HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BILTRICIDE safely and effectively. See full prescribing information for BILTRICIDE.

BILTRICIDE (praziquantel) tablets, for oral use
Initial U.S. Approval: 1982

---------- RECENT MAJOR CHANGES ----------

Warnings and Precautions (5.6) 12/2023

---------- INDICATIONS AND USAGE ----------

Biltricide is an anthelmintic indicated in patients aged one year and older for the treatment of the following infections:

- Schistosomiasis due to all species of schistosoma (for example, *Schistosoma mekongi*, *Schistosoma japonicum*, *Schistosoma mansoni* and *Schistosoma hematobium*), and,
- Clonorchiasis and Opisthorchiasis due to the liver flukes, *Clonorchis sinensis* and *Opisthorchis viverrini*

---------- DOSAGE AND ADMINISTRATION ----------

- Schistosomiasis: 20 mg/kg bodyweight 3 times a day separated by 4 to 6 hours for 1 day only. (2.1)
- Clonorchiasis and Opisthorchiasis: 2 5 mg/kg 3 times a day separated by 4 to 6 hours for 1 day only. (2.1)
- Take with water during meals. Do not chew or keep segments in the mouth. (2.2)
- For pediatric patients under 6 years of age, the tablets may be crushed or disintegrated and mixed with semi-solid food or liquid. (2.2)
- For additional administration instructions see the full prescribing information.

---------- DOSAGE FORMS AND STRENGTHS ----------

- Tablets: 600 mg (with three scores (notches) on the tablet) (3)

---------- CONTRAINDICATIONS ----------

- Known hypersensitivity to Biltricide or any of its ingredients. (4.1)
- Concomitant administration with strong Cytochrome P450 3A enzyme (CYP 3A) inducers such as rifampin. (4, 5.6 7.1)

---------- WARNINGS AND PRECAUTIONS ----------

- Clinical Deterioration: Potentially life threatening clinical deterioration can occur in patients treated during the acute phase of schistosomiasis. (5.1)
- Central Nervous System (CNS) Effects: Biltricide can exacerbate central nervous system pathology due to schistosomiasis. Consider whether to administer to individuals reporting a history of epilepsy and/or other signs of potential central nervous systems involvement such as subcutaneous nodules suggestive of cysticercosis. (5.2)
- Potential Lack of Efficacy for Acute Schistosomiasis: This has been reported in observational studies (5.3).
- Cardiac Arrhythmias: Bradycardia, ectopic rhythms, ventricular fibrillation, and AV blocks has been observed with Biltricide administration. Monitor patients with cardiac arrhythmias during treatment (5.4).

---------- ADVERSE REACTIONS ----------

The adverse reactions reported were malaise, headache, dizziness, abdominal discomfort (with or without nausea), pyrexia and urticaria. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Bayer HealthCare Pharmaceuticals Inc. at 1-888-842-2937 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

---------- DRUG INTERACTIONS ----------

- Moderate CYP 3A Inducers: Avoid concomitant administration of moderate CYP 3A inducers, for example, efavirenz (5.6, 7.1)

---------- USE IN SPECIFIC POPULATIONS ----------

- Pediatrics: Safety has not been established in pediatric patients younger than 1 year of age. (8.4)
- Hepatic Impairment: Monitor patients for adverse reactions when administering the recommended dose of Biltricide to hepatosplenic schistosomiasis patients with moderate to severe liver impairment (Child-Pugh Class B or C). (8.6)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 12/2023

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Biltricide is indicated in patients aged 1 year and older for the treatment of the following infections:

- Schistosomiasis due to all species of schistosoma (for example, *Schistosoma mekongi, Schistosoma japonicum, Schistosoma mansoni and Schistosoma hematobium*), and
- Clonorchiasis and Opisthorchiasis due to the liver flukes, *Clonorchis sinensis/Opisthorchis viverrini* (approval of this indication was based on studies in which the two species were not differentiated)

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dosage

Schistosomiasis The recommended dosage for the treatment of schistosomiasis is 20 mg/kg bodyweight administered orally three times a day separated by 4 to 6 hours, for 1 day only.

