SCHEDULING STATUS:

S1

TELLERGE TABLETS

TELLERGE 120 mg film-coated tablets

TELLERGE 180 mg film-coated tablets

Fexofenadine hydrochloride

Sugar free

Read all of this leaflet carefully 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 health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 5 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

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 hydrochloride 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

Special care should be taken with 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).
- 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.

Children and adolescents

Do not give TELLERGE to children under the age of 12 years old because the safety and efficacy has not been studied.

Other medicines and TELLERGE

Always tell your health care provider if you are taking any other medicine (this includes all 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.

TELLERGE with food, drinks and alcohol

Do not take TELLERGE with alcohol as this could enhance the sedative effect (it could make you drowsy or sleepy).

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 health care provider for advice before taking this medicine.

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.

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.

Children under 12 years of age:

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

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 center.

If you forget to take / missed a dose of TELLERGE

Do not take 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 professional for advice.

If any of the following happens, stop using TELLERGE 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;
- 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.

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

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, maize starch and titanium dioxide.

Sugar free

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, maize starch 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 Certificate of Registration

Adcock Ingram Limited

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Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

26 July 2024

Registration numbers

TELLERGE 120 mg: 41/5.7.1/0352

TELLERGE 180 mg: 41/5.7.1/0353

Botswana: S2

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

PASIËNTINLIGTINGSBILJET

SKEDULERINGSTATUS:

S1

TELLERGE TABLETTE

TELLERGE 120 mg film-bedekte tablette

TELLERGE 180 mg film-bedekte tablette

Feksofenadienhidrochloried

Suikervry

Lees hierdie hele voubiljet noukeurig omdat dit belangrike inligting vir u bevat.

TELLERGE is sonder ’n doktersvoorskrif beskikbaar, sodat u ’n ligte siekte kan behandel.

Nogtans moet u steeds TELLERGE versigtig gebruik om die beste resultate te kry.

- Hou hierdie voubiljet. U sal dit dalk weer moet lees.
- Moenie TELLERGE met enigiemand anders deel nie.
- Vra u verskaffer van gesondheidsorg of apteker as u meer inligting of raad benodig.
- U moet ’n dokter sien as u simptome vererger of ná 5 dae nie verbeter nie.

Wat in hierdie voubiljet staan

1. Wat TELLERGE is en waarvoor dit gebruik word

2. Wat u moet weet voor u TELLERGE neem

3. Hoe om TELLERGE te gebruik

4. Moontlike newe-effekte

5. Hoe om TELLERGE te bêre

6. Inhoud van die pakkie en ander inligting

1. Wat TELLERGE is en waarvoor dit gebruik word

TELLERGE behoort aan ’n groep medisynes wat as antihistamiene bekend staan.

TELLERGE 120 mg is aangedui vir die verligting van simptome geassosieer met hooikoors, soos nies, jeukerige, loperige of toe neus en jeukerige, rooi en waterige oë (seisoenale allergiese rinitis).

TELLERGE 180 mg is aangedui vir die verligting van simptome geassosieer met langtermyn allergiese velreaksies soos jeukerigheid, swelling en uitslae (chroniese idiopatiese urtikaria).

2. Wat u moet weet voor u TELLERGE neem

Moenie TELLERGE neem:

- As u hipersensitief (allergies) vir feksofenadienhidrochloried of enige van die ander bestanddele van TELLERGE (in afdeling 6 genoem) is nie.
- As u jonger as 12 jaar is nie
- As u swanger is of u kind borsvoed nie (sien Swangerskap, borsvoeding en vrugbaarheid).

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet met TELLERGE geneem word:

- As u bejaard is.
- As u nierprobleme het (kan simptome soos swakheid, kortasemheid, lusteloosheid, swelling en verwarring insluit).
- As u lewerprobleme het (kan simptome soos vel en oë wat geel voorkom [geelsug], maagpyn en -swelling, swelling in die bene en enkels, jeukerige vel, chroniese afmatting, naarheid of braking, kleiner eetlus, neiging om maklik te kneus insluit).
- As u ’n geskiedenis van, of huidige hartprobleme het (simptome wissel baie en strek van borskaspyn tot vinnige hartklop) aangesien dit ’n onreëlmatige hartklop kan veroorsaak.
- As u gesedeer (slaperig) voel nadat u TELLERGE neem.
- As u alkohol drink of ander medisyne neem wat breinaktiwiteit vertraag, soos sedatiewe of kalmeermiddels (sentrale senuweestelsel onderdrukkers), terwyl u TELLERGE neem.

