

TITLE - RIZATRIPTAN BENZOATE ODT / MAXALT-MLT MAXALT RPD MEDICATION PATIENT INFORMATION IN ENGLISH

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**LABEL: RIZATRIPTAN BENZOATE tablet,
orally disintegrating**



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NDC Code(s): 51991-362-78, 51991-362-99, 51991-363-78, 51991-363-99

Packager: Breckenridge Pharmaceutical, Inc.

Category: HUMAN PRESCRIPTION DRUG LABEL

DEA Schedule: None

Marketing Status: Abbreviated New Drug Application

DRUG LABEL INFORMATION

Updated May 21, 2020

If you are a consumer or patient please visit [this version](#).

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use RIZATRIPTAN BENZOATE ORALLY DISINTEGRATING TABLETS safely and effectively. See full prescribing information for RIZATRIPTAN BENZOATE ...

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1 INDICATIONS AND USAGE

Rizatriptan benzoate orally disintegrating tablets are indicated for the acute treatment of migraine with or without aura in adults and in pediatric patients 6 to 17 years old. Limitations of ...

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Information in Adults - The recommended starting dose of rizatriptan benzoate orally disintegrating tablets is either 5 mg or 10 mg for the acute treatment of migraines in adults. The ...

3 DOSAGE FORMS AND STRENGTHS

Rizatriptan Benzoate Orally Disintegrating Tablets - The 5 mg tablets are white to off-white, round, uncoated tablets, debossed "5" on one side and plain on the other side. The 10 mg tablets ...

4 CONTRAINDICATIONS

Rizatriptan benzoate orally disintegrating tablets are contraindicated in patients with: Ischemic coronary artery disease (angina pectoris, history of myocardial infarction, or documented silent ...

5 WARNINGS AND PRECAUTIONS

5.1 Myocardial Ischemia, Myocardial Infarction, and Prinzmetal's Angina - Rizatriptan benzoate should not be given to patients with ischemic or vasospastic coronary artery disease. There have ...

6 ADVERSE REACTIONS

The following adverse reactions are discussed in more detail in other sections of the labeling: Myocardial Ischemia, Myocardial Infarction, and Prinzmetal's Angina [see Warnings and Precautions ...

7 DRUG INTERACTIONS

7.1 Propranolol - The dose of rizatriptan benzoate should be adjusted in propranolol-treated patients, as propranolol has been shown to increase the plasma AUC of rizatriptan by 70% [see Dosage ...

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy - Risk Summary - Available human data on the use of rizatriptan benzoate orally disintegrating tablets in pregnant women are not sufficient to draw conclusions about ...

10 OVERDOSAGE

No overdoses of rizatriptan benzoate were reported during clinical trials in adults. Some adult patients who received 40 mg of rizatriptan benzoate either a single dose or as two doses with a ...

11 DESCRIPTION

Rizatriptan benzoate orally disintegrating tablets contain rizatriptan benzoate, a selective 5-hydroxytryptamine_{1B/1D} (5-HT_{1B/1D}) receptor agonist. Rizatriptan benzoate is described chemically as ...

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action - Rizatriptan binds with high affinity to human cloned 5-HT_{1B/1D} receptors. Rizatriptan benzoate presumably exerts its therapeutic effects in the treatment of migraine ...

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility - Carcinogenesis: Oral carcinogenicity studies of rizatriptan were conducted in mice (100 weeks) and rats (106 weeks) at doses of up ...

14 CLINICAL STUDIES

14.1 Adults - The efficacy of rizatriptan benzoate tablets was established in four multicenter, randomized, placebo-controlled trials. Patients enrolled in these studies were primarily female ...

16 HOW SUPPLIED/STORAGE AND HANDLING

Rizatriptan Benzoate Orally Disintegrating Tablets are available in strengths of 5 mg and 10 mg containing 7.265 mg or 14.53 mg of rizatriptan benzoate, USP equivalent to 5 mg or 10 mg of ...

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-Approved Patient Labeling (Patient Information). Risk of Myocardial Ischemia and/or Infarction, Prinzmetal's Angina, Other Vasospasm-related Events, and ...

SPL UNCLASSIFIED SECTION

Manufactured by: Natco Pharma Limited, Kothur- 509228, India. Distributed by: Breckenridge Pharmaceutical, Inc., Berlin, CT 06037 - Rev.: Feb/2020 - 346190

PATIENT INFORMATION

RIZATRIPTAN BENZOATE (rye" za trip' tan ben' zoe ate) ORALLY DISINTEGRATING TABLETS - 5 mg and 10 mg - Read this Patient Information before you start taking rizatriptan benzoate and each time you ...

PRINCIPAL DISPLAY PANEL - 5 MG TABLET BLISTER PACK CARTON

NDC 51991-362-78 - Rizatriptan Benzoate Orally - Disintegrating Tablets - 5 mg* PHARMACIST: Dispense the accompanying Patient Information Leaflet to each patient. APPLY PHARMACY LABEL HERE - breckenridge ...

PRINCIPAL DISPLAY PANEL - 10 MG TABLET BLISTER PACK CARTON

NDC 51991-363-78 - Rizatriptan Benzoate Orally - Disintegrating Tablets - 10 mg* PHARMACIST: Dispense the accompanying Patient Information Leaflet to each patient. APPLY PHARMACY LABEL HERE - breckenridge ...

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