

PATIENT INFORMATION LEAFLET

TRIDAT FORTE 200 mg Tablets

Oral use

- **Active substance:** Each tablet contains 200 mg of trimebutine maleate.
- **Excipients:** Lactose monohydrate, corn starch, microcrystalline cellulose, gelatin, magnesium stearate and talk.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you personally. Do not pass it on to others.*
- *If you go your doctor's office or hospital during the use of this medicine, please tell your doctor that you use this medicine.*
- *Please strictly follow the instructions given in this leaflet. Do not ever use higher or lower dose than that recommended to you.*

In this patient information leaflet:

- 1. What TRIDAT FORTE is and what it is used for?**
- 2. What you need to know before you use TRIDAT FORTE.**
- 3. How to use TRIDAT FORTE?**
- 4. Possible side effects**
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1. What TRIDAT FORTE is and what it is used for?

Trimebutine, the active ingredient of TRIDAT FORTE, is a digestive motility regulating agent. Acts as a stimulator on the action on digestive muscle if digestive muscle motility is decreased, and as an anti-spasmodic if digestive muscle motility is increased. This regulatory activity is seen in the whole digestive tract. It restores a physiologic motility in functional digestive diseases related to mobility disorders.

TRIDAT FORTE is used

- for the treatment of irritable bowel syndrome signs (a disease characterized by abdominal pain, flatulence, cramps, spasms, abdominal distension, diarrhea and/or constipation)
- for the treatment of functional digestive disorders signs (conditions in which the digestive system does not function properly and intestinal motility is impaired, and for which an underlying disease is absent/cannot be determined, and
- for the treatment of polymorph symptoms relating to the stomach and intestines (multiple different symptoms seen in the stomach and intestines).

2. What you need to know before you use TRIDAT FORTE

NOT USE TRIDAT FORTE if:

You are hypersensitive to trimebutine or any of the other ingredients of the formulation.

Take special care with TRIDAT FORTE if: No special warnings for use.
If any of these warnings applies to you, even in the past, please consult your doctor.

Taking with food and drink No interactions with food and drink.

Pregnancy

Please consult your doctor before taking the medicine.

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. *If you notice that you are pregnant during your treatment, contact your doctor right away.*

Breastfeeding

Please consult your doctor before taking the medicine.

Should not be given to breastfeeding mothers since it may be excreted into breast milk.

Effects on ability to drive and use of machines

None reported.

Important information on some of the ingredients in TRIDAT FORTE

TRIDAT FORTE contains lactose.

If you have previously been told by your doctor that you are intolerant to some sugars, please contact your doctor before taking this medicine.

Taking with other medicines No interactions with any medicine were reported.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

3. How to use TRIDAT FORTE?

Instructions on appropriate use and dose/administration frequency Used according to the physician's advice.

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

Route and method of administration: The tablets should be swallowed without chewing, with a sufficient amount of fluid, e.g. a glass of water.

Follow these instructions unless otherwise recommended by your doctor.

Various age groups:

Use in children: Oral suspension form is available for pediatric use.

Use in elderly: No restrictions were reported for use in elderly.

Special uses None.

If you think that the effect of TRIDAT FORTE is too strong or too weak, talk to your doctor or pharmacist.

If you take more TRIDAT FORTE than you should

Talk to a doctor or pharmacist if you take more TRIDAT FORTE than you should.



If you forget to take TRIDAT FORTE

Do not take a double dose to make up for the missed dose.

Effects that may occur if you stop taking TRIDAT FORTE None expected.

4. Possible side effects

Like with all medicines, side effects may occur in individuals sensitive to the ingredients in TRIDAT FORTE.

Stop taking TRIDAT FORTE and tell your doctor IMMEDIATELY or go to the emergency department at your nearest hospital if you experience any of the following:

- Swelling of the hands, feet, wrists, ankles, face or lips, or swelling of mouth or throat so severely that cause difficulty swallowing or breathing,
- Skin rash
- Feel faint

All these are very serious side effects.

If you experience any of these this means that you are seriously allergic to TRIDAT FORTE. You may need urgent medical attention or hospitalization. All these very serious side effects are very rarely seen.

Tell your doctor if you notice any of the following:

- Skin reaction
- Dizziness
- Drowsiness

These are mild side effects of TRIDAT FORTE.

If you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

Reporting side effects

Please inform your doctor, pharmacist or nurse if you get any side effect whether or not included in this leaflet. In addition, please report the side effect that you are experiencing to Turkish Pharmacovigilance Center (TÜFAM) by clicking to the icon "Reporting Drug Side Effects" at www.tick.gov.tr or call the reporting hotline dialing 0 800 314 00 08. By reporting the side effects, you can help provide more information on the safety of this medicine.

5. How to store TRIDAT FORTE?

Store TRIDAT FORTE in its original packaging, out of sight and reach of children. Store at room temperature under 25°C.

Use in accordance with the expiry date.

Do not use TRIDAT FORTE after the expiry date on the package.



6. Further Information

What TRIDAT FORTE contains

- The active substance of TRIDAT FORTE is trimebutine maleate. Each tablet contains 200 mg of trimebutine maleate.
- The other ingredients are lactose monohydrate, corn starch, microcrystalline cellulose, gelatin, magnesium stearate, talc.

What TRIDAT FORTE looks like and contents of the pack

TRIDAT FORTE is presented in blisters of 20, 40 or 90 tablets packaged in boxes. The tablets are white, biconvex tablets with score line on one side. Printed “TM” over the score line and “20” under the score line.

Marketing Authorization Holder:

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Manufacturer:

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GEBKİM Kimya İhtisas Organize San.
Bölgesi, Çerkeşli Yolu Üzeri, Erol Kiresepi
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