PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S1**

LEVOGEX 5 mg film coated tablets

Levocetirizine dihydrochloride 5 mg

Contains sugar: Lactose monohydrate 64 mg

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

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

- Keep this leaflet. You may need to read it again.
- Do not share Levogex with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve after ten days.

What is in this leaflet:

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

1. WHAT LEVOGEX IS AND WHAT IT IS USED FOR:

LEVOGEX tablets belong to the group of medicines that are called antihistamines. Antihistamines block the action of histamine which is a chemical that is released by the body's immune system (the body's defence system against disease) during an allergic reaction to an allergen.

LEVOGEX tablets are given to patients to relieve the symptoms associated with the following allergic conditions in adults:

- Seasonal allergic rhinitis: seasonal allergic rhinitis occurs in the spring, summer, and early autumn, when airborne plant pollens are at their highest levels.
- Perennial allergic rhinitis: a type of allergic rhinitis that occurs all year and is usually caused by airborne pollutants in the home and other places.
- Chronic idiopathic urticaria: this is a skin disorder where small raised areas occur on the skin (wheals/hives) that are itchy and they occur chronically without a known cause.

2. What you need to know before you take LEVOGEX

Do not take LEVOGEX tablets:

- If you are hypersensitive (allergic) to Levocetirizine Dihydrochloride, piperazine derivative or any of the other ingredients in LEVOGEX tablets (listed in section 6).
- LEVOGEX tablets must not be given to children under the age of 6 years as its safety and efficacy has not been established in children.
- If you are pregnant or breastfeeding (see **Pregnancy and Breastfeeding**).
- If you have reduced kidney function (See section 3).

Warnings and Precautions

Take special care with LEVOGEX tablets:

- LEVOGEX tablets may make you sleepy or tired. Therefore be cautious when taking LEVOGEX tablets and driving or performing any tasks that require concentration and alertness.
- Do not take LEVOGEX tablets together with alcohol or any other medicines that also make you sleepy. (See **Other medicines and LEVOGEX**).
- If you have a liver or kidney disease, please consult your doctor before you take LEVOGEX tablets.
- LEVOGEX should be given with caution to patients with any conditions that may potentially cause difficulty of urination as LEVOGEX may increase the risk of difficulty of urination.
- LEVOGEX may cause fits in people who have seizures or are at risk of having seizures.

- LEVOGEX may cause itching of the skin when stopped- which may stop naturally or when treatment is restarted.
- LEVOGEX reduces the response to allergy skin tests and a wash-out period of three (3) days is required before performing them.
- LEVOGEX contains lactose/fructose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take LEVOGEX.

Other medicines and LEVOGEX tablets:

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

- LEVOGEX may lead to drowsiness and impaired concentration, which may be made worse when taken together with *alcohol* or other *central nervous system depressant agents* (medicines that slow down brain activity).
- Other medicines such as ketoconazole, erythromycin, azithromycin, cimetidine and pseudoephedrine have not shown to have any effect on LEVOGEX tablets.
- Interactions with other medicines have not been recorded.

Pregnancy, breastfeeding and fertility

Pregnancy:

The safety of levocetirizine has not been established in pregnancy and therefore LEVOGEX is not to be used in pregnancy.

Breastfeeding:

Levocetirizine is released into breast milk and therefore LEVOGEX is not to be used in breastfeeding women.

Fertility:

No fertility data available.

If you are pregnant or breastfeeding while taking LEVOGEX tablets please consult your doctor, pharmacist or other health care professional for advice

Driving and using machines

LEVOGEX lacks significant sedative effects. However, patients should be advised that certain individuals may experience a state of calm, sleepiness, tiredness and therefore, patients must be cautious when taking LEVOGEX while driving or performing hazardous tasks as they need to establish their individual reaction to the medication. The sedative effect may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants.

It is not always possible to predict to what extent LEVOGEX 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 LEVOGEX affects them.

Important information about some of the ingredients of LEVOGEX tablets:

LEVOGEX contains lactose monohydrate which may have an effect on the control of your blood sugar if you have diabetes mellitus.

If you have been told by your doctor that you have intolerance to some sugars, you must not take LEVOGEX tablets.

3. HOW TO TAKE LEVOGEX TABLETS

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

Always take LEVOGEX tablets exactly as described in this leaflet or as your health care professional has instructed you. You should check with your health care professional if you are unsure.

