DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Christine Duffy Smith
Promotional Regulatory Affairs, Director
AstraZeneca LP
725 Chesterbrook Blvd.
Wayne, PA 29087-5677

RE: **NDA 20-768**
Zomig® (zolmitriptan) Tablets, 2.5 mg and 5 mg
MACMIS #9983

Dear Ms. Smith:

This letter is to notify you that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified a promotional detail aid (#201906) for Zomig® (zolmitriptan) Tablets that is misleading and in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Specifically, this promotional detail aid makes the following misleading claims that broaden the efficacy of zolmitriptan and imply superiority of zolmitriptan over competitive therapies.

- "Reliable in Recurrent Migraine Headache"
- "Reliable in Persistent Migraine Headache"
- "Consistent Attack after Attack"
- "Eighty-five percent of patients (2096/2425) considered ZOMIG to be similar to, or better than, any previous therapy for migraine, with two-thirds of patients (67%: 1626/2425) rating ZOMIG superior to previous therapies"
- "Analysis of patients who had received previous sumatriptan therapy demonstrated similarly favorable results for ZOMIG, as shown in the chart below" [Chart titled, "Percentage of patients preferring ZOMIG vs other treatments (including sumatriptan); n=2425," shows that 63.7% of patients prefer ZOMIG over other treatments.]

These claims require substantial evidence from adequate and well-controlled studies. The promotional brochure cites the following study as support for these claims:

> Tepper SJ, Donnan GA, Dowson AJ, et al. A Long Term Study to Maximise Migraine Relief with Zolmitriptan. *Curr Med Res Opin* 1999; 15:254-271.

The study was completed in 2 parts, Part 1 and Part 2. Part 1 was blinded, randomized and placebo controlled study of "persistent" migraine patients. "Persistent" migraine headache was defined in the study as migraine headache with residual pain of any intensity two hours after initial treatment. Patients were initially treated with 2.5 mg of zolmitriptan and then received randomized treatment with 2.5 mg or 5 mg zolmitriptan, or placebo. The primary endpoint was the proportion of patients with a reduction in headache severity two hours after taking the second randomized dose. No significant difference between treatment groups was observed. Any claims of clinical benefit based on this study would be unsubstantiated since the study produced no evidence that zolmitriptan was effective in the study population.

Part 2 of the study was a non-comparative, open-label continuation of Part 1, in which patients treated multiple migraine headaches of any intensity with zolmitriptan. Patients were required to take one 2.5 mg zolmitriptan tablet as initial therapy for their first two migraine headaches. Thereafter, patients could choose to treat each subsequent initial, persistent or recurrent headache with either 2.5 mg or 5 mg zolmitriptan. Results of Part 2 of the study provided descriptive data of patients' self-medication behavior. Among the secondary objectives of Part 2, patients were asked their "global impression" of treatment and control of their migraine upon completion or withdrawal from the study. 67.1% (1626/2425) of patients rated zolmitriptan as being better than any previous migraine therapy, and 19.4% (470/2425) as similar to their previous therapy. Of patients with previous sumatriptan experience, 63.7% (1059/1663) rated zolmitriptan better than their previous therapy, and 21.5% (357/1663) rated zolmitriptan to be similar. Part 2 of this study does not represent substantial evidence of superiority because it is not adequate and well-controlled and because it does not directly compare zolmitriptan with sumatriptan in a head-to-head fashion.

We therefore object to the use of the claims above in promotional materials for zolmitriptan because they are not supported by substantial evidence. To address this objection, we recommend that you do the following:

1. Immediately discontinue the use of this detail aid and any other promotional material with the same or similar messages.

2. Respond to this letter within ten days. Your response should include a statement of your intent to comply with the above, a list of promotional materials with the same or similar issues, and your methods for discontinuing these promotional materials.

If you have any questions or comments, please contact me by facsimile at (301) 594-6759, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Room 17B-23, 5600 Fishers Lane Rockville, MD 20857. We remind you that only written communications are considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID #9983 in addition to the NDA number.

Sincerely,

{See appended electronic signature page}

Elaine J. Hu, R.Ph.
Regulatory Review Officer
Evidence Review Branch
Division of Drug Marketing,
Advertising, and Communications

