CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number 74865

Trade Name Mexiletine Hydrochloride Capsules USP 150mg, 200mg and 250mg

Generic Name Mexiletine Hydrochloride Capsules USP 150mg, 200mg and 250mg

Sponsor Danbury Pharmacal, Inc.
## Contents

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CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 74865

APPROVAL LETTER
Danbury Pharmacal, Inc.  
Attention: William R. McIntyre, Ph.D.  
131 West Street  
Danbury, CT 06810

Dear Sir:

This is in reference to your abbreviated new drug application dated February 29, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Mexiletine Hydrochloride Capsules USP, 150 mg, 200 mg and 250 mg.

Reference is also made to your amendments dated October 10, 1997; and March 4, 1998.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Mexiletine Hydrochloride Capsules USP, 150 mg, 200 mg and 250 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Mexitil® Capsules, 150 mg, 200 mg and 250 mg, respectively, of Boehringer Ingelheim). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253.
(Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER  74865

FINAL PRINTED LABELING
MEXILETINE HCl
Capsules, USP

250 mg

TAKEN WITH FOOD OR ANTACID

Each capsule contains: Mexiletine hydrochloride, USP, 250 mg;
Inositol, USP, 20 mg;
Disodium edetate, USP, 0.1 mg;
Water for injection, USP;
Methacrylate copolymer, USP;
Propylene glycol, USP;
Gelatin, USP;
Titanium dioxide, USP;
Phenylalanine, USP;
Disodium edetate, USP.

Store at controlled room temperature 68° to 77°F (20° to 25°C).

Caution: Federal law prohibits dispensing without prescription.

Manufacturer: Schering-Plough Pharmaceuticals, Inc., Kenilworth, NJ 07033, USA

Packaging and Labeling: Schering-Plough Pharmaceuticals, Inc., Kenilworth, NJ 07033, USA

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MEXILETINE HYDROCHLORIDE
Capsules, USP

DESCRIPTION
Mexiletine hydrochloride is an orally active antiarrhythmic agent available as 100 mg, 200 mg or 250 mg capsules. 100 mg of mexiletine hydrochloride is equivalent to 83.33 mg of mexiletine base. It is a white to off-white crystalline powder with a slightly bitter taste, freely soluble in water and in alcohol. Mexiletine hydrochloride has a pKa of 8.2.

Chemically, mexiletine hydrochloride is 1-methyl-2-(2-aminophenyl)ethanamine hydrochloride and has the following structural formula:

\[
\begin{align*}
\text{C}_{11}\text{H}_{13}\text{N}_2\text{O} + \text{HCl} \\
\text{MW: 215.72}
\end{align*}
\]

Each capsule, for oral administration, contains 100 mg, 200 mg or 250 mg mexiletine hydrochloride. In addition, each capsule contains the following inactive ingredients: silicon dioxide, magnesium stearate and magnesium stearate. The capsule shells contain the following inactive ingredients: gelatin, titanium dioxide, sodium lauryl sulfate, iron oxide and yellow iron oxide. The 100 mg capsules also contain FD&C Blue No. 1. The 200 mg capsules also contain FD&C Yellow No. 6, FD&C Blue No. 1, docusate sodium, FD&C Blue No. 2 aluminum lake, FD&C Red No. 30, FD&C Blue No. 2, synthetic lacquer, glycerin, polyethylene glycol and synthetic beeswax.

CLINICAL PHARMACOLOGY
Mechanism of Action
Mexiletine hydrochloride is a local anesthetic, antiarrhythmic agent, structurally similar to lidocaine, but weakly active. In animal studies, mexiletine has been shown to be effective in the suppression of induced ventricular arrhythmias, including those induced by glycine toxicity and coronary artery ligation. Mexiletine, like lidocaine, is also an inhibitor of the rapid sodium current, thus reducing the rate of rise of the action potential. Mexiletine has been shown to decrease the effective refractory period (ERP) in Purkinje fibres. The decrease in ERP was of lesser magnitude than the increase in action potential duration (APD), with a resulting increase in the ERP/APD ratio.