Clonorchiasis and Opisthorchiasis

The recommended dosage for the treatment of clonorchiasis and opisthorchiasis is 25 mg/kg bodyweight administered orally three times a day separated by 4 to 6 hours for 1 day only.

2.2 Administration

Take tablets with water during meals. Do not chew or keep the tablets (or parts of tablets) in the mouth; the bitter taste may cause gagging or vomiting. To prevent choking in pediatric patients under 6 years of age, the tablets may be crushed or disintegrated and mixed with semi-solid food or liquid. Use crushed or disintegrated tablets within 1 hour of mixing.

Biltricide 600 mg tablets have three scores which can be split into four segments at the scores. When broken, each of the four segments contains 150 mg of praziquantel so that the dosage can be adjusted to the patient's bodyweight. Segments are broken off by pressing the score (notch) with thumbnails. If one-quarter of a tablet is required, this is best achieved by breaking the segment from the outer end.

3 DOSAGE FORMS AND STRENGTHS

Biltricide tablets contain 600 mg of praziquantel. The tablets are white to orange tinged, film-coated, oblong with three scores (notches), imprinted with "BAYER" on one side and "LG" on the other side.

4 CONTRAINDICATIONS

Biltricide is contraindicated in:

- Patients who previously have shown hypersensitivity to praziquantel or any of the excipients in Biltricide.
- Patients with ocular cysticercosis; since parasite destruction within the eye that occurs because of hypersensitivity reaction to the dead parasite after treatment may cause irreversible lesions, ocular cysticercosis must not be treated with Biltricide.
- Patients taking strong Cytochrome P450 3A enzyme (CYP3A) inducers, such as rifampin *[see Warnings and Precautions (5.6) and Drug Interactions (7.1, 7.2)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Clinical Deterioration

The use of Biltricide in patients with schistosomiasis may be associated with clinical deterioration (for example, paradoxical reactions, serum sickness Jarisch-Herxheimer like reactions: sudden inflammatory immune response suspected to be caused by the release of schistosomal antigens). These reactions predominantly occur in patients treated during the acute phase of schistosomiasis. They may lead to potentially life-threatening events, for example, respiratory failure, encephalopathy, papilledema, and/or cerebral vasculitis.

5.2 Central Nervous System (CNS) Effects

Biltricide can exacerbate central nervous system pathology due to schistosomiasis, paragonimiasis, or *Taenia solium* cysticercosis. As a general rule, consider whether to administer Biltricide to individuals reporting a history of epilepsy and/or other signs of potential central nervous systems involvement such as subcutaneous nodules suggestive of cysticercosis unless the potential benefit justifies the potential risk. Hospitalize the patient for duration of treatment when schistosomiasis or fluke infection is found to be associated with cerebral cysticercosis.

5.3 Potential Lack of Efficacy During the Acute Phase of Schistosomiasis

Data from two observational cohort studies in patients indicate that treatment with Biltricide in the acute phase of infection may not prevent progression from asymptomatic infection to acute schistosomiasis, or from asymptomatic infection/acute schistosomiasis into chronic phase.

5.4 Cardiac Arrhythmias

Bradycardia, ectopic rhythms, ventricular fibrillation, and AV blocks has been observed with Biltricide administration. Monitor patients with cardiac arrhythmias during treatment.

5.5 Hepatic Impairment in Hepatosplenic Schistosomiasis Patients

Reduced hepatic metabolism of praziquantel results in higher and sustained plasma concentrations of unmetabolized praziquantel in patients with liver impairment *[see Clinical Pharmacology (12.3)]*. Monitor patients for adverse reactions when administering the recommended dose of Biltricide to hepatosplenic schistosomiasis patients with moderate or severe liver impairment (Child-Pugh Class B or C).

5.6 Concomitant Administration with Cytochrome P450 Enzyme Inducers

Strong Cytochrome P450 3A Enzyme (CYP 3A) Inducers

Concomitant administration of strong CYP 3A inducers, such as rifampin, with Biltricide is contraindicated since therapeutically effective levels of praziquantel are unlikely to be achieved. *[see Contraindications (4), Drug Interactions (7.1), and Clinical Pharmacology (12.3)]*.