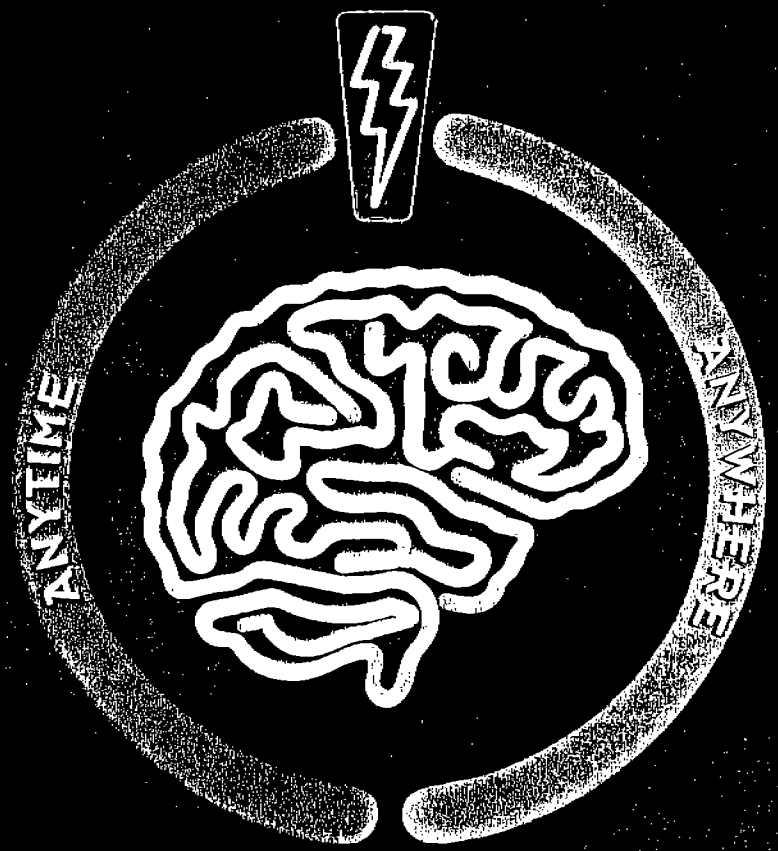
BECAUSE MIGRAINE CAN STRIKE ANYWHERE

FIRST LINE

Zomig

ZOLMITRIPTAN

POWERFUL MIGRAINE RELIEF



ANYTIME—clinically proven to be equally effective whether taken at onset* or when migraine is "full-blown"[1,2†]

- Onset is the ideal time to treat migraine, but patients often wait to take their medication
- ZOMIG® (zolmitriptan) Tablets are available in 2.5-mg and 5-mg dosage strengths

ANYWHERE—now available in 2.5-mg Orally Disintegrating Tablets

- ZOMIG-ZMT™ (zolmitriptan) for effective migraine relief[3]
- Dissolve in seconds on the tongue, without liquids
- Will not dissolve in hand
- Pleasant-tasting orange flavor
- Patient-friendly...when swallowing a conventional tablet is difficult

ZOMIG is indicated for the acute treatment of migraine with or without aura in adults. ZOMIG should only be used where a clear diagnosis of migraine has been established. ZOMIG should not be administered to patients with hemiplegic or basilar migraine. ZOMIG, like other compounds in this class, should not be given to patients in whom unrecognized coronary artery disease (CAD) is predicted by risk factors unless a cardiovascular evaluation provides satisfactory clinical evidence that the patient is reasonably free of coronary artery and ischemic myocardial disease or other significant underlying cardiovascular disease. Phenylketonuric patients should be informed that each ZOMIG-ZMT 2.5-mg Orally Disintegrating Tablet contains 2.81 mg of phenylalanine (a component of aspartame).

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*Defined as a migraine headache that was less than 4 hours postonset when treated.
†Defined as a migraine headache that was greater than 4 hours postonset when treated.

Please see full Prescribing Information and important prescribing considerations on pages 22-23.

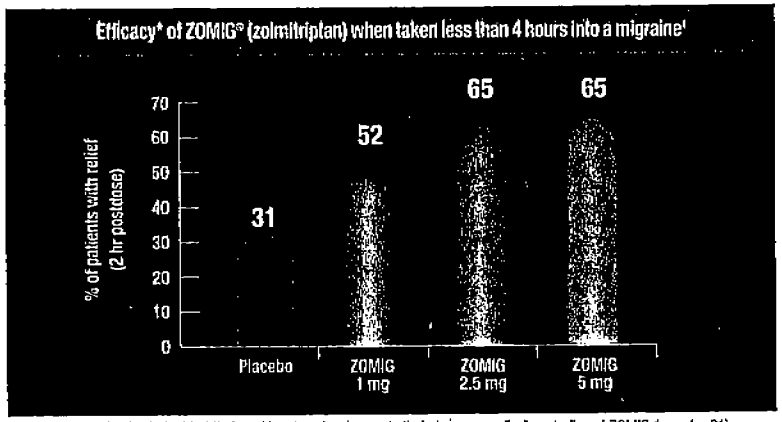
POWERFUL MIGRAINE RELIEF ANYTIME, ANYWHERE

FIRST LINE Zomig® ZOLMITRIPTAN

ONSET

OF MIGRAINE HEADACHE

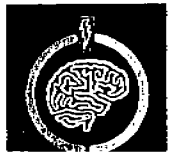
- 5-HT$_1$ migraine therapies are considered more effective when taken early in the migraine headache[4,5]



Data from 4 randomized, double-blind, multicenter, placebo-controlled, dose range-finding studies of ZOMIG 1 mg (n=91), 2.5 mg (n=308), 5 mg (n=294), 10 mg (n=305) versus placebo (n=213) for the treatment of a severe or moderate migraine headache.[1]

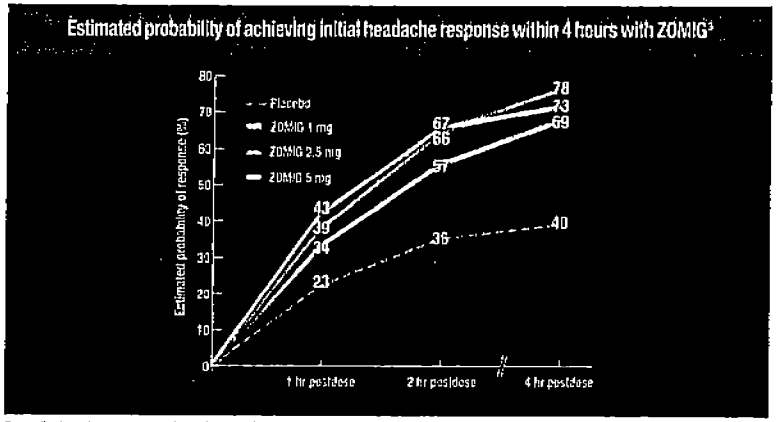
- ZOMIG is effective when taken early in the migraine headache[1,2]

*Defined as reduction of moderate or severe pain to mild or no pain at 2 hours.



