Approval Package for:

APPLICATION NUMBER: ANDA 080198/S018

Name: Lidocaine Ointment USP, 5%

Sponsor: E. Fougera and Co.

Approval Date: May 9, 1998
## CONTENTS

### Reviews / Information Included in this Review

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Letter</td>
<td>X</td>
</tr>
<tr>
<td>Tentative Approval Letter</td>
<td></td>
</tr>
<tr>
<td>Labeling</td>
<td>X</td>
</tr>
<tr>
<td>Labeling Review(s)</td>
<td></td>
</tr>
<tr>
<td>Medical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Chemistry Review(s)</td>
<td></td>
</tr>
<tr>
<td>Bioequivalence Review(s)</td>
<td></td>
</tr>
<tr>
<td>Statistical Review(s)</td>
<td></td>
</tr>
<tr>
<td>Microbiology Review(s)</td>
<td></td>
</tr>
<tr>
<td>Other Review(s)</td>
<td></td>
</tr>
<tr>
<td>Administrative &amp; Correspondence Documents</td>
<td>X</td>
</tr>
</tbody>
</table>
APPLICATION NUMBER:
ANDA 080198/S018

APPROVAL LETTER
ANDA: 80-198/S-018

E. Fougera and Co.
Attention: Andrew G. Clair, Ph.D.
Division of Altana Inc.
60 Baylis Road

Dear Dr. Clair:

Reference is made to your supplemental new drug application submitted pursuant to Section 314.70 of the Regulations, dated October 20, 1987, regarding your abbreviated new drug application for Lidocaine Ointment USP, 5%.

Reference is also made to your communication dated April 12, 1988 amending this supplement.

The supplemental application provides for revised container labels, carton and package insert labeling.

We have completed the review of this supplemental application and it is approved. Our letter of June 30, 1972 detailed the conditions relating to the approval of this abbreviated application.

The material submitted is being retained in our files.

Sincerely yours,

Marvin Seitz, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drug Evaluation and Research

cc: HFN-238
    HFN-83
    JPhillips/TPoux/jc/5-5-88
    approval
    7830A? pg 22
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 080198/S018

LABELING
LIDOCAINE OINTMENT, USP
5% FOR EXTERNAL USE ONLY

DESCRIPTION
Lidocaine Ointment 5% contains a local anesthetic agent and is administered topically. See INDICATIONS in specific uses.
Lidocaine Ointment 5% contains lidocaine, which is chemically designated as 2-diethylaminoethanol, 2-(ethylaminoethyl)-2-naphthylamine, and has the following structural formula:

![Chemical Structure of Lidocaine]

Composition of Lidocaine Ointment 5%:
- Diphenylmethanol-2, 2-dimethyl
- Lidocaine 5% in a water-soluble ointment vehicle containing methylparaben.

CLINICAL PHARMACOLOGY
Mechanism of action:
Lidocaine affects the neuronal membrane by inhibiting the sodium flux required for the initiation and conduction of impulses, thereby affecting the transmission of nerve impulses.

Absorption:
Lidocaine Ointment 5% is applied topically and is not absorbed systemically.

Distribution:
Topical lidocaine is not systemically absorbed.

Metabolism:
Lidocaine is metabolized in the liver and excreted unchanged in the urine.

Excretion:
Lidocaine is excreted in the urine as inactive metabolites.

Overdosage:
Topical lidocaine overdose is unlikely to cause significant systemic effects.

ADVERSE REACTIONS
Topical lidocaine may cause skin reactions such as burning, rash, itching, or other skin reactions.

APPLICATION:
Lidocaine Ointment 5% is indicated for the treatment of acute and chronic pain associated with various local conditions.

PRECAUTIONS
General:
Patients with known hypersensitivity to lidocaine should be monitored carefully.

WARNINGS
EXCESSIVE DOSAGE OR SHORT INTERVALS BETWEEN DOSING CAN RESULT IN HIGH plasma LEVELS and SERIOUS ADVERSE EFFECTS. PATIENTS SHOULD BE INSTRUCTED TO CONSIDER THE RECOMMENDED DOSE AND ADMINISTRATION GUIDELINES AS SET FORTH IN THIS PACKAGE INSERT.

