

# TRIMEDAT

## TRIMEBUTINE

### COMPOSITION

Tablets: each tablet contains 100 mg, of Trimebutine Maleate. Excipients: Polyvinylpyrrolidone, Pregelatinised maize starch, Lactose, Cellulose microcrystalline, Magnesium stearate, Silica precipitated.

Capsules: each capsule contains 150 mg of Trimebutine Maleate. Excipients: Maize starch, Talc, Magnesium stearate. Empty capsule: Gelatine, Ferrous oxide (E 172), Titanium dioxide (E 171), Erythrosine (E 127).

Suspension: 100 g of granules contain 787 mg of Trimebutine. Excipients: ammonium glycyrrhizinate, Polysorbate 80, Methyl p-hydroxybenzoate, essence of lemon powder, saccharose.

**INDICATIONS** - Irritable Bowel Syndrome, spasm related pain of gastrointestinal tract, disturbances of esophageal motility.

**DOSAGE** - Capsules/Tablets: 300-400 mg daily, on average.

Oral suspension: adults: 3-4 table spoonfuls daily, on average.

Children younger than 6 months: half coffeespoonful 3 times daily;

from 6 months to 1 year: 1 coffeespoonful twice daily;

from 1 to 5 years: 1 coffeespoonful 3-4 times daily;

older than 5 years: 2 coffeespoonfuls 3 times daily.

The doses can be increased up to the double on medical advice.

For the extemporary preparation of oral suspension, add drinkable water various times until the liquid level reaches the line on the bottle, when the granular is totally suspended.

Shake the bottle before each administration.

Strictly comply with your physician directions.

**CONTRA-INDICATIONS** - Individual ascertained hypersensitivity to the product.

**SIDE EFFECTS** - Cases of skin reactions.

**PRECAUTIONS** - Oral suspension: diabetic patients should take into account the content in saccharose.

**PREGNANCY AND LACTATION** - Pregnancy: avoid during the first three months of pregnancy.

Lactation: to avoid.

**OVERDOSAGE** - There have been no reports of overdosage in man.

In the event of overdosage a symptomatic treatment should be instituted.

**INTERACTIONS** - No data available about interactions.

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES** - None stated.

**STORAGE** - Store at temperature not exceeding 25° C. After reconstitution, store the oral solution for 4 weeks.

### PACKINGS

20-30 tablets 100 mg.

20-30 capsules 150 mg.

Bottle of 152,5 g of granular powder (containing 1,2 g of Trimebutine) for 250 ml of oral suspension: 5 ml contain 24 mg of Trimebutine.

### KEEP OUT OF THE REACH OF CHILDREN

Manufacturer: **Italfarmaco S.p.A.**

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