FAST

ORAL RELIEF



Data displayed are averages based on pooled data from 3 placebo-controlled, outpatient trials (n=1303) providing evidence of efficacy. This Kaplan-Meier plot displays the probability over time of obtaining headache response (defined as a reduction in headache severity from severe or moderate to mild or no pain) following treatment with ZOMIG 1 mg, 2.5 mg, and 5 mg.[3]

- In controlled clinical trials, an average of 66% of patients who received a single dose of ZOMIG 2.5 mg achieved pain relief* at 2 hours, increasing to 78% at 4 hours[1,3]
- In a separate clinical trial, the headache response rate for ZOMIG 2.5 mg was significantly superior to placebo at 45 minutes ($P<0.001$)[6]

*Defined as reduction of moderate or severe pain to mild or no pain at 2 hours.

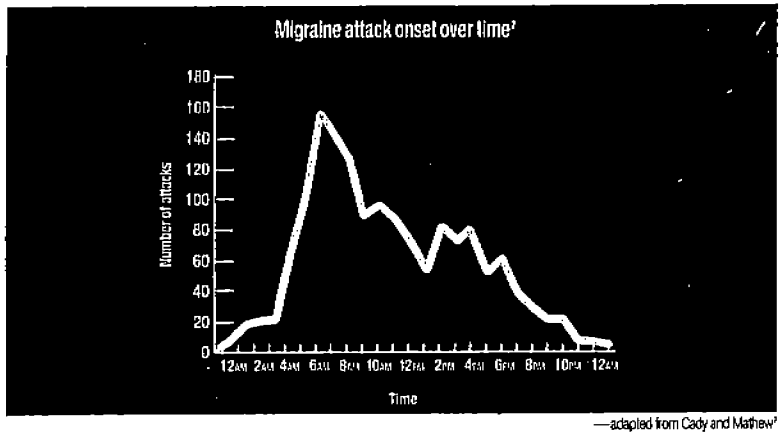
Please see full Prescribing Information and important prescribing considerations on pages 22-23.

POWERFUL MIGRAINE RELIEF ANYTIME

FIRST LINE Zomig® ZOLMITRIPTAN 2.5 & 5 mg TABLETS

TIMING

OF MIGRAINE HEADACHE



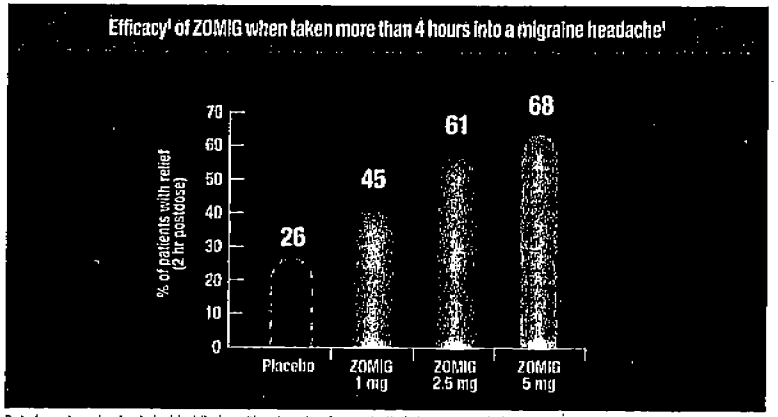
—adapted from Cady and Mathew²

- This retrospective analysis of ZOMIG® (zolmitriptan) 2.5 mg for the treatment of migraine shows that the majority of migraine attacks occurred during the early morning hours²
  - — These migraine attacks may be 4 to 12 hours in duration before a patient seeks treatment²

FULL-BLOWN*

MIGRAINE HEADACHE

- Ideally, patients should take their medication early in an attack; however, patients often wait until their migraine is "full-blown"
- ZOMIG is equally effective at anytime during the headache—even in "full-blown" migraine headache[1,2]



Data from 4 randomized, double-blind, multicenter, placebo-controlled, dose range-finding studies of ZOMIG 1 mg (n=56), 2.5 mg (n=130), and 5 mg (n=151) versus placebo (n=108) for the treatment of a severe or moderate migraine headache.[1]

- Whether ZOMIG is taken early (less than 4 hours) or late (more than 4 hours) into the migraine attack, your patients can expect equally effective relief[1,2]

*Defined as a migraine headache that was greater than 4 hours postonset when treated.
†Defined as reduction of moderate or severe pain to mild or no pain at 2 hours.

Please see full Prescribing Information and important prescribing considerations on pages 22-23.

