1. NAME OF THE MEDICINAL PRODUCT
AC-NOL 1 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each tablet contains Flunitrazepam 1 mg.

Excipients with known effects: None.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Coated tablet.
Pale green, oblong, film-coated tablets with sharp edges.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
AC-NOL 1 mg is indicated for the short-term treatment of severe insomnia when the disorder is debilitating or subjecting the individual to extreme distress.

4.2 Posology and method of administration
Adults:
The recommended dose is 0.5 mg to 1 mg before bedtime. The dose may be increased to 2 mg in exceptional cases based on the patient's response.

Elderly:
A starting dose of 0.5 mg is recommended to reduce the risk of sedation and psychomotor impairment.

Children and adolescents (<18 years):
Flunitrazepam is not recommended for use in this population due to a lack of sufficient data on safety and efficacy.

Method of administration:
For oral use. Swallow the tablet whole with water.

4.3 Contraindications
- Hypersensitivity to flunitrazepam or any of the excipients listed in section 6.1.
- Severe respiratory insufficiency.
- Myasthenia gravis.
- Sleep apnea syndrome.

4.4 Special warnings and precautions for use
- Prolonged use may lead to dependence; restrict treatment duration to no more than 4 weeks.
- Use with caution in patients with a history of substance abuse or psychiatric disorders.
- Caution is advised in patients with impaired hepatic or renal function.

4.5 Interaction with other medicinal products and other forms of interaction

- Concomitant use with central nervous system depressants (e.g., alcohol, opioids, sedatives) increases the risk of sedation, respiratory depression, and coma.
- Avoid combining with strong CYP3A4 inhibitors, as this may increase flunitrazepam plasma levels.

4.6 Fertility, pregnancy, and lactation

- Pregnancy: Flunitrazepam is not recommended during pregnancy, especially in the first and third trimesters.
- Lactation: Not recommended, as Flunitrazepam may be excreted in breast milk.

4.7 Effects on the ability to drive and use machines

AC-NOL 1 mg impairs attention, coordination, and reaction time. Patients should not drive or operate machinery during treatment.

4.8 Undesirable effects

Common side effects include drowsiness, fatigue, dizziness, and amnesia. Refer to the full list of adverse effects in section 6.6.

4.9 Overdose

Symptoms include severe sedation, respiratory depression, and coma. Immediate gastric lavage and supportive treatment are recommended.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Benzodiazepines, ATC code N05CD03.
Flunitrazepam enhances GABAergic neurotransmission, producing sedative, hypnotic, anxiolytic, and muscle-relaxant effects.

5.2 Pharmacokinetic properties

- Absorption: Rapidly absorbed, with peak plasma levels reached within 30–90 minutes.
- Metabolism: Primarily metabolized in the liver by CYP3A4.
- Elimination: Excreted in urine and feces, with a half-life of 16–35 hours.

5.3 Preclinical safety data

No significant findings in standard toxicity studies other than those related to the known pharmacological effects of benzodiazepines.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Lactose
- Starch
- Magnesium stearate
- Gelatin
- Brilliant Blue
- Methyl
- Talc

For Coating

- IPA
- Methylene
- HPMC
- Talc
- Titanium
- Colour – Army Green Lake

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store in a cool, dry place below 30°C. Protect from light and moisture.

6.5 Nature and contents of container
AC-NOL 1 mg tablets are packaged in aluminum foil blisters containing 10 tablets.

6.6 Special precautions for disposal
No special requirements.

7. MARKETING AUTHORISATION HOLDER
AC Drugs Limited, Plot C5/C6 Old Airport Road, Emene, Enugu State, Nigeria.

8. MARKETING AUTHORISATION NUMBER(S)
[To be provided by the regulatory authority.]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
[To be completed upon approval.]

10. DATE OF REVISION OF THE TEXT