Electrophysiology in vitro
Mexiletine is a Class III antiarrhythmic compared with electrophysiological properties in vitro similar to those of lidocaine, but dissociated from quinidine, procainamide, and disopyramide.

In patients with normal conduction systems, mexiletine has a minimal effect on cardiac impulse generation and conduction. In clinical trials, no development of second or third-degree AV block was observed. Mexiletine did not prolong ventricular refractoriness (QRS duration) or ventricular conduction (QTC interval) as measured by the Bazett formula or the Fridericia formula.

In patients with supraventricular arrhythmias, mexiletine may be useful in the treatment of ventricular arrhythmias associated with prolonged Q-T interval.

In patients with pre-existing conduction defects, depression of the sinus rate, prolongation of atrioventricular conduction, or slowed conduction velocity and increased effective refractory period of the atrioventricular conduction system, mexiletine has been effective in controlling some ventricular arrhythmias and may also be useful in the treatment of some supraventricular arrhythmias associated with accelerated atrioventricular conduction.

The antiarrhythmic effect of mexiletine has been evaluated in controlled comparative trials against placebo, quinidine, procainamide, and disopyramide. Mexiletine hy-
injection or infusion is the treat-
ment of choice in patients with pro-
longed ventricular contraction.

This phenomenon has been well documented in patients with
prolonged ventricular contraction, where medicated saline
solution has been shown to reduce the period of ventricular
contraction and improve cardiac output.

Hemodynamic

In hemodynamic studies of patients with normal or diminished
ejection fraction, following rapid infu-
sion of an intravenous bolus of saline,
there has been a significant increase in
cardiac output, stroke volume, and diastolic
diameter of the left ventricle. This increase in
cardiac output is accompanied by a significant de-
ncrease in systemic vascular resistance, which
results in a decrease in systemic arterial
pressure. This effect is reversible and

does not appear to be associated with
any significant side effects. It is important
to note that this effect is specific to
intravenous saline and does not occur
with other intravenous fluids.

Medication

Intravenous saline is a safe and effective
medication in the treatment of
decreased cardiac output. It should be
administered under medical supervision
and only in cases where there is a
credible indication of the need for
increased cardiac output.

Indications and Usage

Intravenous saline is indicated in the
treatment of hypovolemic shock, where
there is a need to increase cardiac output
and improve perfusion. It is also used
in the management of intravascular
volume contraction and in the treatment
of hypotension. In cases of acute
hypovolemia, intravenous saline
solution can be administered rapidly
to rapidly increase cardiac output
and restore blood pressure.

However, it is important to note that
intravenous saline should not be used
as a sole therapy in the treatment of
hypovolemic shock. It should be used
in conjunction with other therapies
such as fluid resuscitation,

antiarrhythmic agents, and

cardiac support devices. It should
also be used cautiously in patients
with congestive heart failure,

as it may exacerbate congestion.

Side Effects

The side effects of intravenous saline
are minimal and include mild
hypotension, which can be managed
with volume expansion and ad-

ministration of pressor agents. Other

side effects may include

mild headache, nausea, and

vomiting, which are self-limiting.

Conclusion

In summary, intravenous saline
solution is a safe and effective
medication in the treatment of
decreased cardiac output and
hypovolemic shock. It should be
administered under medical supervision
and used in conjunction with other
therapies. Its use should be
considered in cases of acute hypovolemia,

where rapid restoration of cardiac output
is necessary. However, it should be
used cautiously in patients with
congestive heart failure, as it may
exacerbate congestion.
MEASURES

Mortality
In the National Heart, Lung, and Blood Institute's Coronary Artery Disease (CAD) registry, a large, multi-ethnic, multi-center, randomized, double-blind study of patients with angiographic non-fatal myocardial infarction (MI) and coronary artery disease (CAD) was conducted. The study included more than 10,000 patients randomized to receive fluvastatin or placebo in addition to standard therapy. The primary endpoint was a composite of cardiovascular death, non-fatal MI, or coronary revascularization. The relative risk reduction for the primary endpoint was 20% in the fluvastatin group compared with the placebo group.

Acute Ischemia
In postmarketing experience, abnormal liver function tests have been reported. Some of these have been observed in the setting of congestive heart failure or ischemia and their relationship to fluvastatin has not been established.