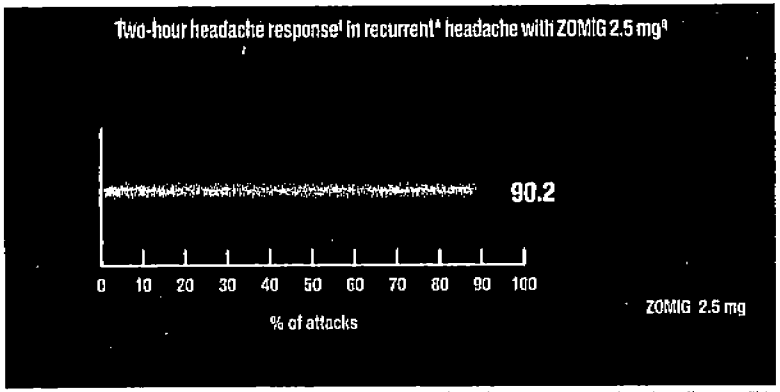
POWERFUL MIGRAINE RELIEF ANYTIME

FIRST LINE Zomig® ZOLMITRIPTAN 2.5 & 5 mg TABLETS

RELIABLE

IN RECURRENT* MIGRAINE HEADACHE

- In a 12-month, open-label study (n=2499), 12.5% of migraine attacks were treated for recurrent* headache with ZOMIG® (zolmitriptan) 2.5 mg, and overall, 90.2% of these migraine attacks were successfully treated[8]



Results from a 12-month, open-label, international, multicenter study in which patients (n=2499) were allowed to self-treat multiple migraine attacks of any severity.[8]

- In another 12-month, open-label study using ZOMIG 5 mg (n=2058), in which the median percentage of attacks where a second dose was used for recurrence was 9.5%, the overall 2-hour headache response rate was 90%[9]

*Defined as headache response at 2 hours, but headache returns within 24 hours.
†Defined as reduction of moderate or severe pain to mild or no pain at 2 hours.

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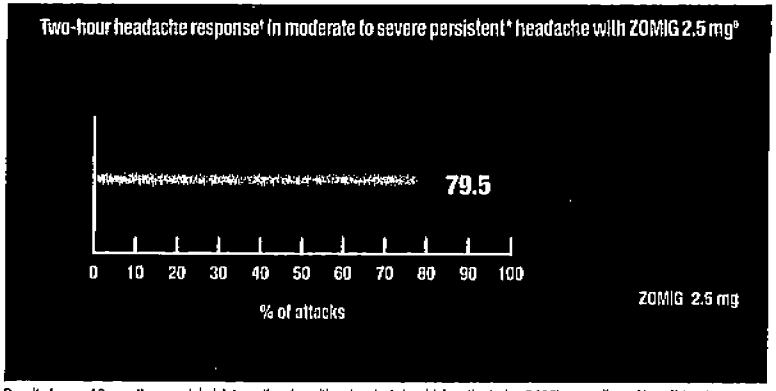
RELIABLE

IN PERSISTENT* MIGRAINE HEADACHE

- In a 12-month, open-label study, 20.7% of migraine attacks were treated for persistent* headache; 79.5% of these migraine attacks were successfully treated with ZOMIG 2.5 mg[8]



Results from a 12-month, open-label, international, multicenter study in which patients (n=2499) were allowed to self-treat multiple migraine attacks of any severity.[8]

*Defined as migraine headache with *any* residual pain 2 hours after the first dose of treatment.
†Defined as reduction of moderate or severe pain to mild or no pain at 2 hours.

Please see full Prescribing Information and important prescribing considerations on pages 22-23.

POWERFUL MIGRAINE RELIEF ANYTIME

FIRST LINE Zomig® ZOLMITRIPTAN 2.5 & 5 mg TABLETS

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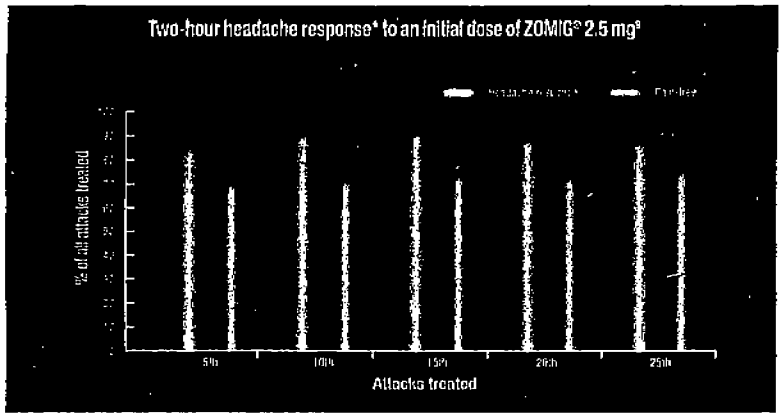
CONSISTENT

ATTACK AFTER ATTACK

- In a 12-month, open-label study (n=2499), 85.2% of attacks were successfully treated with an initial dose of ZOMIG® (zolmitriptan) 2.5 mg[8]



Results from a 12-month, open-label, international, multicenter study in which patients (n=2499) were allowed to self-treat multiple migraine attacks of any severity.[8]