How to take LEVOGEX tablets:

- LEVOGEX tablets must be taken orally i.e. by mouth.
- LEVOGEX tablets must be swallowed with a glass of water.
- LEVOGEX tablets can be taken with or without food.

- Take LEVOGEX tablets once a day, at about the same time each day.

Dosages for LEVOGEX tablets:

Adults or children 6 years of age or older:

The daily recommended dose is one 5 mg tablet.

Patients with reduced liver function:

No dosage adjustment is needed in patients with reduced liver function.

Patients with reduced kidney function:

Dosages in patients with reduced kidney function:		
Renal status	**Creatinine clearance (CLcr)**	**Dose**
Moderate impairment	30 to 49 ml/min	5 mg every second day
Severe impairment	< 30 ml/min	5 mg every third day
End stage renal disease or receiving dialysis	< 10 ml/min	Contraindicated

How long may LEVOGEX tablets be taken:

LEVOGEX tablets can be stopped once the symptoms have disappeared and can be restarted when the symptoms reappear.

Do not take LEVOGEX tablets for longer than six weeks.

If you have the impression that the effect of LEVOGEX tablets is too strong or too weak, talk to your doctor or pharmacist.

If you take more LEVOGEX tablets than you should:

In the event of overdosage of LEVOGEX tablets, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take LEVOGEX tablets:

- Use your next dose at your regular time.
- Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

LEVOGEX tablets can have side effects.

Not all side effects reported for LEVOGEX tablets are included in this leaflet. Should your general health worsen while taking LEVOGEX tablets, please consult your doctor, pharmacist or other health care professional for advice.

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

- Hypersensitivity (allergic) reactions together with skin reactions.
- Urticaria (hives, raised areas of the skin that are often red, warm and itchy and which appear suddenly and then disappear without a trace).
- Pruritus (severe itching, especially of undamaged skin).
- Angioedema (swelling of the deeper layers of the skin, sometimes occurs with hives. It is not red or itchy. It usually occurs in soft tissue such as eyelids, lips, tongue, throat, mouth or genitals).

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Drowsiness
- Dry mouth
- Nausea
- Tiredness
- Muscle pain

Less frequent side effects:

- Discomfort of the stomach
- Nausea
- Lack of energy
- General feeling of being ill

Unknown side effects:

- Hypersensitivity reactions together with skin reactions
- Swelling of the skin
- Severe allergic reactions
- Seizures
- Visual disturbances
- Pounding of the heart
- Increased heart rate
- Shortness of breath
- Swelling of the liver
- Abnormal liver function
- Itchy rash
- Recurring skin disorders
- Weight increase

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

Reporting of side effects

If you have any side effects, talk to your health care professional.

You can report side effects to the **Adcock Ingram Pharmacovigilance** department by e-mail to Adcock.Aereports@adcock.com, fax to +27 86 553 0128 or call 011

635 0134.

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 LEVOGEX.

5. How to store LEVOGEX TABLETS:

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from moisture.
- Do not use after the expiry date stated on the label.
- Store in blisters in outer carton until required for use.
- 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 LEVOGEX contains:

The active substance is Levocetirizine dihydrochloride 5 mg.

Contains sugar: Lactose monohydrate 64 mg

The other ingredients are: Lactose monohydrate, microcrystalline cellulose, magnesium stearate, Hypromellose, titanium dioxide, macrogol 400.

What LEVOGEX looks like and contents of the pack:

White to off-white, oval, biconvex tablets debossed with "L9CZ" on one side and "5" on the other side.

The tablets are available in transparent white opaque, PVC/PVDC or oPA/Al/PVC with aluminium lidding foil blister packs with 10 tablets per blister strip. Blister strips are stored in a unit carton in packs of 10 or 30 tablets.

Holder of Certificate of Registration:

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PASIËNT INLIGTINGSBLAD

SKEDULERINGSTATUS: **S1**

LEVOGEX 5 mg filmbedekte tablette

Levosetirisien dihidrochloried 5 mg

Bevat suiker: Laktosemonohidraat 64 mg

Lees die hele voubiljet noukeurig deur, want dit bevat belangrike inligting vir u.

LEVOGEX tablette is beskikbaar aan u sonder 'n dokter se voorskrif om 'n minder ernstige siekte mee te behandel. Nietemin moet u steeds LEVOGEX tablette versigtig gebruik om die beste resultate daaruit te verkry.

- Bewaar hierdie voubiljet. U sal dit dalk weer moet lees.
- Moenie LEVOGEX met enige ander persoon deel nie.
- Raadpleeg u gesondheidsorgkundige of apteker indien u meer inligting of advies benodig.
- U moet u dokter besoek indien u simptome vererger of nie na tien dae verbeter nie.