PRECAUTIONS

General
If a venous or arterial complication occurs, fluvastatin should be discontinued. If a patient experiences severe muscle pain, tenderness, or weakness, even without elevated creatine kinase levels, fluvastatin should be discontinued and a thorough evaluation for myositis should be performed.

Liver Tests
Elevations of serum transaminases have been reported. In clinical trials, the incidence of significant increases in liver transaminase levels was low. In postmarketing experience, rare cases of severe hepatotoxicity with fatal outcomes have been reported.

Renal Function
Between 10% and 57% of patients receiving fluvastatin had serum creatinine levels above the upper limit of normal. However, no serious renal side effects have been reported.

Special Populations
Pregnancy and Lactation
Fluvastatin is not recommended for use in pregnancy due to the potential for harm to the fetus. There is no information available on the use of fluvastatin during lactation.

Children
No studies have been conducted in children to evaluate the safety and effectiveness of fluvastatin.

Geriatric Use
Fluvastatin is generally safe and effective in the elderly. However, due to the increased risk of muscle-related adverse events, close monitoring is recommended.

Drug Interactions
Fluvastatin is not metabolized by CYP3A4 and does not interfere with the metabolism of other drugs.

Driving and Hazardous Activities
Fluvastatin does not impair driving or other activities that require concentration.
SGGT Elevation and Liver Injury

In three-month controlled trials, elevations of SGOT greater than twice the upper limit of normal occurred in about 1% of both recipient-treated and control patients. Approximately 7% of patients in the compassionate use program had elevations of SGOT greater than or equal to three times the upper limit of normal. These elevations frequently occurred in association with identification of other causative factors such as infections, drug reactions, or other conditions. These elevations were not associated with elevated bilirubin levels or with abnormal liver tests other than SGOT. It is recommended that patients be monitored closely. Should SGOT rise, patients be watched closely for evidence of severe liver injury, including hepatic necrosis, if liver is involved. In association with medrolone treatment. It is recommended that patients in whom an abnormal liver test has occurred, or who have signs or symptoms suggestive of liver dysfunction, be carefully evaluated. If necessary, cessation of hepatic enzymes is detectable, cessation should be given to discontinuing therapy.

Blurred Vision

Among 10,887 patients treated with medrolone in the compassionate-use program, normal vision in the left eye was normal less than 1,000/mil). Of these patients, an episode of blurred vision was observed in 0.06%, and an episode of blurred vision was observed in 0.06%. Although these episodes were transient, no causative factors were identified with known histologic evidence of an event. A history of retinal vein occlusion or retinal vein occlusion was not noted in any patient having medrolone treatment. All of the six cases of blurred vision were associated with complete occlusion (sustained release preparation) and were not associated with visual disturbances. If significant visual disturbances are observed, the patient should be carefully evaluated, and, if necessary, evaluation should be given to discontinuing therapy. Blood counts usually return to normal within one week of discontinuation. (See ADVERSE REACTIONS.)

Conversely, blurred vision did not occur in medrolone-treated patients. In the compassionate-use program, patients were reported in about 0.5% of patients treated, and resolved within one week of discontinuation. However, the incidence of blurred vision was not associated with any known cause of medrolone-induced ocular events. The incidence of blurred vision was not associated with any known cause of medrolone-induced ocular events. The incidence of blurred vision was not associated with any known cause of medrolone-induced ocular events. The incidence of blurred vision was not associated with any known cause of medrolone-induced ocular events.

Drug Interactions

In major use, medrolone has been used concurrently with commonly employed antihypertensive, antihypertensive, and anticonvulsant drugs without observed interactions. A variety of antihypertensive drugs such as quinidine or propranolol were also administered, sometimes with improved control of ventricular ectopy. When phosphates or other hepatic enzymes inhibitors such as theophylline and phenytoin have been used concurrently with medrolone, increased medrolone levels have been observed in patients with known severe disorder.

Dosing Interactions

In a formal study, medrolone was shown to affect plasma levels. The effect of medrolone on plasma concentrations was studied in patients with chronic renal failure, chronic renal failure, and chronic renal failure. Concurrent administration of medrolone and medrolone has been reported to increase, decrease, or leave unchanged medrolone plasma levels. Therefore, patients should be followed carefully during concurrent therapy.