Moderate CYP 3A Inducers

Avoid concomitant administration of Biltricide with moderate CYP 3A inducers, such as efavirenz, due to risk of a clinically significant decrease in praziquantel plasma concentrations which may lead to reduced therapeutic effect of Biltricide. *[see Drug Interactions (7.1)]*.

In patients receiving a clinically significant CYP 3A inducer drug who need immediate treatment for schistosomiasis, alternative agents for schistosomiasis should be considered, where possible. If Biltricide is necessary immediately, increase monitoring for reduced anthelmintic efficacy associated with Biltricide *[see Drug Interactions (7.1)]*.

In patients receiving a clinically significant CYP 3A inducer drug whose treatment could be delayed, discontinue the CYP 3A inducer drug at least 2 weeks to 4 weeks before administration of Biltricide and, where possible, consider starting alternative medications that are not CYP 3A inducers. The CYP 3A inducer drug can be restarted one day after completion of Biltricide treatment, if needed *[see Drug Interactions (7.1)]*

6 ADVERSE REACTIONS

The following serious or otherwise important adverse reactions are discussed elsewhere in the labeling:

- Clinical Deterioration *[see Warnings and Precautions (5.1)]*
- Central Nervous System (CNS) Effects *[see Warnings and Precautions (5.2)]*
- Potential Lack of Efficacy During the Acute Phase of Schistosomiasis *[see Warnings and Precautions (5.3)]*
- Cardiac Arrhythmias *[see Warnings and Precautions (5.4)]*
- Hepatic Impairment in Hepatosplenic Schistosomiasis Patients *[see Warnings and Precautions (5.5)]*
- Concomitant Administration with Strong Cytochrome P450 Inducers *[see Warnings and Precautions (5.6)]*

The following adverse reactions associated with the use of Biltricide were identified in clinical studies, published literature or postmarketing reports. Because some of these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions were observed in both adults and pediatric patients:

General disorders and administration site conditions: malaise, pyrexia

Nervous system disorders: headache, dizziness

Gastrointestinal disorders: abdominal discomfort, nausea

Skin and subcutaneous tissue disorders: urticaria

Such adverse reactions may be more frequent and/or serious in patients with a heavy worm burden.

Additional adverse reactions reported from worldwide post marketing experience and from publications with Biltricide and various formulations of praziquantel include:

Blood and lymphatic system disorders: eosinophilia

Cardiac disorders: arrhythmia (including bradycardia, ectopic rhythms, ventricular fibrillation, AV blocks)

Ear and labyrinth disorders: vertigo, tinnitus

Eye disorders: visual disturbance

Gastrointestinal disorders: abdominal pain, bloody diarrhea, vomiting

General disorders and administration site conditions: polyserositis, asthenia, fatigue, gait disturbance

Hepatobiliary disorders: hepatitis

Immune system disorders: allergic reaction, generalized hypersensitivity, anaphylactic reaction

Metabolism and nutrition disorders: anorexia

Musculoskeletal and connective tissue disorders: myalgia

Nervous system disorders: convulsion, somnolence, intention tremor

Respiratory, thoracic and mediastinal disorders: pneumonitis, dyspnea, wheezing

Skin and subcutaneous tissue disorders: pruritus, rash, Stevens-Johnson syndrome

Pediatric patients 1 to 17 years of age treated with Biltricide and various formulations of praziquantel experienced similar adverse reactions as those observed in adult patients.

7 DRUG INTERACTIONS

7.1 CYP 3A Inducers

Strong and Moderate CYP 3A Inducers

Concomitant administration of Biltricide with Strong and Moderate CYP 3A inducers decrease praziquantel AUC and Cmax *[see Clinical Pharmacology (12.3)]* which may reduce the efficacy of Biltricide. Concomitant administration of a Strong CYP 3A inducer, such as rifampin, with Biltricide is contraindicated *[see Contraindications (4)]*. Concomitant administration of a Moderate CYP 3A inducer, such as efavirenz, should be avoided unless the benefit outweighs the risks

[see Warnings and Precautions (5.6) and Clinical Pharmacology (12.3).]

