

PATIENT INFORMATION LEAFLET

TRIBUDAT 24 mg/5 ml granule for preparing oral suspension

For oral use

- **Active substance:** Each 5 ml (one scale) suspension contains 24 mg trimebutine.
- **Excipients:** Sugar, FDC Yellow 6, tween 80, natural orange flavor.

Read all of this 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 any further questions, ask to your doctor or pharmacist.*
- *This medicine has been prescribed for you only; do not share it with another person.*
- *During the usage of this drug, when you visit the doctor or the hospital, inform your doctor about this.*
- *Respect the instructions given to you about your drug. Do not use a dose above or below the dose prescribed for you.*

In this Leaflet:

1. ***What TRIBUDAT is and what it is used for?***
2. ***What you need to know before you take TRIBUDAT***
3. ***How to take TRIBUDAT?***
4. ***Possible side effects***
5. ***How to store TRIBUDAT***

Sections are presented.

1. What TRIBUDAT is and what it is used for?

TRIBUDAT is presented in 250 ml-labeled glass bottle with 5 mL-labeled scale. It is from light orange color to orange color, a homogeneous crystalline powder without foreign particles.

The active ingredient of TRIBUDAT is an agent regulating gastrointestinal motility. If there is a reduction in gastrointestinal muscle movements, it stimulates gastrointestinal muscle; if there is an increase in gastrointestinal muscle movements, it removes the spasm in that area. This regulatory efficacy is seen over the entire gastrointestinal tract. In functional gastrointestinal disorders due to the motility disorders; it regulates physiological motility.

TRIBUDAT is used for the treatment of:

- In the treatment of symptoms of irritable bowel syndrome (abdominal pain, wind, cramp, spasm, swelling, disease characterized by symptoms such as diarrhea and/ or constipation)
- In the treatment of symptoms of functional gastrointestinal disorders (situations where there is no underlying disease or unidentified, the digestive system does not work regularly, bowel movements are not smooth)
- In the treatment of various symptoms (associated with stomach and intestines).

2. What you need to know before you take TRIBUDAT

DO NOT USE TRIBUDAT

Do not use this medicinal product if you have an allergic to trimebutine or any of the other ingredients of TRIBUDAT.

Do not use the drug in children under 2 years.

TAKE SPECIAL CARE WITH TRIBUDAT

There is no special precaution for use.

If these warnings at any time in history even apply to you, please consult your doctor.

Using TRIBUDAT with food and drink

Not applicable.

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

Since there is no sufficient study; it is not proposed to use in the first 3 months of pregnancy. It should be used by the decision of your doctor in second and third periods, if necessary.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Breast Feeding

Ask your doctor or pharmacist for advice before taking this medicine.

It should not be given to nursing mothers as it may pass into breast milk.

Driving and using machine

Not applicable.

Important information regarding some excipients in TRIBUDAT

As this medicinal product contains “FDC Yellow 6” which is an azo colorant; it may cause allergic reactions.

TRIBUDAT contains 2.96 g sugar per scale (5 mL). If you have been told by your doctor that you cannot tolerate some sugar (hereditary problems such as fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency); talk to your doctor before taking this medicinal product.

Pediatric population:

Since 10 mL of the suspension contains 5.92 g sucrose, this should be considered in patients with diabetes mellitus.

Adults:

Since 15 mL of the suspension contains 8.88 g sucrose, this should be considered in patients with diabetes mellitus.

Taking with other drugs

If you are taking or have recently taken any other medicines including medicines obtained with or without a prescription, please tell your doctor or pharmacist.

3. How to take TRIBUDAT?

Instruction for appropriate use and dose/application frequency:

Adults:

15 mL scale three times in a day.

In exceptional cases, the dose may be increased up to 6 times a day in a 15 mL scale.

Route and method of application:

The oral suspension is prepared by filling water up to the line on the bottle and should be shaken well. The suspension should be allowed to stand for 5 minutes. Additional water should be added to the suspension to the line level to complete the reduced suspension volume and should be shaken well again.

The suspension may be administered directly or with a sufficient amount of fluid.

The scale should be thoroughly cleaned after each use.

Different age groups:

Children:

TRIBUDAT could only be given to children older than 2 years; Do not use this medicine in children under 2 years.

The proposed dose for children:

- Children 2 – 5 years: 5 mL (one 5 mL scale) three times in a day
- Children over the age of 5 years: 10 mL (two 5 mL scales) three times in a day

In other words, daily dose is 5 mL scale per 5 kg of the body weight.

Elderly:

Not applicable.

Special population:

Renal/hepatic impairment:

There is no special use in patients with renal/hepatic impairment.

If you think that the effect of TRIBUDAT is very strong or very poor, please tell your doctor or pharmacist.

If you use more TRIBUDAT than you should:

If you have used more than necessary to use from TRIBUDAT, please tell your doctor or pharmacist or contact nearest hospital emergency department immediately.

If you forget to take TRIBUDAT

Do not take double doses to compensate for forgotten dose.

Before stopping TRIBUDAT treatment

There is no discontinuation symptom.

4. Possible side effects

Like all medicines, side effects may occur in people who are hypersensitive to the ingredients of TRIBUDAT.

STOP taking TRIBUDAT and contact a doctor immediately if you notice any of the following serious side effects:

- Swelling of your hands, feet, ankles, face, lips or throat that have difficulties in breathing or swallowing
- Skin rash
- Syncope

All of these are very serious side effects.

If you experience one of these side effects, it means that you are allergic to TRIBUDAT. Urgent medical intervention or hospitalization may be required.

These very serious side effects are seen very rare.

Tell your doctor if you notice any of the followings:

- Skin reaction
- Dizziness
- Somnolence

This side effect is a mild side effect of TRIBUDAT.

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

5. How to store TRIBUDAT

Keep out of TRIBUDAT sight and reach of children in its original packaging.

Store at room temperature below 25 °C. Following dilution, the oral suspension should not be stored for more than 4 weeks.

Use within shelf life.

Do not use TRIBUDAT after the expiry date which is stated on the package/outer box.

Do not use TRIBUDAT if you notice any defects on the product and/or packaging.

Manufacturing authorization holder:

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