No Deprine (tolcapone) is indicated as an adjuvant therapy to control psychosomatic symptoms such as headaches, fatigue, tachycardia, sweating.
3. No Deprine (tolcapone) is effective as adjuvant therapy for treatment of paroxysmal supraventricular tachycardia.
4. No Deprine (tolcapone) is indicated as an adjuvant therapy to improve intestinal passage in patients with incontinent colon syndrome.
5. No Deprine (tolcapone) is indicated as an adjuvant therapy in the treatment of the biliary duct.
6. No Deprine (tolcapone) is indicated for reduction of preoperative anxiety.

**Dosage and administration:**
- The average daily dose is 1 to 2 tablets once to three times daily (50 to 300 mg per day). In case of occasional administration 1 to 2 tablets should be used.
- Concerns about the presence of intrinsic hypotension sensitivity to any of the product ingredients.

**Side effects:**
- No Deprine (tolcapone) is well tolerated. It has a very low toxicity and mild side effects. The administration of tolcapone does not lead to physical or psychic dependence.
- Side effects are rare and include: nausea, anorexia, stomach discomfort, increased individual sensitivity.

**Discontinuation:**
- High doses of tolcapone enhance the effect of barbiturates and ethanol.
- Tolcapone, by itself, is a short-acting inhibitor of the liver enzyme CYP2C9. This seems to be of significant clinical importance.
- Tolcapone increased the blood level of medications metabolized by CYP2C9, such as aspirin, diclofenac, and diclofenac-related agents leading to clinically relevant adverse drug reaction and necessitating reduction of the dose of the drugs or discontinuation of the administration of tolcapone.

**Usage in pregnancy and lactation:**
- Usage in pregnancy: Negative results have been reported in prospective studies investigating the teratogenicity of human exposure with diazepam, alprazolam, oxazepam, lorazepam, diazepam, clobazam, clomethiazole, clobazam, and clonazepam. Usage in Lactation: No data available.

**Storage:**
- Store at temperature not exceeding 30°C and in dry place.