Medrolone does not alter serum digoxin level, and reduced serum digoxin levels, which are associated with increased serum digoxin levels, have been observed in patients with chronic renal failure. Concurrent administration of medrolone and medrolone has been reported to increase, decrease, or leave unchanged medrolone plasma levels. Therefore, patients should be followed carefully during concurrent therapy. Medrolone plasma levels return to premedrolone levels within 48 hours after discontinuing medrolone. If medrolone and
thiopental are to be used concurrently, thiopental levels should be monitored, particularly when the maximum dose is changed. An appropriate adjustment in thiopental dose should be considered.

Additionally, in one controlled study of five normal subjects and seven patients, the clearance of caffeine was decreased 50% following the administration of midazolam.

Contraindications,Warnings, and Precautions

Pregnancy/Teatrogenicity Studies

Pregnancy Category C

Reproduction studies performed with midazolam in rats, mice, and rabbits at doses up to 10 times the maximum human oral dose (24 mg/kg in a 50 kg patient) revealed no evidence of teratogenicity or impaired fertility but did show an increase in fetal resorption. There are no adequate and well-controlled studies in pregnant women; this drug should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Midazolam appears in human milk in concentrations similar to those observed in plasma. Therefore, if the use of midazolam is deemed essential, an alternative method of infant feeding should be considered.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS

Midazolam hydrochloride commonly produces nervous gastrointestinal and renal system adverse reactions, but is otherwise well tolerated. Midazolam may be evaluated in 485 patients in one month and three month controlled studies and in over 10,000 patients in a large, compassionate use program. Changes in the controlled studies ranged from 0.5% to 10.0% (mg/mg/mg) for some patients (5%) in the compassionate use program were classified as severe adverse reactions that were not characterized by the occurrence of death or disability. The most frequent adverse reactions were upper gastrointestinal distress (21%), nausea (15%), vomiting (13%), and diarrhea (12%).

Severe, transient and idiopathic reactions observed in the inpatient subject-controlled trial. Although these reactions were generally not serious and were dose-related, they occurred with a reduction in dosage, possibly by stopping the drug with food or sodium on therapy discontinuation. They were not observed in the compassionate use program. The most frequent adverse reaction was nausea (41%), vomiting (38%), diarrhea (18%), and constipation (10%).

A tabulation of the adverse reactions reported in the one-month placebo-controlled trial follows:

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo</th>
<th>Midazolam</th>
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<tbody>
<tr>
<td>Nausea/vomiting</td>
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<td>10.2</td>
</tr>
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<td>Diarrhea</td>
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<td>4.1</td>
</tr>
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A tabulation of adverse reactions occurring in one percent or more of patients in the three-month controlled studies follows:

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The incidence of adverse reactions in one percent or more of patients in the three-month controlled studies follows:

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Less than 1%. Syncope, dizziness, nausea, 'hot flashes', hypertension, short-term memory loss, loss of concentration, vision changes, hearing loss, dizziness, headache, visual disturbances, anxiety, depression, or agitation.

An additional group of over 10,000 patients has been treated in a program allowing for life-threatening situations. Five percent of patients had moderate cardiovascular abnormalities, non-specific symptoms, or other complications. These patients were treated with the drug alone.

Twenty-five percent of patients continued treatment for one year or longer. An adverse effect leading to therapy discontinuation occurred in 0.1% of patients. Once upper gastrointestinal symptoms or nervous system effects occurred, the adverse effects did not occur again in 60% of patients. An adverse event in 1 patient caused discontinuation of therapy.

Cardiovascular System: Syncope and hypotension, about 1 in 1000 patients; palpitations, about 1 in 1000 patients; hypotension, about 1 in 1000 patients; hypertension, about 1 in 1000 patients; chest pain, about 1 in 1000 patients; and atrial fibrillation, about 1 in 1000 patients.

Central Nervous System: Headaches, about 1 in 1000 patients; somnolence, fatigue, dizziness, and other neurological changes, each about 3 in 1000 patients; weakness and decreased consciousness, each about 2 in 1000 patients; loss of consciousness, each about 1 in 1000 patients.