7.2 CYP450 inhibitors

Concomitant administration of drugs that decrease the activity of drug metabolizing liver enzymes (CYP450 inhibitors), for example, cimetidine, ketoconazole, itraconazole, erythromycin, and ritonavir may increase plasma concentrations of praziquantel. In addition, grapefruit juice was also reported to produce a 1.6-fold increase in the C_{max} and a 1.9-fold increase in the AUC of praziquantel. The effect of this exposure increase on the safety of Biltricide has not been systematically evaluated *[see Dosage and Administration (2.2)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Published studies have not identified an association with Biltricide use during pregnancy and major birth defects, miscarriage or adverse maternal or fetal outcomes *(see Data)*. In animal reproduction studies conducted in pregnant rats and rabbits no adverse developmental outcomes were observed with oral administration of praziquantel during organogenesis at approximately 0.65 times (rats) or 1.3 times (rabbits) the highest recommended human daily dose of 75 mg/kg/day, based on body surface area.

The estimated background risk of major birth defects and miscarriage for the indicated population are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Human Data

Two randomized controlled clinical trials have been conducted using praziquantel for the treatment of schistosoma infection in pregnant women. In one randomized controlled trial in pregnant women with schistosoma (*S. japonicum)* infection, 186 pregnant women were treated with praziquantel compared to 184 women who received placebo. Treatment with praziquantel during pregnancy had no effect on birthweight, and there were no differences in rates of miscarriage, fetal death and major birth defects between the praziquantel-treated and control patients. In another randomized controlled trial that included 2507 pregnant women in Uganda, 18% of women were infected with schistosoma infection. Treatment with praziquantel during pregnancy had no effect on mean birth weight, perinatal mortality or major birth defects.

In other published studies, including a retrospective observational study, case series and case reports, there have been no reports of major birth defects, stillbirths or other adverse pregnancy outcomes associated with the use of praziquantel during pregnancy.

Animal Data

No evidence of fetal harm was observed in rats and rabbits at praziquantel dose levels of 30 to 300 mg/kg body weight given repeatedly by oral administration during the period of organogenesis. These doses were up to 0.65 times (rats) or 1.3 times (rabbits) the highest recommended human daily dose of 75 mg/kg/day, based on body surface area.

8.2 Lactation

Risk Summary

Limited data from published literature reports the presence of praziquantel in human milk at low concentrations. There is no information on the effects of praziquantel in the breastfed infant or effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Biltricide and any potential adverse effects on the breastfed infant from Biltricide or from the underlying maternal condition.

8.4 Pediatric Use

Safety and dosing recommendations of Biltricide in pediatric patients 1 to 17 years have been established. Safety of Biltricide in pediatric patients younger than 1 year of age has not been established.

Post-marketing experience and published literature indicates that pediatric patients 1 to 17 years of age treated with praziquantel experience similar adverse reactions as adults treated with praziquantel *[see Adverse Reactions (6)]*.

8.5 Geriatric Use

Clinical studies of Biltricide did not include a sufficient number of subjects ages 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older patients cannot be ruled out. This drug is known to be substantially excreted by the kidney. Because elderly patients are more likely to have decreased renal function, the risk of toxic reactions to this drug may be greater in these patients *[see Clinical Pharmacology (12.3)]*.

8.6 Hepatic Impairment

Following oral administration of Biltricide to patients with liver impairment, reduced hepatic metabolism of praziquantel results in higher and sustained plasma concentrations of unmetabolized praziquantel *[see Clinical Pharmacology (12.3)]*. Monitor patients for adverse reactions when administering the recommended dose of Biltricide to hepatosplenic schistosomiasis patients with moderate or severe liver impairment (Child-Pugh Class B or C).

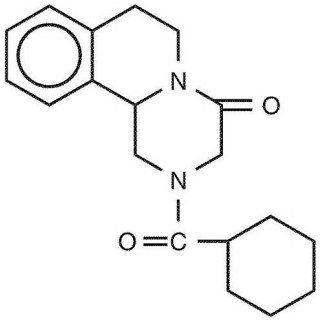
8.7 Renal Impairment

No dosage adjustment of Biltricide is necessary in patients with renal impairment. Nephrotoxic effects of Biltricide or its metabolites are not known *[see Clinical Pharmacology (12.3)]*.

