

PATIENT INFORMATION LEAFLET FOR TEXA 10 mg TABLETS AND TEXA SYRUP

SCHEDULING STATUS:

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

TEXA 10 mg (tablets)

TEXA SYRUP (syrup)

Read this entire leaflet carefully before you start taking TEXA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **TEXA** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT TEXA CONTAINS:

TEXA 10 mg: Each film-coated tablet contains 10 mg cetirizine hydrochloride.

TEXA SYRUP: Each 1 ml contains 1 mg cetirizine dihydrochloride.

2. WHAT TEXA IS USED FOR:

TEXA is used to relieve symptoms of allergic conditions such as hay fever (allergic rhinitis) and allergic skin conditions such as hives (urticaria).

3. BEFORE YOU TAKE TEXA:

Do not take TEXA:

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- If you are hypersensitive (allergic) to cetirizine, or any of the ingredients of **TEXA**
- If you are hypersensitive (allergic) to hydroxyzine (a medicine used to treat allergic conditions or anxiety)
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**)

Children younger than two years, should not be given **TEXA**.

Take special care with TEXA:

- Use **TEXA** with caution if you suffer from a condition called porphyria (a hereditary disease affecting the blood)
- **TEXA** lacks significant sedative (tranquilizing) effects, but can have an effect on certain individuals, especially when alcohol is consumed at the same time (see **Taking other medicines with TEXA and Driving and using machines**)

Taking TEXA with food and drink

TEXA may be taken with or without meals.

Pregnancy and breastfeeding:

If you are pregnant or breast feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **TEXA**.
(see **Do not take TEXA**).

Driving and using machines:

TEXA lacks significant sedative (tranquilizing) effects, however, a small number of individuals may experience drowsiness, which can worsen when

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TEXA is combined with alcohol consumption or other calming medicine. Do not drive or operate any machinery before you know how **TEXA** affects you.

Taking other medicines with TEXA:

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

Please inform your doctor or pharmacist if you are taking or have taken any of the following:

- Alcohol
- Tranquilizers (medicines causing sedation or drowsiness)

4. HOW TO TAKE TEXA:

Always take **TEXA** exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of **TEXA** is too strong or too weak, talk to your doctor or pharmacist.

TEXA 10 mg tablets:

Adults or children 12 years of age or older:

The usual dose is 10 mg (one tablet), once daily.

Children 6 to 12 years old:

The usual dose is 5 mg (half tablet) twice daily or 10 mg (one tablet), once daily.

TEXA SYRUP:

Adults or children 12 years of age or older:

The usual dose is 10 mg (10 ml) once daily.

Children 6 to 12 years old:

The usual dose is 10 mg (10 ml) once daily, either as a single dose or as

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divided doses of 5 ml in the morning and 5 ml in the evening.

Children age 2 to 6 years:

The usual dose is 5 mg (5 ml) as a single dose or as divided doses of 2,5 ml in the morning and 2,5 ml in the evening.

Elderly patients:

No dose adjustment is necessary in healthy elderly patients with normal kidney function.

Kidney and liver impairment

Your doctor will determine the dose.

If you take more TEXA than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Symptoms of overdose may be drowsiness and in children cause anxiety, sleepiness, rash, not emptying the bladder when urinating, fatigue, tremor, and rapid heartbeat.

If you forget to take TEXA:

Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

TEXA can have side effects. Not all side effects reported for **TEXA** are included in this leaflet. Should your general health worsen while taking **TEXA**, please consult your doctor, pharmacist or other health care

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professional for advice.

If any of the following happens, stop taking **TEXA** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, lips, mouth or throat which may cause difficulty in breathing
- rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **TEXA**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

- Nausea, vomiting, stomach discomfort, diarrhoea
- Constipation
- Increased appetite
- Dry mouth
- Thickening of mucous
- Drowsiness
- Fatigue, not feeling well, lack of energy
- Headache, dizziness
- Feeling anxious or nervous

6. STORING AND DISPOSING OF TEXA:

- Store in a cool, (below 25 °C), dry place.
- Keep the blisters in the carton until required for use.
- **KEEP OUT OF REACH OF CHILDREN.**
- Do not use after the expiry date printed on the container or carton.

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- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF TEXA:

TEXA 10 mg tablets: Aluminium/PVC blister packs of 10, 30 or 500 tablets.

TEXA SYRUP: Type 3 amber glass bottle with a tamper evident, white coloured polyethylene closure. Pack sizes: 50 ml, 150 ml and 200 ml.

8. IDENTIFICATION OF TEXA:

TEXA 10 mg tablets: Film-coated, white to off-white convex, elliptical tablets scored on one side.

TEXA SYRUP: Clear or almost clear, colourless solution with taste and odour of banana.

9. REGISTRATION NUMBERS:

TEXA 10 mg tablets: 35/5.7.1/0314

TEXA SYRUP: 41/5.7.1/0086

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Pharma Dynamics (Pty) Ltd

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7945

11. DATE OF PUBLICATION:

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