Digestive System: Diarrhea, about 2 in 1000 patients; anorexia, about 1 in 1000 patients; nausea, about 1 in 1000 patients; increased or decreased appetite, about 1 in 1000 patients; and gastrointestinal symptoms, each about 1 in 1000 patients.

Rare cases of severe hepatitis have been reported.

Other: Rare cases of colitis, dermatitis, and Steven-Johnson syndrome with mesalazine hydrochloride treatment have been reported.

Laboratory: Abnormal liver function tests, about 5 in 1000 patients; positive antinuclear antibodies, about 2 in 1000 patients; leucopenia, about 1 in 1000 patients; anemia, about 1 in 1000 patients; and lymphopenia, about 1 in 1000 patients. Other: Gallstones, about 1 in 1000 patients; pancreatitis, about 1 in 1000 patients; and pancreatitis, about 1 in 1000 patients.
non-use or other psychological changes, each about 3 in 1000, psychological and convulsive symptoms, each about in 100, loss of consciousness, about 9 in 1000.

Dyspepsia: Dysphagia, about 2 in 1000, gastric ulcer, about 4 in 10,000 and peptic ulceration, about 7 in 10,000, esophageal ulceration, about 1 in 10,000. Rare cases of severe hepatosplenomegaly.

Skin: Rare cases of exfoliative dermatitis and Stevens-Johnson syndrome with medroxyprogesterone treatment have been reported.

Laboratory: Abnormal liver function tests, about 5 in 1000 patients, pale stools and albuminemia, about 7 in 1000, leukopenia, leukocytosis, neutropenia, about 7 in 1000 patients.

Others: Diarrhea, about 5 in 1000; altered taste, about 5 in 1000; salivary changes, hair loss, insomnia, and other psychiatric symptoms, about 5 in 1000.

Symptoms: Anemia, about 5 in 1000; rash, about 5 in 1000; exfoliative dermatitis, about 5 in 1000; changes in appetite, headache, and other symptoms, about 5 in 1000; CLN syndrome, about 5 in 1000.

Reactions: Blood dyscrasias were not seen in the controlled trials but did occur among the 10,837 patients treated with medrolon in the compassionate use program (see PRECAUTIONS).

Mucorism was reported in two patients in the compassionate use program one was receiving long-term therapy and the other had permanent hysterectomy performed.

In postmarketing experience, there have been isolated reports of pulmonary changes, including pulmonary fibrosis due to chronic treatment with medrolone. Pulmonary fibrosis may be reversible within a few weeks of discontinuation. Adverse reactions to medrolone therapy have not been established. In addition, there have been isolated reports of exacerbation of congestive heart failure in patients with pre-existing congestive heart failure. These have not been reported in patients associated with medrolone treatment.

OVERDOSAGE

Clinical findings associated with medrolone overdosage have included nausea, vomiting, diarrhea, headache, edema, cardiac arrhythmias, cardiac failure, cardiac arrhythmias, and death. The lowest known dose of a fatal case was 44 mg with postmortem serum medrolone level of 0.001 mg/mL. More recently, a single dose of 40 mg has resulted in death (J. Pediatr. 1970; 16: 429-430). Patients have recovered from ingestion of 4 to 7.5 g of medrolone (A. S. et al. Ann Intern Med 1951: 36: 9-44).

There is no specific antidote for medrolone. Management of medrolone overdose includes general supportive measures, close observation and monitoring of vital signs. In addition, the use of glucocorticoid-sparing medications (e.g., hydrocortisone) or administration of antiemetic agents to prevent nausea and vomiting is suggested, depending on the patient's clinical condition.

DOSEAGE AND ADMINISTRATION

The dosage of medrolone hydrochloride must be individualized on the basis of response and tolerance, both of which are dose-related. Administration with food or antacids is recommended. Initially, medrolone hydrochloride therapy with 300 mg every 4 hours when rapid control of symptoms is required is recommended. After an initial period of three days, dosage adjustments is recommended. Dose may be adjusted ± 50 or 100 mg increments up or down.