Kinders en adolessente

Moenie TELLERGE aan kinders jonger as 12 jaar gee nie, aangesien veiligheid en doeltreffendheid nog nie bestudeer is nie.

Ander medisynes en TELLERGE

Vertel altyd vir u verskaffer van gesondheidsorg as u enige ander medisyne neem (dit sluit alle komplementêre of tradisionele medisynes in).

Sê vir u dokter as u enige van die volgende medisynes neem:

- Eritromisien: medisyne wat gebruik word om bakteriële infeksies te behandel.
- Ketokonasool: medisyne wat gebruik word om swaminfeksies te behandel.
- Teensuurmiddels wat aluminiumhidroksied- en magnesiumhidroksied-jel bevat: medisynes wat gebruik word om sooibrand of ’n omgekrapte maag te verlig. U word aangeraai om TELLERGE en teensuurmiddels wat aluminiumhidroksied- en magnesiumhidroksied-jels bevat 2 uur uitmekaar te neem.
- Middels wat die sentrale senuweestelsel onderdruk: medisynes wat breinaktiwiteit vertraag of u lomerig of minder wakker maak.
- As u apalutamied (’n medisyne om prostaatkanker te behandel) neem, omdat die effek van feksofenadien kan verminder.

TELLERGE met kos, drank en alkohol

Moenie TELLERGE met alkohol neem nie aangesien dit die sedatiewe effek kan versterk (dit kan u lomerig of slaperig maak).

Swangerskap, borsvoeding en vrugbaarheid

U moenie TELLERGE neem as u swanger is of u baba borsvoed nie.

As u swanger is of borsvoed, vermoed dat u swanger is of van plan is om ’n baba te kry, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir raad voor u hierdie medisyne neem.

Bestuur en gebruik van masjinerie

Dit is nie altyd moontlik om te voorspel in watter mate TELLERGE by ’n pasiënt se alledaagse aktiwiteite sal inmeng nie. Pasiënte moet seker maak dat hulle nie die bogenoemde aktiwiteite verrig tot hulle weet in watter mate TELLERGE hulle aantas nie (sien afdeling 4).

3. Hoe om TELLERGE te neem

Moenie medisynes wat vir u voorgeskryf is met enigiemand anders deel nie.

Neem altyd TELLERGE presies soos hierdie voubiljet voorskryf of soos u dokter, apteker of verpleegkundige vir u gesê het. Raadpleeg u dokter, apteker of verpleegkundige as u onseker is.

Die gewone dosis is:

Volwassenes en kinders van 12 jaar en ouer:

Simptome geassosieer met langtermyn allergiese velreaksies soos jeukerigheid, swelling en veluitslae (chroniese idiopatiese urtikaria): Een 180 mg-tablet daagliks.

Simptome geassosieer met hooikoors, soos nies, jeukerige, loperige of toe neus en jeukerige, rooi en waterige oë (seisoenale allergiese rinitis). Een 120 mg-tablet daagliks.

As u nierprobleme het, word ’n dosis van 60 mg een keer daagliks as die aanvangsdosis aanbeveel.

As u voel dat die effek van TELLERGE te sterk of te swak is, sê vir u dokter of apteker.

Kinders jonger as 12 jaar:

Die doeltreffendheid en veiligheid van TELLERGE is nog nie by kinders onder 12 bestudeer nie.

As u meer TELLERGE neem as wat u moet

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van die twee beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet om ’n dosis TELLERGE te neem of een oorslaan

Moenie ’n dubbele dosis neem om vir vergete individuele dosisse te vergoed nie.

4. Moontlike newe-effekte

TELLERGE kan newe-effekte hê.

Nie alle newe-effekte wat vir TELLERGE aangemeld is, is in hierdie voubiljet ingesluit nie.

Indien u algemene gesondheid sou vererger of as u enige ongewenste effekte ervaar terwyl u TELLERGE neem, raadpleeg asseblief u verskaffer van gesondheidsorg vir advies.

As enige van die volgende gebeur, hou op om TELLERGE te neem en sê dadelik vir u dokter of gaan na die ongevalle-afdeling by u naaste hospitaal:

- swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik kan maak om te sluk of asem te haal;
- uitslag of gejeuk;
- benoude bors, moeilike asemhaling, (dispnee), blosing, jeukerigheid, fluitende asemhaling, ’n skielike daling in bloeddruk (sistemiese anafilakse).

