

PATIENT INFORMATION LEAFLET

ANTHIX 10 mg tablet

Administered orally.

- **Active Substance:** Each tablet contains 12.80 mg rupatadine fumarate, equivalent to 10 mg rupatadine.
- **Excipients:** Bovine lactose, microcrystalline cellulose, red iron oxide, yellow iron oxide, pregelatinized starch, magnesium stearate and deionized water .

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

- *Keep this **PATIENT INFORMATION LEAFLET**. You may need to read it again.*
- *If you have any additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you. Do not pass it on to others.*
- *When you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*

In these leaflets Please completely follow the instructions in this information leaflet. Do not use **higher or**

lower doses of ANTHIX than what is intended for you.

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

2. What you need to know before you take ANTHIX?

3. How to use ANTHIX?

4. Possible side effects

5. How to store ANTHIX?

are explained.

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

ANTHIX in each tablet contains 12.80 mg rupatadine fumarate, equivalent to 10 mg rupatadine; it is presented in 20 and 30 tablet blister packages. Tablets are biconvex, round, light salmon-colored tablets.

ANTHIX removes the symptoms of seasonal (intermittent) or perennial (persistent) allergic rhinitis, such as sneezing, nasal discharge, eye and nose itching in the 12 years and older patients.

ANTHIX is also used in removal of symptoms, related to urticaria (an allergic rash) such as itching, redness and swelling on skin.

2. What you need to know before you take ANTHIX?

DO NOT TAKE ANTHIX in the following conditions

If:

- You are allergic to the effective substance or any excipients of ANTHIX.
- You must not use in children under 12 years of age.

TAKE special care with ANTHIX in the following conditions

If:

- You have a heart condition,
- You have low blood potassium levels and in case your heartbeat is significantly low,
- You are adolescent,
- You have some metabolic conditions, use with caution (in case you are intolerant to certain sugars).
- You are older than 65 years of age.
- You have liver and kidney function problems.

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

Taking ANTHIX with food and drink

Do not use with grapefruit juice.

Pregnancy

Please consult your doctor or pharmacist before using the medicine.

Do not use during pregnancy without consulting your physician.

If you notice that you have been pregnant during treatment, consult immediately your doctor.

Breastfeeding

Please consult your doctor or pharmacist before using the medicine.

Since it is unknown whether ANTHIX is excreted in breastmilk, do not use it without consulting your physician.

Driving and using machinery

Be careful when driving or using machinery.

Important information on some excipients present in ANTHIX

If you have been told by your doctor that you had intolerance against some sugars (your intolerance) because of the bovine lactose in, contact your doctor before taking this medicinal product.

Taking with other medicines

There is no evidence, pointing that ANTHIX has any interactions with any medicines.

Do not use ANTHIX together with ketoconazole (a pharmaceutical, used in the treatment of fungal infections), erythromycin (an antibiotic) and grapefruit juice.

In case you take statins (general name, given to cholesterol lowering drugs) or in case you take alcohol, use your medication with caution.

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

3. How to use ANTHIX?

- **Instructions for appropriate usage and dosage/application frequency:**

Recommended dose is 1 tablet (10 mg) per day.

- **Route and method of administration:**

Only for oral administration.

Swallow the tablets with some water. Do not chew.

- **Different age groups:**

Use in children:

Must not be used in children below 12 years of age.

Use in elderly:

ANTHIX must be used carefully in elderly.

- **Special usage conditions:**

Kidney/Liver failure:

Due to lack of clinical experience, using in patients with liver and kidney failure is not recommended.

If you have the impression that the effect of ANTHIX is too strong or weak, talk with your doctor or pharmacist.

If you take more ANTHIX than you should

If you used more ANTHIX than was prescribed, tell your doctor or pharmacist.

If you forget to use ANTHIX

Take the skipped dose as soon as you remember.

Do not take double dose to make up the dose you have missed.

Effects that may occur on termination of treatment with ANTHIX

No effects have been reported.

4. What are the possible side effects?

Like all medicines, ANTHIX may cause side effects in patients sensitive to its ingredients.

If any of the following reactions happen, stop taking ANTHIX and tell your doctor immediately or contact the casualty department at your nearest hospital

Swelling of hands, feet, ankles, face, lips or in particular hindrance of swallowing or breathing due to swelling of mouth or throat.

These are all very serious side effects.

If you experience one of these side effects it means that you are severely allergic to ANTHIX. You may need urgent medical attention or to be hospitalized.

These very serious side effects are all rare.

If any of the following occurs, call your doctor IMMEDIATELY and refer to the emergency service of the nearest hospital:

- Distress
- Nosebleeding
- Upper and lower abdominal pain
- Nausea, vomiting
- Muscle, back or joint pain

“These are all very serious side effects. Immediate medical response may be required.”

“These very serious side effects are all rare.”

If you experience any of the following side effects, you should inform your doctor:

- Dizziness
- Headache
- Dizziness
- Fatigue, exhaustion
- Disturbance in attention
- High fever or sore throat
- Increased appetite
- Mouth, throat or nose dryness
- Diarrhea or constipation
- Disturbance in stomach or burning sensation in chest
- Redness on skin

“These are mild side effects of ANTHIX.”

Tell your doctor or pharmacist if you notice any other effects not listed in this leaflet.

Reporting of side effects

Talk to your doctor, pharmacist or nurse if you experience any side effects listed or not listed in this leaflet. Also reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system

5. Storage of ANTHIX

Store ANTHIX in its original packaging and keep out of the reach and sight of children.

Store at room temperature below 30°C.

Use in compliance with the expiry date.

Do not use ANTHIX after the expiry date which is stated on the packaging.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

Santa Farma İlaç San. A.Ş.

Halide Edip Adıvar Mahallesi, Boruçiçeği Sokak, No: 16 34382 Şişli- İSTANBUL 24

Tel: (+90 212) 220 64 00

Fax: (+90 212) 222 57 59

Manufacturing Site:

Santa Farma İlaç San. A.Ş. GEBKİM 41455 Dilovası - KOCAELİ

Tel: (+90 262) 674 23 00

Fax: (+90 262) 674 23 21

This leaflet has been approved on