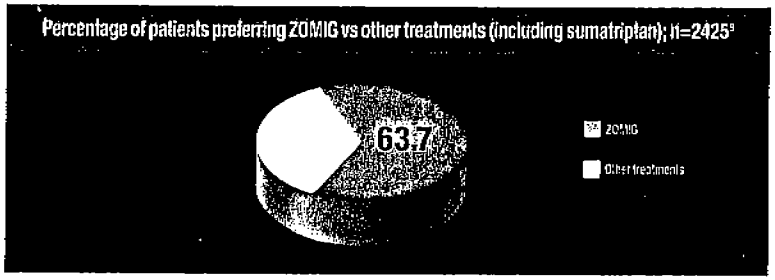
- According to subgroup analysis, headache response* rate seen with a single dose of ZOMIG 2.5 mg at 2 hours was similar whether the migraine attack was related to menses (83.2%) or not (85.4%)[10]

*Defined as reduction of moderate or severe pain to mild or no pain at 2 hours.

PATIENT-FRIENDLY

FOR MIGRAINE HEADACHE

- Eighty-five percent of patients (2096/2425) considered ZOMIG to be similar to, or better than, any previous therapy for migraine, with two-thirds of patients (67%: 1626/2425) rating ZOMIG superior to previous therapies[8]
- Analysis of patients who had received previous sumatriptan therapy demonstrated similarly favorable results for ZOMIG, as shown in the chart below[8]



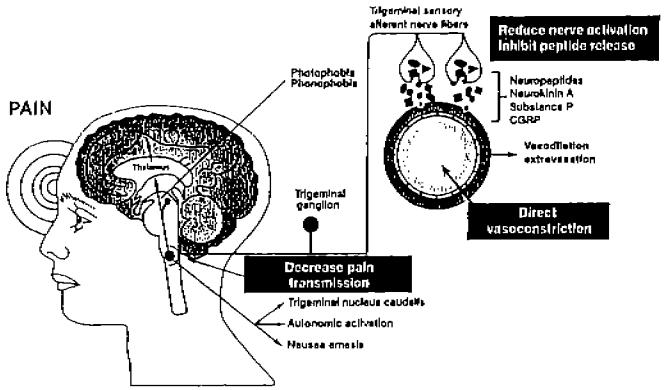
Please see full Prescribing Information and important prescribing considerations on pages 22-23.

POWERFUL MIGRAINE RELIEF ANYTIME

FIRST LINE Zomig® ZOLMITRIPTAN 2.5 & 5 mg TABLETS

MODE OF ACTION*

5-$HT_{1B/1D}$ RECEPTOR AGONISTS



- ZOMIG® (zolmitriptan) acts both centrally and peripherally to produce cranial vessel constriction and inhibition of neuropeptide release in experimental models[11]*
- ZOMIG has lipophilic properties, which facilitate its movement across the intact blood brain barrier[12]
- Because the 5-$HT_{1B/1D}$ potency of the N-desmethyl metabolite is 2 to 6 times that of the parent compound, this metabolite may contribute a substantial portion of the overall effect after administration of ZOMIG[3]
- The mean elimination half-life of ZOMIG and of the active N-desmethyl metabolite is 3 hours[3]

*Because the etiology and pathophysiology of migraine are theoretical, the mechanism of action of ZOMIG remains theoretical.

FLEXIBLE

ORAL DOSING

- Starting dose: 1 ZOMIG 2.5-mg Tablet or lower
- A second dose may be taken a minimum of 2 hours after the first dose
- The maximum daily dose of ZOMIG is 10 mg
- For a dose lower than 2.5 mg, break a 2.5-mg tablet in half
- Also available: ZOMIG 5 mg
- A greater proportion of patients had headache response following a 2.5-mg or 5-mg dose than a 1-mg dose, but side effects were generally increased at 5 mg

ZOMIG should not be used within 24 hours of treatment with another 5-HT_1 agonist or an ergotamine-containing or ergot-type medication like dihydroergotamine or methysergide. Concurrent administration of MAO-A inhibitors or use of ZOMIG within 2 weeks of discontinuation of MAO-A inhibitor therapy is contraindicated.

Please see full Prescribing Information and Important prescribing considerations on pages 22-23.

POWERFUL MIGRAINE
RELIEF ANYTIME

FIRST LINE
Zomig
ZOLMITRIPTAN 2.5 & 5 mg TABLETS

TOLERABILITY

- In clinical studies, ZOMIG® (zolmitriptan) was well tolerated in over 8500 patients treating more than 89,000 migraine attacks[10,13,14]
- At all doses of ZOMIG, most adverse events were typically mild and transient, and did not lead to long-lasting effects[3]
- Convenient for patients to use
  - —ZOMIG is not known to interfere with commonly employed clinical laboratory tests[3]
- ZOMIG is caffeine-free

Adverse experience incidence in 5 placebo-controlled migraine clinical trials[3]*

Adverse Event	Placebo (n=401) %	ZOMIG 1 mg (n=163) %	ZOMIG 2.5 mg (n=498) %	ZOMIG 5 mg (n=1012) %
Dizziness	4	6	8	10
Neck/throat/jaw—pain/tightness/pressure	3	4	7	10
Asthenia	3	5	3	9
Paresthesia	2	5	7	9
Somnolence	3	5	6	8
Sensation warm/cold	4	6	5	7
Nausea	4	4	9	6
Heaviness other than chest or neck	1	1	2	5
Dry mouth	2	5	3	3

*Adverse events occurring at the frequency of 5% or greater in the active treatment group are listed.

