

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TRIBUDAT 24 mg/5 ml granule for oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Drug substance:

Each 5 mL (one scale) suspension contains 24 mg trimebutine.

Excipients:

Each 5 mL (one scale) suspension contains 0.05 mg FDC Yellow and 2.96 g sugar .

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

from light orange color to orange color, a homogeneous crystalline powder without foreign particles.

4. CLINICAL PARTICULARS

4.1 Therapeutical Indications

It is indicated for the symptomatic treatment of following conditions:

- Irritable bowel syndrome (spastic colon)
- Functional gastrointestinal disorders
- Gastrointestinal polymorphic symptoms

4.2 Posology and method of administration

Posology/frequency and duration of administration:

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.

Children:

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.

Method of administration:

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

The scale should be thoroughly cleaned after each use.

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. Following the dilution of the medicinal product; an opaque, orange colored, orange flavored and sugar-tasted syrup-like suspension is obtained.

Additional information on special population:

Renal/hepatic insufficiency:

Not applicable.

Pediyatrik popülasyon:

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

Geriatric population:

Not applicable.

4.3 Contraindications

It is contraindicated in patients have hypersensitivity to any of the components.
Contraindicated using in children under 2 years.

4.4 Special warnings and precautions for use

TRIBUDAT should not be used in children under 2 years.

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

This medicinal product contains 2.96 g sucrose per 5 mL scale. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Pediatric population:

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

Adults:

Since 10 mL of the suspension contains 8.88 g sucrose, this should be considered in patients with diabetes mellitus.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

Additional information on special population

Not applicable.

Pediatric population:

There are no interaction studies of the pediatric population.

4.6 Pregnancy and lactation

General recommendation

Pregnancy category: B

Women of childbearing potential/Contraception

No teratogenic effects were found in animal's studies. Since there was no teratogenic effect in animals, TRIBUDAT is not expected to lead malformation in human. To date, in studies conducted on both sexes, the compounds known to lead malformation in humans were also shown to have teratogenic potential in animals.

Pregnancy

Studies in animals are insufficient in terms of effects on pregnancy / and / or / embryonal / fetal development / or / birth / and / or / postnatal development.

The potential risk for humans is unknown.

Should be cautious when giving pregnant.

Due to insufficient studies, it is not recommended to use TRIBUDAT in the first trimester of pregnancy. In second and third trimester; it should only be used, when necessary.

Lactation

TRIBUDAT may be used in lactation period.

Fertility

No effect on fertility has been reported.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

Frequencies of adverse reactions are defined as follows: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1000$ to $< 1/100$), rare ($\geq 1/10.000$ to $< 1/1000$), very rare ($< 1/10.000$), or not known (cannot be estimated from the available data).

Nervous system diseases

Rare: Dizziness, somnolence

Skin and subcutaneous tissue diseases

Very rare: Cutaneous reactions

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

4.9 Overdose

In case of overdose, symptomatic treatment should be administered.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in Functional Gastrointestinal Disorders
(musculotropic antispasmodics)

ATC code: A03AA05

The active ingredient of TRIBUDAT is an agent regulating gastrointestinal motility

By acting encephalinergetic agonist on excitatory and inhibitory receptors; stimulates the hypokinetic digestive muscles; as spasmolytic effect on hyperkinetic digestive muscles. This regulatory activity occurs throughout the entire digestive tract. In functional digestive diseases due to motility disorders; reorganize physiological motility.

5.2 Pharmacokinetic properties

General properties

Absorption

Taking together with food does not significantly affect the bioavailability.

Distribution

Trimebutine reaches the highest plasma level after 1-2 hours from enteral administration.

Biotransformation

4-6 % of the drug substance remains unchanged as a result of first pass metabolism in liver.

Elimination:

Trimebutine is excreted in the urine, about 70 % of the drug substance is eliminated within 24 hours. The half-life of the most prominent metabolite is about 4 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 occurs as a respiratory arrest within 24 hours following oral dosing.

b) Chronic toxicity

Trimebutin was given to rats at doses of 40, 220 and 1210 mg / kg / day for 26 weeks. No clinical signs or significant specific organ toxicity were observed in rats. Mortality was observed at low incidence at high doses. Weight gain was observed in female and male rats at a dose of 1210 mg / kg / day. A moderate increase was observed in SGPT values at the end of the treatment period in female rats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sugar

FDC Yellow 6

Tween 80

Natural Orange Flavor

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

36 months

6.4 Special precautions for storage

Store at room temperature below 25°C.

6.5 Nature and contents of container

Presented in 250 mL-labeled gravure amber colored glass/white plastic pilfer proof cap along with 5 mL-labeled spoon and packaging information leaflet.

6.6 Special precautions for disposal and other handling

Unused products or waste materials should be disposed in accordance with the “Medical Waste Disposal Directive” and “Packaging and Packaging Waste Directive”.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

221/75

9. DATE OF FIRST AUTHORISATION /RENEWAL OF THE AUTHORISATION

Date of first authorization: 09.11.2009
Renewal of the authorization: 09.07.2018

10. DATE OF REVISION OF THE SPC