Dit is alles baie ernstige newe-effekte. As u dit ervaar, het u dalk ’n ernstige allergiese reaksie op TELLERGE gehad. U het dalk dringende mediese aandag of hospitalisering nodig.

Sê dadelik vir u dokter of gaan na die ongevalle by u naaste hospitaal as u enige van die volgende opmerk:

- vinnige onreëlmatige werking van die hart, onreëlmatige hartklop (tagikardie, palpitasies)

Sê vir u dokter as u enige van die volgende opmerk:

Die volgende newe-effekte is dikwels aangemeld:

- hoofpyn, lomerigheid, duiseligheid
- voel siek (naarheid)

Die volgende newe-effekte is minder dikwels aangemeld:

- moegheid (afmatting)

Die volgende newe-effekte is aangemeld, maar die frekwensie daarvan is onbekend:

- onvermoë om te slaap (insomnie), senuweeagtigheid, slaapsteurings of nagmerries (paronirie),
- virale infeksies soos verkoues of griep,
- gereelde/loperige waterige stoelgange (diarree), sooibrand of swak spysvertering (dispepsie),
- ontsteking of swelling van die weefsel in die sinusse (sinusitis),
- pynlike menstruasie (dismenorree),
- dowwe sig.

As u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem is nie, sê asseblief vir u dokter of apteker.

Aanmelding van newe-effekte

As u enige newe-effekte opmerk wat nie in hierdie voubiljet genoem is nie, sê asseblief vir u dokter of apteker. U kan newe-effekte ook by SAHPRA aanmeld via die **“**6.04 Adverse Drug Reaction Reporting Form” wat aanlyn onder SAHPRA se publikasies verskyn: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van TELLERGE te bekom. U kan dit ook aan Adcock Ingram Limited meld by die volgende e-posadres: Adcock.AEReports@adcock.com

5. Hoe om TELLERGE te bêre

Bêre alle medisynes buite bereik van kinders. Bêre teen of benede 25°C.

Moenie in ’n badkamer bêre nie.

Moenie gebruik ná die vervaldatum wat op die etiket aangedui is nie. Bring alle ongebruikte medisyne na u apteker terug.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat TELLERGE bevat:

Die aktiewe stof is 120 mg feksofenadienhidrochloried.

Die ander bestanddele is kroskarmellosenatrium, hipromellose, ysteroksied rooi, ysteroksied geel, makrogol, magnesiumstearaat, mikrokristallyne sellulose, povidoon, mieliestysel en titaandioksied.

Suikervry

Die aktiewe stof is 180 mg feksofenadienhidrochloried.

Die ander bestanddele is kroskarmellosenatrium, hipromellose, ysteroksied geel, makrogol, magnesiumstearaat, mikrokristallyne sellulose, povidoon, mieliestysel en titaandioksied.

Suikervry

Hoe TELLERGE lyk en inhoud van die pakkie

TELLERGE 120 mg: Perskekleurige, langwerpige, bikonvekse film-bedekte tablet; glad aan beide kante.

TELLERGE 120 mg: 10 of 30 film-bedekte tablette is verpak in ’n deursigtige, kleurlose polivinielchloried- en polivinielideenchloried-film wat met ’n aluminiumfoelie rugkant verseël is.

Die stulpstroke word binne ’n kartondosie verpak.

TELLERGE 180 mg: Geelkleurige, langwerpige, bikonvekse film-bedekte tablet; glad aan die een kant met ’n sentrale breeklyn op die ander.

TELLERGE 180 mg: 10 of 30 film-bedekte tablette is verpak in ’n deursigtige, kleurlose polivinielchloried-/ polivinielideenchloried-film wat met ’n aluminiumfoelie rugkant verseël is.

Die stulpstroke word binne ’n kartondosie verpak.

Nie alle pakkies en pakkiegroottes word noodwendig bemark nie.

Houer van Registrasiesertifikaat

Adcock Ingram Limited

New Road 1,

Erand Gardens,

Midrand, 1685

Kliëntesorg: 0860 ADCOCK / 232625

Hierdie voubiljet is laas hersien op

26 July 2024

Registrasienommers

TELLERGE 120 mg: 41/5.7.1/0352

TELLERGE 180 mg: 41/5.7.1/0353

Botswana: S2

TELLERGE 120 mg: BOT1402530

TELLERGE 180 mg: BOT1402529

Namibië: NS1

TELLERGE 120 mg: 12/5.7.1/0019

TELLERGE 180 mg: 12/5.7.1/0018