SAFETY

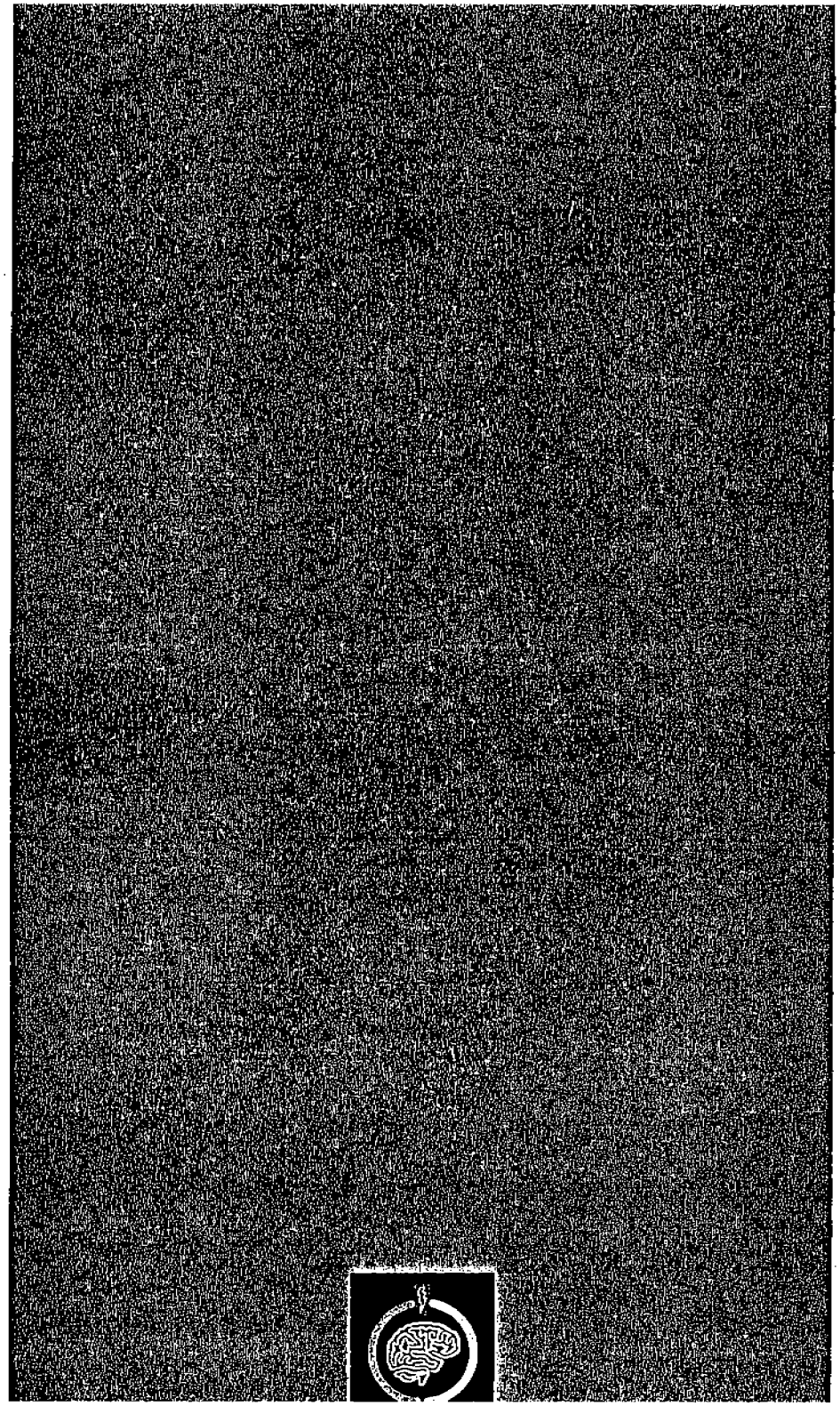
PROVEN SAFTEY PROFILE

- ZOMIG is not contraindicated in patients with hepatic or renal impairment
- Patients with moderate to severe hepatic impairment have decreased clearance of ZOMIG, and a significant elevation in blood pressure was observed in some patients; therefore, use of a low dose with blood pressure monitoring is recommended
- ZOMIG is nonnarcotic and nonhabit-forming
- The zolmitriptan molecule has no sulfonamide group that may cause an allergic reaction in patients hypersensitive to sulfa compounds
- ZOMIG has been used safely with fluoxetine, acetaminophen, propranolol, and metoclopramide in premarketing clinical trials
- The efficacy of ZOMIG is unaffected by use of oral contraceptives[1]

Please see full Prescribing Information and important prescribing considerations on pages 22-23.

