

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TRIDAT FORTE 200 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Each tablet contains 200 mg of trimebutine maleate.

Excipients:

Contains lactose monohydrate (180 mg).

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM:

Tablet.

White, biconvex tablets with score line on one side. Printed "TM" over the score line and "20" under the score line.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Used

- for the symptomatic treatment of irritable bowel syndrome (spastic kolon),
- for the symptomatic treatment of functional digestive disorders, and -
- for the symptomatic treatment of gastrointestinal pain.

4.2 Posology and method of administration

Posology/frequency and duration of administration

Used as advised by the physician.

For adults, the usual dose is 1 tablet three times a day.

Treatment with TRIDAT FORTE should be of short duration.

Method of administration:

The tablets should be swallowed without chewing, with a sufficient amount of fluid, e.g. a glass of water.

Additional Information on special populations:

Renal/hepatic failure: No special use.

Pediatric population: Oral suspension form is available for pediatric use.

4.3 Contraindications

Contraindicated in cases of previously demonstrated hypersensitivity to any of the ingredients listed in section 6.1.

Although this medication is reserved for adults, please remember that trimebutine is contraindicated in children under 2 years old.

4.4 Special warnings and precautions for use

TRIDAT FORTE contains lactose monohydrate as excipient. Patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption syndrome (rare hereditary diseases) should not take this medicine.

4.5 Interactions with other medicinal products and other forms of interaction

None reported.

Pediatric population: Oral suspension form is available for pediatric use.

4.6 Pregnancy and lactation

Women of childbearing potential/Contraception

No sufficient information is available on the effect of TRIDAT FORTE on contraception. Women of childbearing potential should consult their physicians about use of a suitable contraceptive method while taking TRIDAT FORTE.

Pregnancy

Studies on animals are insufficient with respect to effects on pregnancy/and-or/embryonic/fetal development/and-or/natal/and-or/postnatal development. Potential risk for humans is unknown. Should be cautiously given to pregnant women.

Given the lack of sufficient studies, use of TRIDAT FORTE during the first trimester of pregnancy is not recommended. Should be used only if required during the 2nd and 3rd trimesters.

Lactation

It is not known whether trimebutine passes into breast milk.

As a precaution, it is best to avoid using trimebutine while breastfeeding.

Fertility

No effects were reported on fertility.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

The undesirable effects have been specified according to the following frequency: Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$); unknown (cannot be estimated from the available data)

Immune system disorders

Frequency not known: hypersensitivity reactions (pruritus, urticaria, angioedema and exceptionally anaphylactic shock)

Skin and subcutaneous tissue disorders

Uncommon: rash

Frequency not known: generalized maculopapular rash, erythema, eczematiform reactions and exceptionally severe skin reactions including cases of acute generalized exanthematous pustulosis (PEAG), erythema multiforme, febrile toxiciderma.

Reporting of suspected adverse reactions

Post approval reporting of suspected adverse drug reactions is of great importance. Reporting allows continuous monitoring of the drug's benefit/risk balance. Healthcare professionals must report any suspected adverse reaction to Turkish Pharmacovigilance Center (TUFAM).

(www.titck.gov.tr; e- mail: tufam@titck.gov.tr; tel: 0 800 314 00 08; fax: 0 312 218 35 99)

4.9 Overdose

In the event of overdose, cardiac disorders such as bradycardia, prolongation of the QTc interval, or tachycardia and neurological disorders such as drowsiness, convulsion and coma may have been observed. Monitoring in a specialized environment is required and symptomatic treatment should be implemented.

5. PHARMACOLOGICAL PARTICULARS

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in functional bowel diseases (Musculotropic Antispasmodic).

ATC Code: A03AA05

(A: digestive system and metabolism)

The effects of trimebutine are exerted in the digestive tract on intestinal motility.

Trimebutine has enkephalinergic agonist properties.

It stimulates intestinal motility by triggering propagated phase III waves of the migrating motor complex and inhibiting it during prior stimulation (in animals).

In vitro, it acts by blocking sodium channels ($IC_{50} = 8.4 \mu M$) and inhibits the release of a nociception mediator (glutamate).

In rats, it inhibits the animal's response to rectal and colonic distension in various experimental models.

5.2 Pharmacokinetic properties

General properties

Absorption

The maximum blood level of trimebutine after oral administration of tablets was obtained after 1 to 2 hours.

Elimination

The elimination of trimebutine after oral administration of tablets was mainly urinary and rapid: 70% on average in 24 hours.

5.3 Preclinical safety data

a) Acute toxicity

Mice LD50 = 5000 mg/kg

Rats LD50 = 5000 mg/kg

Rabbits LD50 = 2500 ± 800 mg/kg

Death is seen as respiratory arrest 24 hours following oral dose.

Repeated dose oral toxicity studies for up to 6 months with trimebutine did not show any deleterious toxicological effects in rats and dogs. Genotoxicity studies (Ames test in vitro, chromosomal aberration and the micronucleus test in vivo) have not shown any mutagenic or clastogenic effect of trimebutine. Trimebutine has no effect on the development and fertility of male and female rats. Reproduction and developmental studies on trimebutine did not demonstrate any teratogenic effects in rats and rabbits. Carcinogenicity studies on trimebutine have not been performed.

b) Chronic toxicity

Trimebutine was given to rats at doses of 40, 220 and 1210 mg/kg/day for 26 weeks. Neither clinical signs nor significant specific organ toxicity were observed. At higher doses, mortality was observed at low incidence. Increased weight was observed in female and male rats at 1210 mg/kg/day dose.

Moderately increased SGPT values were observed in female rats at the end of the treatment period.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Lactose monohydrate

Corn Starch

Microcrystalline Cellulose

Gelatin

Magnesium Stearate

Talc

6.2 Incompatibilities

None reported.

6.3 Shelf Life

36 months.

6.4 Special Precautions for Storage

Store in a dry place at room temperature under 25°C.

6.5 Nature and Contents of Container

In Al/PVC blister packs of 20, 40 or 90 Tablets.

6.6 Special Precautions for Disposal and Other Handling

Any unused product or waste materials should be disposed of in accordance with the “Regulation on Control of Medical Wastes” and “Regulation on Control of Packages and Package Wastes”.
No special requirements.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER(S)

19-00983

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorization: 24.04.2001

Date of renewal: 07.11.2024

10. DATE OF REVISION OF THE TEXT

01.11.2019