Applicant: Oethmaan Biosims (Pty) Ltd	**SAHPRA APPROVAL DATE:** 16 August 2022
Product: SENSAFEX 180 mg	**Dosage form and strength:** Each film-coated tablet contains: 180 mg Fexofenadine Hydrochloride

APPROVED PATIENT INFORMATION LEAFLET-CLEAN

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S1

SENSAFEX 180 mg, film-coated tablet

Fexofenadine Hydrochloride 180 mg

Contains sugar (lactose monohydrate 228.63 mg)

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

SENSAFEX 180 mg is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SENSAFEX 180 mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SENSAFEX 180 mg with any other person.
- Ask your doctor or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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1. What SENSAFEX 180 mg is and what it is used for

2. What you need to know before you take SENSAFEX 180 mg

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5. How to store SENSAFEX 180 mg

6. Contents of the pack and other information

1. What SENSAFEX 180 mg is and what it is used for

SENSAFEX 180 mg contains fexofenadine hydrochloride which belongs to a group of medicines called antihistamines.

SENSAFEX 180 mg: is used in adults and adolescents of 12 years and older to relieve the symptoms that occur with long term allergic skin reactions (chronic idiopathic urticarial) such as sneezing, itching, swelling and rashes.

2. What you need to know before you take SENSAFEX 180 mg

Do not take SENSAFEX 180 mg if:

- you are hypersensitive (allergic) to fexofenadine hydrochloride or any of the other ingredients of SENSAFEX 180 mg (listed in section 6: **See what SENSAFEX 180 mg contains** below).
- you are pregnant or breastfeeding your baby.

Warnings and precautions

Special caution should be taken with SENSAFEX 180 mg:

- If you have kidney disease.
- If you have liver disease.
- If you have or ever had heart disease, since SENSAFEX 180 mg may lead to a fast or irregular heartbeat.
- If you are elderly.

If any of these apply to you, or you are not sure, inform your doctor or pharmacist before taking SENSAFEX 180 mg.

Children:

SENSAFEX 180 mg should not be given to children under the age of 12 years old as the safety and efficacy has not been studied.

Other medicines and SENSAFEX 180 mg

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

The following medicines may increase the level of SENSAFEX 180 mg in your blood:

- erythromycin (an antibiotic)
- ketoconazole (a medicine used to treat fungal infections).

The following medicine may lower the amount of SENSAFEX 180 mg in your blood:

- Aluminium and magnesium hydroxide containing antacids for indigestion may affect the action of SENSAFEX 180 mg, by lowering the amount of medicine absorbed. It is recommended that you leave about 2 hours between the time that you take SENSAFEX 180 mg and your medicine for indigestion.

No interaction between SENSAFEX 180 mg and the medicine omeprazole (for ulcers and heartburn) was observed.

SENSAFEX 180 mg with food and drink and alcohol

Taking SENSAFEX 180 mg with alcohol should be avoided.

Pregnancy and breastfeeding and fertility

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 SENSAFEX 180 mg.

Pregnancy

You should not take SENSAFEX 180 mg when you are pregnant as there are no studies performed in pregnant women.

Breastfeeding

You should not breastfeed your baby when you are on SENSAFEX 180 mg treatment as SENSAFEX 180 mg may be secreted in breast milk.

Fertility

There are no studies of the effect of SENSAFEX 180 mg on human fertility.

Driving and using machines

SENSAFEX 180 mg is unlikely to affect your ability to drive or operate machinery. However, you should check that SENSAFEX 180 mg does not make you feel sleepy or dizzy before driving or operating machinery. If you take alcohol or other sedatives, these effects may be worsened.

SENSAFEX 180 mg contains:

SENSAFEX 180 mg contains sugar (lactose monohydrate). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SENSAFEX 180 mg.

3. How to take SENSAFEX 180 mg

Do not share medicines prescribed for you with any other person.

Always take SENSAFEX 180 mg exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose is:

For adults and children aged 12 years and over:

SENSAFEX 180 mg: The recommended dose is one tablet daily.

Take your tablet with water before a meal.

Do not chew the tablets.

If you take more SENSAFEX 180 mg 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 overdosage include dizziness, drowsiness and dry mouth.

If you forget to take SENSAFEX 180 mg

If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. In that case, just carry on with the next dose as normal.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking SENSAFEX 180 mg

Tell your doctor or pharmacist if you want to stop taking SENSAFEX 180 mg before you have finished your course of treatment. If you stop taking SENSAFEX 180 mg earlier than planned, your symptoms may return.

4. Possible side effects:

SENSAFEX 180 mg can have side effects.

Not all side effects reported for SENSAFEX 180 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SENSAFEX 180 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking SENSAFEX 180 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Sudden signs of allergy – including skin rash, itching or hives; swelling of the face, lips or tongue, shortness of breath or difficulty breathing, chest tightness and flushing.

These are all very serious side effects. If you have them, you may have had a serious reaction to SENSAFEX 180 mg. 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

Less frequent side effects

- Difficulty sleeping, sleep disorders, bad dreams, excessive dreaming, nervousness
- Skin rash and itching, hives
- Tiredness

Frequency unknown

- Fast or irregular heartbeat
- Diarrhoea

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SENSAFEX 180 mg.

5. How to store SENSAFEX 180 mg

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Protect from light and moisture.

Store in the original package/container.

Keep the HDPE container closed.

Keep the blister in the carton until required for use.

Do not store in a bathroom.

Do not use SENSAFEX 180 mg after the expiry date stated on the carton.

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 SENSAFEX 180 mg contains

SENSAFEX 180 mg, film-coated tablet:

The active substance in each tablet is 180 mg fexofenadine hydrochloride.

The other ingredients are:

Lactose monohydrate, hydroxypropylcellulose, pregelatinised starch, colloidal anhydrous silica, microcrystalline cellulose, croscarmellose sodium, magnesium stearate. Film-coating containing hypromellose, polyvinylpyrrolidone, titanium dioxide, iron oxide red, iron oxide yellow, colloidal anhydrous silica and polyethylene glycol.

What SENSAFEX 180 mg looks like and contents of the pack

SENSAFEX 180 mg, film-coated tablet: Peach coloured capsule shaped film-coated tablets debossed as “180” on one side and “FX” on the other side.

SENSAFEX 180 mg is presented in the following packs:

1. Alu/PVC/PVDC Blister Pack:

Alu/PVC/PVDC blister pack comprising of hard tempered aluminium foil and thick, white-opaque, well thermoformable PVC film coated with PVDC on outer side. This blister will be further packed in preprinted cartons along with package leaflet.

Initial:	16/08/2022

Pack sizes: 10 and 30 tablets.

2. Alu/PVC/PE/ACLAR Blister Pack:

Alu/PVC/PE/ACLAR blister pack comprising of hard tempered aluminium foil and clear, transparent PVC film coated with ACLAR on other side, sandwiched with PE layer (Triplex film). This blister will be further packed in preprinted cartons along with package leaflet.

Pack sizes: 10 and 30 tablets.

3. High Density Polyethylene (HDPE) Bottle Pack:

White opaque high density polyethylene (HDPE) bottle packs with white opaque polypropylene continuous threaded closure with wad having induction sealing liner.

Pack sizes: 500 and 1000 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Initial:	16/08/2022

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2195

This leaflet was last revised in

Not applicable.

Registration number

47/5.7.1/0978

Initial:	16/08/2022 