11 DESCRIPTION

Biltricide (praziquantel) is an anthelmintic, trematodicide provided in tablet form for oral administration.

Praziquantel is 2-(cyclohexylcarbonyl)-1,2,3,6,7, 11b-hexahydro-4H-pyrazino [2, 1-a] isoquinolin-4-one with the molecular formula; $C_{19}H_{24}N_2O_2$. The structural formula is as follows:



Praziquantel is a white to nearly white crystalline powder of bitter taste. The compound is stable under normal conditions and melts at 136 to 140°C with decomposition. The active substance is hygroscopic. Praziquantel is easily soluble in chloroform and dimethylsulfoxide, soluble in ethanol and very slightly soluble in water.

Biltricide tablets contain 600 mg of praziquantel. Inactive ingredients: corn starch, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, sodium lauryl sulfate, and titanium dioxide .

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Praziquantel is an anthelmintic drug *[see Microbiology (12.4)]*.

12.3 Pharmacokinetics

Absorption

After oral administration, 80% of an administered Biltricide dose is absorbed, with maximal serum concentrations of praziquantel achieved 1 to 3 hours after dosing.

Elimination

Following oral administration of Biltricide, the elimination half-life of praziquantel in serum ranges between 0.8 to 1.5 hours.

Metabolism

Praziquantel is rapidly metabolized by the cytochrome P450 enzyme system and undergoes a first pass effect after oral administration of Biltricide.

Excretion

Approximately 80% of an oral dose of Biltricide is excreted in the kidneys, almost exclusively (greater than 99%) in the form of praziquantel metabolites.

Specific Populations

Patients with Hepatic Impairment

The pharmacokinetics of praziquantel were studied in 40 patients with *Schistosoma mansoni* infections with varying degrees of hepatic impairment (See Table 1). In patients with schistosomiasis, the pharmacokinetic parameters did not differ significantly between those with normal hepatic function (Group 1) and those with mild (Child-Pugh class A) hepatic impairment. However, in patients with moderate-to-severe hepatic impairment (Child-Pugh class B and C), praziquantel half-life, $C_{max,}$ and AUC increased progressively with the degree of hepatic impairment. In Child-Pugh class B, the increases in mean half-life, $C_{max,}$ and AUC relative to Group 1 were 1.58-fold, 1.76-fold, and 3.55-fold, respectively. The corresponding increases in Child-Pugh class C patients were 2.82-fold, 4.29-fold, and 15-fold for half-life, $C_{max,}$ and AUC.

Table 1: Pharmacokinetic parameters of praziquantel in four groups of patients with varying degrees of liver function following administration of 40 mg/kg of Biltricide under fasting conditions.

Patient Group	Half-life (hr)	T_{max} (hr)	C_{max} (µg/mL)	AUC (µg/mL* hr)
Normal hepatic function (Group 1)	2.99 ± 1.28	1.48 ± 0.74	0.83 ± 0.52	3.02 ± 0.59
Child-Pugh A (Group 2)	4.66 ± 2.77	1.37 ± 0.61	0.93 ± 0.58	3.87 ± 2.44
Child-Pugh B (Group 3)	4.74 ± 2.16[a]	2.21 ± 0.78[a,b]	1.47 ± 0.74[a,b]	10.72 ± 5.53[a,b]
Child-Pugh C (Group 4)	8.45 ± 2.62[a,b,c]	3.2 ± 1.05[a,b,c]	3.57 ± 1.30[a,b,c]	45.35 ± 17.50[a,b,c]

a) $p<0.05$ compared to Group 1

b) $p<0.05$ compared to Group 2

c) $p<0.05$ compared to Group 3

Patients with Renal Impairment

Excretion of praziquantel following oral administration of Biltricide might be delayed in patients with impaired renal function, but accumulation of unchanged drug would not be expected.

