SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

LEVO-25 TABLETS (Levomepromazine Tablets BP 25 mg)

2. Qualitative and Quantitative Composition:

Each uncoated tablet contains: Levomepromazine Maleate BP 25 mg

3. Pharmaceutical form:

White, circular, flat uncoated tablets having breakline on one side and other side is plain of each tablet.

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4. Clinical particulars:

4.1 Therapeutic Indications:

Levomepromazine, also known as **methotrimeprazine**, is a phenothiazine neuroleptic drug. Brand names include Nozinan, Levoprome, Detenler, Hirnamin, Levotomin and Neurocil. It is a low-potency antipsychotic (approximately half as potent as chlorpromazine) with strong analgesic, hypnotic and antiemetic properties that are primarily used in palliative care.

4.2 Posology and Method of Administration:

Ambulant Patient: Initially the total daily dose should not exceed 25-50 mg usually divided into three doses. A large portion of the doses may be taken atbed time to minimize diurnal sedation.

Bed patient:

Initially the total doses may be 100 mg to 200 mg usually divided into three doses gradually increased to 1 g daily if necessary.

Children:

Children are very susceptible to the hypersensitivity ans soporific effect of levomepromazine. It is advised that the total daily oral doses of 40 mg should not be exceeded.

Method of administration : Oral.

4.3 Contraindications:

Hypersensitivity to levomepromazine or any of the ingredients. Safety in pregnancy has not been-established. There are no absolute contraindication to the use of levomepromazine in terminal care. The medicine should be avoided or used with caution in patients with liver dysfunction or cardiac disease.

5. Pharmacological properties:

5.1 Pharmacokinetic Properties:

Plasma levels of levomepromazine and its sulphoxide were measured in 8 psychiatric patients after repeated doses of levomepromazine tablets or syrup. The rate and extent of absorption of the drug were similar for the two dosage forms, although the extent of presystemic metabolism appeared to be slightly greater after administration of syrup than of tablets. The biological half-life of levomepromazine ranged from 16.5 h to 77.8 h, and a 13-fold variation was seen in the ratio of the total clearance to the absorbed fraction of the dose (Cl/Fpo). It is postulated that individual variation in the dose required for therapy was due in part to individual variation in the pharmacokinetics of the drug.

5.2 Pharmacodynemic Properties:

Although the exact mechanism of action of **levomepromazine** is not fully known, upon administration, this agent appears to act as an antagonist for a variety of receptors in the central nervous system (CNS), including adrenergic, dopamine, histamine, cholinergic and serotonin (5-hydroxytryptamine; 5-HT) receptors.

6. Pharmaceutical particulars:

6.1 List of Excipients:

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Di Basic Calcium Phosphate	BP
Maize starch	BP
Poly Vinyl pyrrilidone K-30	BP
Iso Propyl alcohol	BP
Purified talc	BP
Magnesium stearate	BP
Colloidal silicon dioxide	BP
Cross Povidone	USP
Cross Carmellose Sodium	BP
Polacrillin Potassium	USP

AGOG Pharma Ltd.
(WHO - GMP CERTIFIED - GOVT RECOGNISED EXPORT HOUSE)
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6.2 Incompatibilities:

None Reported

6.3 Shelf-Life:

36 months from the date of manufacture.

6.4 Special Precautions for Storage:

Store in a cool, dry and dark place. Protect from light.

6.5 Nature and Contents of Container:
10 tablets packed in one Blister. Such 2 blister packed in unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper.

6.6 Special precautions for disposal:
None reported.

7. Registrant:

AGOG PHARMA LTD.
Plot No. 33, Sector II,
The Vasai Taluka Industrial
Co-Op. Estate Ltd., Gauraipada,
Vasai (E), Dist. Thane, India.

8. Manufacturer:

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9. Date of revision of the text :