The management of serious adverse reactions may require the use of RESUSCITATIVE EQUIPMENT, RESUSCITATION, AND OTHER RESUSCITATIVE DRUGS.

Lidocaine Ointment 5% should be used with extreme caution in patients with known drug sensitivities. Patients allergic to pyrimidines and/or derivatives (quinidine, lidocaine, procainamide, etc.) have not shown cross-reactivity in these products.

PREPARATIONS
General:
The efficacy and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions, and readiness for emergencies. See WARNINGS and ADVERSE REACTIONS. The exact dose may vary at different levels of irritation and various adverse effects. Specific doses of lidocaine that cause significant systemic effects have been provided because of the need for accurate dosing of lidocaine to achieve its maximum activity in patients and because of the need for adequate doses to be given in patients with severe and/or physical conditions. Lidocaine should be used with caution in patients with known drug sensitivities or those with cardiovascular disease.

Lidocaine Ointment 5% should be used with caution in patients with known drug sensitivities. Patients allergic to pyrimidines and/or derivatives (quinidine, lidocaine, procainamide, etc.) have not shown cross-reactivity in these products.
available.

Early unexplained signs of tachycardia, tachypnea, miosis, sweating and muscular weakness may indicate chloral hydrate poisoning. Any patient who exhibits these signs, or who appears toxic, should be promptly given an appropriate dose of atropine. Agents such as physostigmine, neostigmine, or pyridostigmine bromide may be effective in reversing the effects of some of the more serious symptoms of chloral hydrate poisoning. Nebular oxygen and atropine should be used in the treatment of coma, respiratory depression and death.

8. Monitoring the Patient

The patient should be observed carefully for evidence of respiratory depression or coma. Ventilation should be supported if necessary by artificial respiration. The patient should be watched closely for signs of a nervous system change from the drug's tranquilizing effects. This is especially important when the patient is given large or repeated doses of chloral hydrate.

9. Summary

Chloral hydrate is a safe and effective sedative that is widely used to induce sleep and to relieve anxiety. However, it is important to use it only as directed by a healthcare professional, and to avoid it during pregnancy or while breastfeeding. The patient should be monitored closely for any signs of overdose, and treatment should be administered if necessary.
LIDOCAINE OINTMENT, USP 5%

Usual Dosage: Apply topically. Do not administer more than one-half tube (approximately 17.20g) of ointment in any 24 hour period.

For External Use Only. Not for Ophthalmic Use.

Store at controlled room temperature -15°-30°C (59°-86°F).

E. FOUGERA & CO.
a division of Altana Inc., MELVILLE, NEW YORK 11747

6505-00-785-4357  NDC 0168-0204-37

CONTAINS: Lidoceaine base 5% in a water soluble base consisting of polyethylene glycol 300, and polyethylene glycol 1450.

NET WT. 1 1/4 OZ. (35.44g)

See insert for complete information.

WARNING: Keep out of reach of children.

CAUTION: Federal law prohibits dispensing without prescription.
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
ANDA 080198/S018

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS
Altana Inc.
Attention: Andrew G. Clair, Ph.D.
60 Baylis Road
Melville, NY 11747

Dear Sir:

Reference is made to your supplemental new drug application submitted pursuant to Section 314.70 of the Regulations, dated October 20, 1987, regarding your abbreviated new drug application for Lidocaine Ointment, USP - 5%.

The supplemental application provides for revised container labels, carton and package insert labeling.

We have reviewed the draft labeling submitted and have the following comments:

A) Container - Satisfactory

B) Carton - Satisfactory

C) Package Insert - Not Satisfactory

1) You have omitted one whole column of information including WARNINGS and PRECAUTIONS.

2) DOSAGE AND ADMINISTRATION - you have used the brand name XYLOCAINE.

Please revise the package insert labeling, then prepare and submit final printed labeling (or draft copy if you prefer) as an amendment to this supplement.

Please let us have your response promptly.

Sincerely yours,

[Signature]

Marvin Seife, M.D.
Director
Division of Generic Drugs
Office of Drug Standards
Center for Drug Evaluation and Research

cc:
HFN-238
HFN-83
TPoux/je/12-14-87
rfw
7679A/ pg 21