Drug Interaction Studies

Rifampin (Strong CYP 3A Inducer)

In a crossover study with a 2-week washout period, 10 healthy subjects ingested a single 40 mg/kg oral dose of Biltricide following pre-treatment with oral rifampin (600 mg daily for 5 days). Plasma praziquantel concentrations were undetectable in 7 out of 10 subjects. When a single 40 mg/kg oral dose of Biltricide was administered to these same healthy subjects two weeks after discontinuation of rifampin, the mean praziquantel AUC and C_{max} were 23% and 35% lower, respectively, then when Biltricide was given alone.

Efavirenz (Moderate CYP 3A Inducer)

In a crossover study, 20 healthy subjects ingested a single 40 mg/kg oral dose of Biltricide following pre-treatment with oral efavirenz (400 mg daily for 13 days). Oral efavirenz reduced the mean praziquantel AUC and C_{max} by 77% (95% confidence interval: 38% to 91%) and 79% (95% confidence interval: 41% to 92%), respectively, when coadministered with Biltricide compared to Biltricide given alone.

12.4 Microbiology

Praziquantel induces a rapid contraction of schistosomes by a specific effect on the permeability of the cell membrane. The drug further causes vacuolization and disintegration of the schistosome tegument. However, the mechanism of action is unknown.

Praziquantel is active against schistosoma (for example, *Schistosoma mekongi*, *Schistosoma japonicum*, *Schistosoma mansoni* and *Schistosoma hematobium*), and infections due to the liver flukes, *Clonorchis sinensis/Opisthorchis viverrini [*see *Indications and Usage (1)]*. Published *in vitro* data have shown a potential lack of efficacy of praziquantel against migrating schistosomulae *[see Warnings and Precautions (5.3)]*.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Mutagenicity studies of praziquantel published in the scientific literature are inconclusive. Long term oral carcinogenicity studies in rats and golden hamsters did not reveal any carcinogenic effect at doses up to 250 mg/kg/day (about half of the human daily dose based on body surface area). Praziquantel had no effect on fertility and general reproductive performance of male and female rats when given at oral doses ranging from 30 to 300 mg/kg body weight (up to 0.65 times the human daily dose based on body surface area).

16 HOW SUPPLIED/STORAGE AND HANDLING

Biltricide is supplied as 600 mg tablets containing praziquantel. The tablets are white to orange tinged, film-coated, oblong tablets with three scores. The tablet is coded with “BAYER” on one side and “LG” on the reverse side.

Biltricide is available in bottles of six 600 mg tablets, NDC 50419-747-01.

Store below 86°F (30°C).

17 PATIENT COUNSELING INFORMATION

- Advise patients to take Biltricide during meals as directed *[see Dosage and Administration (2.2)]*.
- Advise patients not to chew tablets and to take them with water *[see Dosage and Administration (2.2)]*
- Advise patients that tablets may be crushed or disintegrated and mixed with semi-solid food or liquid or disintegrated to prevent choking in children under 6 years of age. Crushed or disintegrated tablets should be used within 1 hour of mixing *[see Dosage and Administration (2.2)]*.
- Advise patients not to take Biltricide if they are allergic to Biltricide or any of its components *[see Contraindications (4)]*.
- Advise patients not to take Biltricide if they are taking rifampin *[see Contraindications (4) and Warnings and Precautions (5.6), Drug Interactions (7.1)]*.
- Advise patients not to take Biltricide if they are taking efavirenz *[see Warnings and Precautions (5.6), Drug Interactions (7.1)]*.
- Advise patients that the use of praziquantel can be associated with clinical deterioration during the acute phase of schistosomiasis *[see Warnings and Precautions (5.1)]*.
- Advise patients that Biltricide should not be used if they have epilepsy of or other CNS effects *[see Warnings and Precautions (5.2)]*.
- Advise patients to report any cardiac irregularities to their healthcare provider *[see Warnings and Precautions (5.4)]*.
- Advise patients not to drive a car and not to operate machinery on the day of Biltricide treatment and the following day.

Manufactured for:

Bayer HealthCare Pharmaceuticals Inc.

Whippany, NJ 07981 USA