

DIRECTIONS FOR USE

TENEDES 0,5 mg / mL Syrup
Oral

- Active ingredient: Each 1 ml contains 0.5 ml of Desloratadine
- Excipients: Propylene glycol, sorbitol, Anhydrous citric acid, sodium citrate, sodium benzoate, disodium EDTA, deionized water, sucrose, bubble gum flavor and fd & c 6 sunset yellow.

You should read this DIRECTIONS FOR USE carefully before you start using this medicine, because it contains important information for you.

- Save these directions for use. You can need to read again.
- This medicine has been prescribed for you personally, do not give it to anyone else.
- When using this medicine, if you see a doctor or go to hospital, tell them you are using this medicine.
- Adhere to the instructions in this instrument. Do not use **high or low** doses other than recommended dose for the medication.

In this DIRECTIONS FOR USE, following titles are indicated:

1. What is TENEDES and what is it used for?
2. Points to consider before using TENEDES
3. How to use TENEDES?
4. What are the possible side effects?
5. Storage of TENEDES

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

TENEDES is a syrup that is presented in a box with amber-colored Type III glass bottle (150 ml) and has a PP measuring spoon scaled with 2, 2.5 and 5 ml.

TENEDES is an anti-allergic drug which does not cause drowsiness. It helps to control allergic reactions and allergic symptoms.

TENEDES relieves symptoms such as sneezing, nasal flow and itching, palate itching and eye itching, redness or lachrymation (eg hay fever, allergy to house dust mite) associated with allergic rhinitis.

TENEDES is also used to eliminate symptoms such as rash with urticaria, papilloma and redness.

Elimination of these symptoms will last all day and will help you to continue your regular daily activities and sleep.

2. Points to consider before using TENEDES

DO NOT use TENEDES in the following situations:

If,

- You have hypersensitivity (allergic) to any of the excipients of TENEDES such as desloratadine, loratadine or, in particular, the coloring agent FD & C 6 sunset yellow.

TENEDES is indicated for children aged 6 months to 11 years, adolescents (12 years and older) and adults including old people.

Use TENEDES cautiously in the following situations:

If,

- your kidney functions are weak.

Please consult your doctor if these warnings apply to you at any time in the past.

Using TENEDES with food and beverages:

TENEDES can be taken on empty or full stomach.

Pregnancy

Consult your doctor or pharmacist before using this medication.

If you are pregnant, do not use TENEDES.

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

Breast-feeding

Consult your doctor or pharmacist before using this medication.

If you are breastfeeding, do not use TENEDES.

Vehicle and machine use

At the recommended doses, it is unlikely that TENEDES will cause you to be asleep or lose your attention. Although rare, TENEDES may cause drowsiness in some patients. This can affect your ability to drive vehicle and use machines.

Important information about some of the excipients contained in TENEDES

TENEDES contains sucrose and sorbitol. If you have previously been told by your doctor that you are unstable to some sugars, you should consult your doctor before taking this medicinal product.

TENEDES contains FD & C 6 sunset yellow as colourant. It may cause allergic reactions.

This medicinal product contains less than 1 mmol (23 mg) of sodium per dose; No side effects associated with it are expected.

This medicinal product contains 100mg / ml propylene glycol. Side effects due to propylene glycol are not expected at this dose.

Using with other medicines

TENEDES has no known interaction with other drugs.

If you are currently using or have used a prescription or non-prescription drug, please tell your doctor or pharmacist about them.

3. How to use TENEDES?

Instructions for proper use and dose / application frequency:

Children from 6 to 11 months:

Take 2 ml syrup once a day. Use the measuring spoon by fill up to 2 ml.

Children from 1 to 5 years:

Take 2.5 ml syrup once a day. Use the measuring spoon by fill up to 2.5 ml.

Children between 6 and 11 years:

Take 5 ml syrup once a day. Use the measuring spoon by fill up to 5 ml.

Adults, children 12 years and over:

Take 10 ml of syrup once a day. Use the measuring spoon twice by filling up to 5 ml.

Regarding the duration of the treatment, your doctor will decide how long you should take TENEDES by deciding what type of allergic rhinitis you have.

If your allergic rhinitis, intermittent type (symptoms occur less than 4 days a week or less than 4 weeks), your doctor will evaluate the history of the disease and will give you a treatment schedule in this direction.

If your allergic rhinitis is a permanent / persistent type (symptoms last for 4 days or more per week and longer than 4 weeks), your doctor may offer you a longer treatment.

The duration of treatment with urticaria may vary from patient to patient, so you should follow your doctor's instructions.

Route and method of administration:

Drink some water after taking syrup. You can get TENEDES with or without food.

Different age groups:

Use in children:

TENEDES is used since 6 months.

Use in old people:

The efficacy and reliability of TENEDES has not yet been determined in old people.

Specific using cases

Liver failure

There are no data on liver failure.

Kidney failure

TENEDES should be used with caution in severe renal failure.

If you have an impression that the effect of TENEDES is too strong or weak, talk to your doctor or pharmacist.

If you used more TENEDES than you need

Use TENEDES only as long as you are prescribed. Serious problems associated with accidental overdose are not expected.

If you used more TENEDES than you need, talk to a doctor or pharmacist.

If you forget to use TENEDES

If you forget to take dose you need in time, take this dose when you remember, then continue with your treatment as usual.

Do not take double doses to compensate forgotten doses.

Effects that may occur when treatment with TENEDES is terminated

No effect has been reported.

4. What are the possible side effects?

As with all medicines, there may be side effects in people sensitive to substances in TENEDES. Side effects in adults are similar to placebo (a type of drug without therapeutic properties). However, side effects that are common in children less than 2 years are diarrhea, fever and insomnia and fatigue, mouth dryness and headache in adult are more frequently observed side effects than placebo.

The undesirable events are listed below according to the system organ class. The frequencies are defined as follows:

In different organ systems;

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 given data).

Common: Fatigue.

Uncommon: Mouth dryness, headache.

Very rare: Allergic reactions (difficulty in breathing, wheezing, itching, urticaria, rash), hallucinate, stroke, restlessness with increased body movement, palpitations, acceleration of heart beat, abnormality in liver function tests, inflammation in the liver, dizziness, mental hyperactivity, stomach ache, nausea (illness), vomiting, diarrhea, insomnia, drowsiness, muscle aches, swelling, bloating.

If you experience any side effects not mentioned in these directions for use, inform your doctor or pharmacist.

Reporting of side effects:

Talk to your physician, pharmacist or nurse if you have any side effects that are not included in this Directions for Use. You should also notify the Turkish Pharmacovigilance Center (TÜFAM) about the side effects you are encountering by clicking on the "Drug Side Effects" icon on www.titck.gov.tr or by calling the side effect notification line 0 800 314 00 08. By reporting side effects, you will contribute to learning more about the safety of the medicine you are using.

If you encounter a side effect not mentioned in these instructions, please tell your doctor or pharmacist.

5. Storage of TENEDES

Store at places to which children cannot see, reach and in their original packaging.
Store at room temperature and below 25 ° C.

Use in accordance with expiry date.

Do not use TENEDES after the expiration date on the packaging.
Do not use TENEDES if you notice any defects in the product and / or packaging.

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