POWERFUL MIGRAINE RELIEF ANYTIME

FIRST LINE Zomig® ZOLMITRIPTAN 2.5 & 5 mg TABLETS



FIRST LINE

Zomig-ZMT™

ZOLMITRIPTAN

2.5 mg ORALLY DISINTEGRATING TABLETS

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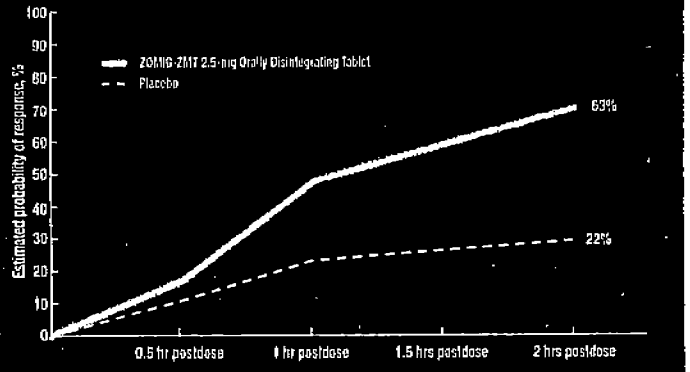
Please see full Prescribing Information and Important prescribing considerations on pages 22-23

POWERFUL

MIGRAINE RELIEF

Estimated probability of achieving initial headache response* within 2 hours with ZOMIG-ZMT™ (zolmitriptan) 2.5-mg Orally Disintegrating Tablets[3]



Data displayed are averages based on data from a placebo-controlled, outpatient trial (N=470) providing evidence of efficacy. This Kaplan-Meier plot displays the probability over time of obtaining headache response (defined as a reduction in headache severity from severe or moderate to mild or no pain) following treatment with ZOMIG-ZMT 2.5-mg Orally Disintegrating Tablets.[3] *P* values for ZOMIG-ZMT versus placebo were 0.054 at 0.5 hour postdose and <0.0001 at 1 hour and 2 hours postdose.[3,15]

- In controlled clinical trials, an average of 16% of patients who received a single 2.5-mg dose of Orally Disintegrating Tablets achieved pain relief at 30 minutes vs 10% in the placebo group[15]
- The 63% headache response* rate seen at 2 hours is similar to that of the conventional tablet where an average of 66% of patients achieved pain relief at 2 hours following administration of a ZOMIG® (zolmitriptan) 2.5-mg Tablet[3] (see page 5)

*Defined as reduction of moderate or severe pain to mild or no pain.

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TOLERABILITY

OF MIGRAINE

- In a placebo-controlled clinical trial, ZOMIG-ZMT 2.5-mg Orally Disintegrating Tablets were well tolerated[15]
- Most adverse events following administration of ZOMIG-ZMT 2.5-mg Orally Disintegrating Tablets were mild and transient and did not lead to long-lasting effects—similar to those reported with the conventional oral tablet

Adverse experience incidence in a placebo-controlled migraine clinical trial[15]

Adverse Event	Placebo (n=240) %	ZOMIG-ZMT 2.5-mg Orally Disintegrating Tablets (n=231) %
Asthenia	1	3
Tightness	<1	3
Nausea	1	2
Dizziness	1	3
Hyperesthesia	0	2
Paresthesia	2	3
Somnolence	2	3
Pharyngitis	0	2

Please see full Prescribing Information and Important prescribing considerations on pages 22-23.

POWERFUL MIGRAINE RELIEF ANYTIME, ANYWHERE

FAST LIKE Zomig-ZMT™
ZOLMITRIPTAN
2.5 mg ORALLY DISINTEGRATING TABLETS

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CONVENIENT

MIGRAINE RELIEF

ZOMIG-ZMT™ (zolmitriptan) 2.5-mg ORALLY DISINTEGRATING TABLETS

- Dissolve in seconds on the tongue, without liquids
- Will not dissolve in hand
- Pleasant-tasting orange flavor
- Patient-friendly... when swallowing a conventional tablet is difficult

IN CLINICAL TRIALS

- 70% of patients taking a ZOMIG-ZMT 2.5-mg Orally Disintegrating Tablet found it more convenient than a conventional tablet[15]
- Approximately 90% of patients in both the ZOMIG-ZMT 2.5-mg and orally disintegrating placebo tablet treatment groups found the medication form easy to handle[15]
- 80% of patients in each treatment group liked the taste of the orange flavor of the Orally Disintegrating Tablet[15]

SIMPLE

ORAL DOSING

- Starting dose: 1 ZOMIG-ZMT 2.5-mg Orally Disintegrating Tablet
- If a headache comes back after the initial dose, a second dose may be taken a minimum of 2 hours after the first dose
- Maximum daily dose of ZOMIG-ZMT is 10 mg
- ZOMIG-ZMT Orally Disintegrating Tablets contain phenylalanine*
- ZOMIG-ZMT may be taken with or without food and liquids

*Phenylketonuric patients should be informed that each ZOMIG-ZMT Orally Disintegrating Tablet contains 2.81 mg of phenylalanine (a component of aspartame).

Please see full Prescribing Information and important prescribing considerations on pages 22-23.