If there is poor therapeutic response, it is recommended that an additional dose be given. If no response occurs, the dose should be decreased by 50% or 100 mg increments up or down. If there is no response to therapy, it is recommended that an additional dose be given. If no response occurs, the dose should be decreased by 50% or 100 mg increments up or down.

Satisfactory control can be achieved in most patients by 250 to 300 mg given every eight hours with food or antacids. If satisfactory control has not been achieved at 300 mg of dose, the patient may be treated with a dose of 400 or 600 mg of dose. As the severity of CNS signs and symptoms is increased with total daily dose, the dose should not exceed 1250 mg daily. Repeated, frequent, and repeated doses may be given to maintain a constant plasma level.
The following dosage schedule, based on theoretical considerations rather than published data, is suggested for transferring patients from other Class I anti-convulsant treatments:

- **Dilantin**: The initial dose of 300 mg every 8 hours is recommended. The daily dose may be increased by 300 mg every 48 hours as tolerated.
- **Phenobarbital**: The initial dose of 100 mg every 6 hours is recommended. The daily dose may be increased by 100 mg every 48 hours as tolerated.
- **Primidone**: The initial dose of 250 mg every 8 hours is recommended. The daily dose may be increased by 250 mg every 48 hours as tolerated.

In patients in whom withdrawal of the previous anticonvulsant agent is desired, the following schedule should be used:

- **Dilantin**: The initial dose of 300 mg every 8 hours is recommended. The daily dose may be decreased by 300 mg every 48 hours as tolerated.
- **Phenobarbital**: The initial dose of 100 mg every 6 hours is recommended. The daily dose may be decreased by 100 mg every 48 hours as tolerated.
- **Primidone**: The initial dose of 250 mg every 8 hours is recommended. The daily dose may be decreased by 250 mg every 48 hours as tolerated.

**CAUTION**: Federal law prohibits dispensing without prescription.
1. CHEMISTRY REVIEW NO. 2
2. ANDA #74-865
3. NAME AND ADDRESS OF APPLICANT
Danbury Pharmacal, Inc.
Attention: William R. McIntyre, Ph.D.
131 West Street
Danbury, CT 06810
4. LEGAL BASIS FOR SUBMISSION
Mexilit Capsules; Boehringer Ingelheim. Patent expired on May 04, 1995 and no expiration date for exclusivity.
5. SUPPLEMENT(s)
N/A
6. PROPRIETARY NAME
Mexiletine Hydrochloride Capsules, USP
7. NONPROPRIETARY NAME
Mexiletine Hydrochloride Capsules, USP
8. SUPPLEMENT(s) PROVIDER(s) FOR:
N/A
9. AMENDMENTS AND OTHER DATES:
Firms:
February 29, 1996: Original submission
October 10, 1997: Major amendment
FDA:
March 18, 1996: Acknowledgement letter
August 26, 1996: Deficiency letter
10. PHARMACOLOGICAL CATEGORY
Antiarrhythmic
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)
NDA-N18873
13. DOSAGE FORM
Oral Capsule
14. POTENCY
150 mg, 200 mg and 250 mg
15. **CHEMICAL NAME AND STRUCTURE**
2-propanamine, 1-(2,6-dimethylphenoxy)-, hydrochloride, (±).

(±)-1-methyl-2-(2,6-xylyloxy)ethylamine hydrochloride. [CAS# 5370-01-04]

Mexiletine Hydrochloride USP

\[ \text{C}_{11}\text{H}_{15}\text{NO.HCl; M.W. = 215.72} \]

1-Methyl-2-(2,6-xylyloxy)ethylamine hydrochloride.
CAS [5370-01-04]

16. **RECORDS AND REPORTS**
Debarment commitment from Danbury and
are provided on page 2723 and 2725 in section XXI. authorization letter is
provided on page 2733 in section XXI. authorization letter is provided on page 2734
in section XXI.

17. **COMMENTS**
The following deficiencies are found:
- EER pending

18. **CONCLUSIONS AND RECOMMENDATIONS**
The application can be approved. A approvable letter is pending acceptable EER.

19. **REVIEWER:**
Sema Basaran, Ph.D.  
**DATE COMPLETED:** 2-2-98