

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS**S1****PATIENT INFORMATION LEAFLET****TELLERGE 120 mg film-coated tablets****TELLERGE 180 mg film-coated tablets****Fexofenadine hydrochloride****Sugar free**

Read all of this leaflet carefully before you start taking TELLERGE because it contains important information for you.

TELLERGE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use TELLERGE carefully to get the best results from it.

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

You must see a doctor if your symptoms worsen or do not improve after a few days.

What is in this leaflet:

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

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1. What TELLERGE is and what it is used for

TELLERGE belongs to the group of medicines known as antihistamines.

TELLERGE 120 mg is indicated for the relief of symptoms associated with hay fever such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes (seasonal allergic rhinitis).

TELLERGE 180 mg is indicated for the relief of symptoms associated with long term allergic skin reactions such as itching, swelling and rashes (chronic idiopathic urticaria).

2. What you need to know before you take TELLERGE**Do not take TELLERGE:**

- if you are hypersensitive (allergic) to fexofenadine or any of the other ingredients of TELLERGE (listed in section 6).
- If you are under the age of 12 years.
- If you are pregnant or breastfeeding your baby (see Pregnancy, breastfeeding and fertility).

Warnings and precautions**Talk to your doctor or pharmacist before taking TELLERGE:**

- If you are elderly.
- If you have kidney problems (may include symptoms such as weakness, shortness of breath, lethargy, swelling, and confusion).
- If you have liver problems (may include symptoms such as skin and eyes that appear yellowish (jaundice), stomach pain and swelling, swelling in the legs and ankles, itchy skin, chronic fatigue, nausea or vomiting, loss of appetite, tendency to bruise easily).

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- If you have a history of or current heart problems (symptoms vary widely, ranging from chest pain to rapid heartbeat) as it may cause an irregular heartbeat.
- If you feel sedated (sleepy) after taking TELLERGE.
- If you are drinking alcohol or taking other medicines that slow brain activity such as sedatives or tranquilizers (central nervous system depressants) while taking TELLERGE.

Other medicines and TELLERGE

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following medicines:

- Erythromycin: medicine used to treat bacterial infections.
- Ketoconazole: medicines used to treat fungal infections.
- Antacids containing aluminium and magnesium hydroxide gels: medicines used to relieve heartburn or an upset stomach. It is advisable to leave 2 hours between taking TELLERGE and antacids containing aluminium and magnesium hydroxide gels.
- Central nervous system depressants: medicines that slow down the activity in the brain or make you feel drowsy or less alert.
- If you are taking apalutamide (a medicine to treat prostate cancer), as the effect of fexofenadine may be decreased.

Pregnancy, breastfeeding and fertility

You should not take TELLERGE if you are pregnant or breastfeeding your baby.

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 healthcare provider for advice before taking this medicine.

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Driving and using machines

It is not always possible to predict to what extent TELLERGE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TELLERGE affects them (see section 4).

3. How to take TELLERGE

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

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

The usual dose is:

Adults and children aged 12 years and over:

Symptoms associated with long term allergic skin reactions such as itching, swelling and rashes of the skin (chronic idiopathic urticaria): One 180 mg tablet daily.

Symptoms associated hay fever such as sneezing, itchy, runny or blocked nose and itchy, red and watery eyes (seasonal allergic rhinitis): One 120 mg tablet daily.

Children under 12 years of age:

The efficacy and safety of TELLERGE has not been studied in children under 12.

If you have problems with your kidneys, a dose of 60 mg once daily is recommended as the starting dose.

If you have the impression that the effect of TELLERGE is too strong or too weak, tell your doctor or pharmacist.

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If you take more TELLERGE 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.

If you forget to take / missed a dose of TELLERGE

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

4. Possible side effects

TELLERGE can have side effects.

Not all side effects reported for TELLERGE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TELLERGE, please consult your healthcare provider for advice.

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

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- chest tightness, difficulty in breathing (dyspnoea), flushing, itching, wheezing, a sudden drop in blood pressure (systemic anaphylaxis),

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

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Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- rapid irregular action of the heart; irregular heartbeat (tachycardia, palpitations),

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- headache, drowsiness, dizziness,
- feeling sick (nausea),

The following side effects have been reported less frequently:

- tiredness (fatigue),

The following side effects have been reported but the frequency is unknown:

- inability to sleep (insomnia), nervousness, sleep disorders or nightmares (paroniria),
- viral infections such as cold or flu,
- frequent/loose watery stools (diarrhoea), heartburn or indigestion (dyspepsia),
- inflammation or swelling of the tissue in the sinuses (sinusitis),
- painful menstrual periods (dysmenorrhoea).
- blurred vision

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

Reporting of side effects

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

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<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ALLERGEX MEPYRAMINE CREAM.

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

5. How to store TELLERGE

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the blister strips in the unit carton until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 TELLERGE contains**

The active substance is 120 mg of fexofenadine hydrochloride.

The other ingredients are croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, macrogol, magnesium stearate, microcrystalline cellulose, povidone, starch maize and titanium dioxide.

Sugar free

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The active substance is 180 mg of fexofenadine hydrochloride.

The other ingredients are croscarmellose sodium, hypromellose, iron oxide yellow, macrogol, magnesium stearate, microcrystalline cellulose, povidone, starch maize and titanium dioxide.

Sugar free

What TELLERGE looks like and contents of the pack

TELLERGE 120 mg: Peach coloured, oblong, bi-convex film-coated tablet; plain on both sides.

TELLERGE 120 mg: 10 or 30 film-coated tablets are packed in a clear, colourless polyvinylchloride and polyvinylidene chloride film sealed with an aluminium foil backing. The blister strips are packed in an outer cardboard carton.

TELLERGE 180 mg: Yellow coloured, oblong, bi-convex film-coated tablet; plain on one side with a central breakline on the other.

TELLERGE 180 mg: 10 or 30 film-coated tablets are packed in a clear, colourless polyvinylchloride/ polyvinylidene chloride film sealed with an aluminium foil backing. The blister strips are packed in an outer cardboard carton.

Not all packs and pack sizes are necessarily marketed.

Holder of the certificate of registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69, Bryanston, 2021

www.adcock.com

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TELLERGE 120 mg: BOT1402530

TELLERGE 180 mg: BOT1402529

Namibia: NS1

TELLERGE 120 mg: 12/5.7.1/0019

TELLERGE 180 mg: 12/5.7.1/0018