POWERFUL MIGRAINE RELIEF
ANYTIME, ANYWHERE

FIRST LINE
Zomig-ZMT™
ZOLMITRIPTAN
2.5 mg ORALLY DISINTEGRATING TABLETS

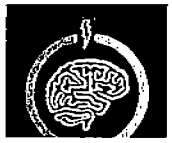
PRESCRIBING CONSIDERATIONS

INDICATIONS

- ZOMIG® (zolmitriptan) is indicated for the acute treatment of migraine with or without aura in adults
- ZOMIG is not intended for the prophylactic therapy of migraine. Safety and effectiveness of ZOMIG have not been established for cluster headache, which is present in an older, predominantly male population

CONTRAINDICATIONS AND WARNINGS

- ZOMIG should not be administered to patients with hemiplegic or basilar migraine
- ZOMIG should not be given to patients with ischemic heart disease (angina pectoris, history of myocardial infarction, or documented silent ischemia), or to patients who have symptoms or findings consistent with ischemic heart disease, coronary artery vasospasm, including Prinzmetal's variant angina, or other significant underlying cardiovascular disease
- Because ZOMIG may increase blood pressure, it should not be given to patients with uncontrolled hypertension
- It is strongly recommended that ZOMIG not be given to patients in whom unrecognized coronary artery disease (CAD) is predicted by the presence of risk factors (eg, hypertension, hypercholesterolemia, smoker, obesity, diabetes, strong family history of CAD, female with surgical or physiological menopause, or male over 40 years of age) unless a cardiovascular evaluation provides satisfactory clinical evidence that the patient is reasonably free of coronary artery and ischemic myocardial disease or other significant underlying cardiovascular disease
- It is recommended that patients who are long-term intermittent users of ZOMIG and who have or acquire risk factors predictive of CAD, as described above, undergo periodic cardiovascular evaluation as they continue to use ZOMIG
- ZOMIG should not be used within 24 hours of treatment with another 5-HT_1 agonist or an ergotamine-containing or ergot-type medication like dihydroergotamine or methysergide
- Concurrent administration of MAO-A inhibitors or use of ZOMIG within 2 weeks of discontinuation of MAO-A inhibitor therapy is contraindicated
- ZOMIG is contraindicated in patients who are hypersensitive to ZOMIG or any of its inactive ingredients
- ZOMIG should only be used where a clear diagnosis of migraine has been established



PRECAUTIONS AND OTHER SAFETY CONSIDERATIONS

- Following administration of cimetidine, the half-life and AUC of ZOMIG and its active metabolite were approximately doubled
- Selective serotonin reuptake inhibitors (SSRIs) (eg, fluoxetine, fluvoxamine, paroxetine, sertraline) have been reported, rarely, to cause weakness, hyperreflexia, and incoordination when coadministered with 5-HT_1 agonists. If concomitant treatment with ZOMIG and an SSRI is clinically warranted, appropriate observation of the patient is advised
- A single 1-g dose of acetaminophen does not alter the pharmacokinetics of ZOMIG and its N-desmethyl metabolite. However, ZOMIG delayed the T_{max} of acetaminophen by 1 hour
- C_{max} and AUC of ZOMIG increased 1.5-fold after 1 week of dosing with propranolol (160 mg/day). C_{max} and AUC of the N-desmethyl metabolite were reduced by 30% and 15%, respectively. There were no interactive effects on blood pressure or pulse rate following administration of propranolol with ZOMIG
- ZOMIG should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus (see PRECAUTIONS in full Prescribing Information)
- Phenylketonuric patients should be informed that each ZOMIG-ZMT™ (zolmitriptan) 2.5-mg Orally Disintegrating Tablet contains 2.81 mg of phenylalanine (a component of aspartame)

ADVERSE REACTIONS

- Serious cardiac events have occurred during postmarketing surveillance following the use of ZOMIG Tablets. These events are extremely rare and most have been reported in patients with risk factors predictive of CAD. Events reported have included coronary artery vasospasm, transient myocardial ischemia, angina pectoris, and myocardial infarction (see CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS)

Please see full Prescribing Information.

AT ANY STAGE OF THE MIGRAINE HEADACHE

POWERFUL MIGRAINE RELIEF ANYTIME, ANYWHERE

ONSET

- All patients should be encouraged to take their medications as soon as symptoms occur, since 5-HT_1 migraine therapies are generally more effective when taken within the first few hours of a migraine headache[4,5]
- ZOMIG® (zolmitriptan) Tablets are effective when taken early in the migraine headache[1,2]

FULL-BLOWN

- ZOMIG Tablets and ZOMIG-ZMT™ (zolmitriptan) Orally Disintegrating Tablets are equally effective anytime during the headache—even in "full-blown" migraine headache[1,2,15]

ZOMIG is indicated for the acute treatment of migraine with or without aura in adults. ZOMIG should only be used where a clear diagnosis of migraine has been established. ZOMIG should not be administered to patients with hemiplegic or basilar migraine. ZOMIG, like other compounds in this class, should not be given to patients in whom unrecognized coronary artery disease (CAD) is predicted by risk factors unless a cardiovascular evaluation provides satisfactory clinical evidence that the patient is reasonably free of coronary artery and ischemic myocardial disease or other significant underlying cardiovascular disease. Phenylketonuric patients should be informed that each ZOMIG-ZMT 2.5-mg Orally Disintegrating Tablet contains 2.81 mg of phenylalanine (a component of aspartame).

FIRST LINE
Zomig
ZOLMITRIPTAN 2.5 & 5 mg TABLETS

FIRST LINE
Zomig-ZMT
ZOLMITRIPTAN
2.5 mg ORALLY DISINTEGRATING TABLETS

Please visit our web site at www.ZOMIG.com

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Please see CONTRAINDICATIONS and WARNINGS in full Prescribing Information and important prescribing considerations on pages 22-23.

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