PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

TELFAST® SUSPENSION, 30 mg/5 mL, oral suspension

Fexofenadine hydrochloride

Contains sugar (1 g sucrose and 0,5 g xylitol per 5 mL).

Read all of this leaflet carefully because it contains important information for you

TELFAST® SUSPENSION is available without a doctor's prescription, for you or your child to treat a mild illness. Nevertheless, you or your child still need to use TELFAST® SUSPENSION carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share TELFAST® SUSPENSION with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What TELFAST® SUSPENSION is and what it is used for
2. What you need to know before you take TELFAST® SUSPENSION
3. How to take TELFAST® SUSPENSION
4. Possible side effects
5. How to store TELFAST® SUSPENSION
6. Contents of the pack and other information.

1. What TELFAST® SUSPENSION is and what it is used for

TELFAST® SUSPENSION contains fexofenadine hydrochloride which belongs to a group of medicines called antihistamines.

TELFAST® SUSPENSION is used in children from 2 to 11 years to relieve the symptoms that occur with seasonal allergic rhinitis (hay fever) such as sneezing, runny nose, itchy nose, mouth, throat, and itchy, watery, red eyes.

TELFAST® SUSPENSION is also used in children from 6 months to 11 years to relieve symptoms of a long-term allergic skin reaction (hives) such as itchy, raised, red bumps.

2. What you need to know before you take TELFAST® SUSPENSION

Do not take TELFAST® SUSPENSION:

- If you or your child are hypersensitive (allergic) to fexofenadine hydrochloride or any of the other ingredients of TELFAST® SUSPENSION (listed in section 6).

Warnings and precautions

Take special care with TELFAST® SUSPENSION:

- If you are an elderly patient.
- If you or your child have any kidney or liver problems.
- TELFAST® SUSPENSION doesn't have notable calming effects.

Other medicines and TELFAST® SUSPENSION

Always tell your health care provider if you or your child are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you or your child are currently taking:

- Erythromycin (used to treat a bacterial infection).
- Ketoconazole (used to treat a fungal infection).
- Antacids (used to neutralise the acid in your stomach to relieve indigestion or heartburn).

TELFAST® SUSPENSION with food and drink

You or your child should not take TELFAST® SUSPENSION with fruit juices such as grapefruit,

orange or apple juice, as it may reduce the absorption and lowers the effect of TELFAST® SUSPENSION.

Pregnancy, breastfeeding and fertility

The safety of TELFAST® SUSPENSION in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking TELFAST® SUSPENSION.

Driving and using machines

TELFAST® SUSPENSION is unlikely to affect your ability to drive a vehicle or use machines. However, if you experience sleepiness, dizziness or feeling overtired or weak, you should not drive or operate machinery.

It is not always possible to predict to what extent TELFAST® SUSPENSION may interfere with your daily activities. Do not engage in the above activities until you are aware of the measure to which TELFAST® SUSPENSION affects you.

TELFAST® SUSPENSION contains sucrose, xylitol, sodium and propylene glycol

TELFAST® SUSPENSION contains sugars (sucrose and xylitol). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TELFAST® SUSPENSION. TELFAST® SUSPENSION may be harmful to the teeth, if taken for chronic use.

TELFAST® SUSPENSION contains less than 1 mmol sodium (23 mg) per 5 mL, that is to say essentially “sodium-free”.

TELFAST® SUSPENSION contains 125 mg propylene glycol in each 5 mL. If your child is less than 5 years old, talk to your doctor or pharmacist before giving them TELFAST® SUSPENSION,

in particular if they use other medicines that contain propylene glycol or alcohol.

3. How to take TELFAST® SUSPENSION

Always take TELFAST® SUSPENSION exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Shake the bottel well, before each use.

Seasonal allergic rhinitis

Children 2 to 11 years:

- The recommended dose of TELFAST® SUSPENSION is 30 mg (5 mL) twice daily.
- A dose of 30 mg (5 mL) once daily is recommended as the starting dose in paediatric patients with decreased renal function.

Chronic idiopathic urticaria

Children 6 months to 11 years:

- The recommended dose of TELFAST® SUSPENSION is 30 mg (5 mL) twice daily for patients 2 to 11 years of age and 15 mg (2,5 mL) twice daily for patients 6 months to less than 2 years of age.
- For paediatric patients with decreased renal function, the recommended starting doses of TELFAST® SUSPENSION are 30 mg (5 mL) once daily for patients 2 to 11 years of age and 15 mg (2,5 mL), once daily for patients 6 months to less than 2 years of age.

If you take more TELFAST® SUSPENSION than you should

Symptoms of overdose may include dizziness, sleepiness and dry mouth.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take TELFAST® SUSPENSION

Take the missed dose as soon as you remember. However, if it is almost time for your next dose, continue to take the next dose at the usual time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

TELFAST® SUSPENSION can have side effects.

Not all side effects reported for TELFAST® SUSPENSION are included in this leaflet. Should you or your child's general health worsen or if you or your child experience any untoward effects while taking TELFAST® SUSPENSION, please consult your health care provider for advice.

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Chest tightness, shortness of breath.
- Rash or itching.
- Fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache, drowsiness, dizziness.
- Nausea (feeling sick).

Less frequent side effects:

- Feeling overtired or weak (fatigue).

- Insomnia (difficulty falling or staying asleep), nervousness, sleep disorders, excess of morbid dreams and nightmares (paroniria).
- Skin rash, itching, hives.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of TELFAST® SUSPENSION.

5. How to store TELFAST® SUSPENSION

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep well closed.
- Shake the bottle well, before each use.
- Do not use after the expiry date printed on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TELFAST® SUSPENSION contains

The active substance is fexofenadine hydrochloride.

Each 1 mL contains 6 mg fexofenadine hydrochloride.

Each 5 mL dose will provide 30 mg of fexofenadine hydrochloride.

The other ingredients are artificial raspberry cream flavour, edetate disodium dihydrate, poloxamer 407, potassium sorbate (0,4 % *m/m*) (preservative), propylene glycol, sodium phosphate dibasic heptahydrate, sodium phosphate monobasic monohydrate, sucrose, titanium dioxide, xanthan gum and xylitol.

What TELFAST® SUSPENSION looks like and contents of the pack

A white to beige, uniform suspension with a raspberry cream aroma.

TELFAST® SUSPENSION is available in amber PET bottles with a purple polypropylene, child-resistant screw closure with a foam liner and induction inner seal. The bottle has a printed label and is packed in a printed outer carton. TELFAST® SUSPENSION is available in the following sizes:

- 60 mL bottle containing 30 mL suspension
- 120 mL bottle containing 60 mL suspension
- 180 mL bottle containing 150 mL suspension
- 360 mL bottle containing 300 mL suspension

Holder of Certificate of Registration:

Opella Healthcare South Africa (Pty) Ltd

Hertford Office Park, Building I, 4th Floor

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Access to the corresponding Professional Information

https://pi-pil-repository.sahpra.org.za