D É B R I D A T

(Trimebutine maleate)

QUALITATIVE AND QUANTITATIVE COMPOSITION

Trimebutine maleate: 100 mg per tablet.

Excipient: lactose monohydrate, pre-gelatinized corn starch, hypromellose, sodium starch glycollate, tartaric acid, anhydrous colloidal silica, magnesium stearate, macrogol 4000, coloring agent: titanium dioxide, purified water q.s. 1 film-coated tablet.

PHARMACEUTICAL FORM

Film-coated tablets (white).

THERAPEUTIC INDICATIONS

Gastroenterology:

Polymorphous symptoms of the gastro-intestinal tract, grouped under the irritable bowel syndrome entity or functional digestive disorders, in particular abdominal pain and cramps, spasms, flatulence, diarrhea and/or constipation.

POSOLOGY AND METHOD OF ADMINISTRATION

Follow the doctor's prescription.

For reference: Adults: 1 or 2 tablets 3 times a day.

CONTRAINDICATIONS – DRUG INTERACTIONS

None.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

None.

FERTILITY, PREGNANCY AND LACTATION

Pregnancy:

Studies in animals have not revealed any teratogenic effect. There are no adequate and well controlled studies of trimebutine in pregnant women. There was no evidence of teratogenicity or other adverse developmental effects when trimebutine was administered to pregnant rats and rabbits. Trimebutine should be used during pregnancy only if the potential benefit to the patient outweighs the risk to the patient and fetus.

Lactation:

Safety for use in lactation has not been established.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effect of trimebutine on the ability to drive or use machinery has not been systematically evaluated.

UNDESIRABLE EFFECTS

The following Adverse Drug Reactions (ADRs) have been reported in patients receiving trimebutine.

MedDRA[#] System Organ Class	Frequency	Adverse Drug Reaction
Immune system disorders	Not Known	Hypersensitivity*[†]
Nervous system disorders	Uncommon	Pre-syncope/Syncope**
Skin and subcutaneous tissue disorders	Uncommon	Rash
	Not Known	Severe skin reactions including Acute generalized exanthematous pustulosis*, Erythema multiforme*, Toxic skin eruption*, Dermatitis exfoliative*, and Contact dermatitis*; Dermatitis*, Erythema*, Pruritus*, and Urticaria*

CIOMS III categories: Very Common ≥1/10 (≥10%), Common ≥1/100 to <1/10 (≥1% and <10%), Uncommon ≥1/1000 to <1/100 (≥0.1% and <1%), Rare ≥1/10,000 to <1/1000 (≥0.01% and <0.1%), Very Rare <1/10,000 (<0.01%), Not Known (cannot be estimated from the available data).

[#]MedDRA version 15.
*ADR identified post-marketing.
**Observed primarily with the injectable formulation.
[†] Drug hypersensitivities reported in the post-marketing setting have mainly involved skin (e.g., contact dermatitis, dermatitis, pruritus, urticaria).

OVERDOSE
In the event of overdose, symptomatic treatment should be implemented.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Gastrointestinal motility modifier. Peripheral enkephalinergic agonist.

Trimebutine stimulates intestinal motility (triggering phase-III waves propagated by the migrating motor complex) and inhibits it in the event of prior stimulation.

Pharmacokinetic properties
Peak blood levels of trimebutine after oral administration of tablets were obtained after 1 to 2 hours.

Rapid elimination of trimebutine after oral administration of tablets was mainly in the urine, on average 70% in 24 hours.

Preclinical safety data
Studies in animals have not revealed any teratogenic effect of trimebutine (see FERTILITY, PREGNANCY AND LACTATION).

STORAGE
Do not exceed the expiry date shown on the folding carton. Store below 30°C.

HOW SUPPLIED
Box of 30 film-coated tablets.

PRODUCT OWNER
Pfizer Inc
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New York, NY 10017
United States

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