Wat in hierdie voubiljet is:

1. Wat LEVOGEX is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LEVOGEX neem.
3. Hoe om LEVOGEX te neem.
4. Moontlike newe-effekte.
5. Hoe om LEVOGEX te bêre.
6. Inhoud van die verpakking en ander inligting.

1. WAT LEVOGEX IS EN WAARVOOR DIT GEBRUIK WORD:

LEVOGEX tablette behoort aan die groep medisyne wat antihistamiene genoem word. Antihistamiene verhoed die werking van histamien wat 'n chemiese middel is wat deur die liggaam se immuunstelsel (die liggaam se verdedigingstelsel teen siektes) vrygestel word tydens 'n allergiese reaksie op 'n allergeen.

LEVOGEX tablette word aan pasiënte gegee om die simptome, wat geassosieer word met die volgende allergiese toestande by volwassenes, te verlig:

- Seisoenale allergiese rinitis: seisoenale allergiese rinitis vind plaas in die lente, somer en vroeë herfs, wanneer lugdraende plant-stuifmeel op hul hoogste vlakke is.
- Voortdurende allergiese rinitis: 'n tipe allergiese rinitis wat die hele jaar voorkom en gewoonlik veroorsaak word deur lugdraende besoedeling in die huis en ander plekke.
- Chroniese idiopatiese urtikaria: dit is 'n velafwyking waar klein verhewe areas op die vel voorkom (swelsels/galbulte) wat jeuk, en dit kom chronies voor sonder 'n bekende oorsaak.

2. Wat u moet weet voordat u LEVOGEX neem

Moenie LEVOGEX tablette neem nie:

- Indien u hipersensitief (allergies) is vir Levosetirisien Dihidrochloried, piperasien-afgeleide middels of enige van die ander bestanddele in LEVOGEX tablette (gelys in afdeling 6).
- LEVOGEX tablette moet nie aan kinders onder die ouderdom van 6 jaar gegee word nie, aangesien die veiligheid en doeltreffendheid daarvan nie by kinders vasgestel is nie.
- Indien u swanger is of borsvoed (sien Swangerskap en Borsvoeding).
- Indien u verminderde nierfunksie het (Sien afdeling 3).

Waarskuwings en Voorsorgmaatreëls

Wees veral versigtig met LEVOGEX tablette:

- LEVOGEX tablette kan u lomerig of moeg maak. Wees dus versigtig wanneer u LEVOGEX tablette neem en bestuur of enige take verrig wat konsentrasie en waaksaamheid vereis.
- Moenie LEVOGEX tablette saam met alkohol of enige ander medisyne neem wat u ook lomerig maak nie. (Sien **Ander medisyne en LEVOGEX**).
- Indien u 'n lewer- of niersiekte het, raadpleeg asseblief u dokter voordat u LEVOGEX tablette neem.
- LEVOGEX moet met omsigtigheid gegee word aan pasiënte met enige toestande wat moontlik probleme met urinering kan veroorsaak, aangesien LEVOGEX die risiko van probleme met urinering kan verhoog.

- LEVOGEX kan aanvalle veroorsaak by mense wat geneig is tot stuipe of die risiko loop om stuipaanvalle te kry.
- LEVOGEX kan jeukerigheid van die vel veroorsaak wanneer dit gestaak word - wat natuurlik kan opklaar of wanneer behandeling weer begin word.
- LEVOGEX verminder die reaksie op allergie-veltoetse, en 'n uitwasperiode van drie (3) dae word vereis voordat die toetse uitgevoer word.
- LEVOGEX bevat laktose/fruktose. Pasiënte met die seldsame oorerflike toestande van laktose/fruktose of galaktose-intoleransie moet nie LEVOGEX neem nie.

Ander medisyne en LEVOGEX tablette:

Lig altyd u gesondheidsorgkundige in indien u enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

- LEVOGEX kan lei tot lomerigheid en verswakte konsentrasie, wat vererger kan word wanneer dit saam met alkohol of ander middels wat die sentrale senuweestelsel onderdruk (medisyne wat breinaktiwiteit vertraag) ingeneem word.
- Ander medisyne soos ketokonasool, eritromisien, azitromisien, simetidien en pseudoefedrien het geen effek op LEVOGEX tablette getoon nie.
- Interaksies met ander medisyne is nie aangeteken nie.

Swangerskap, borsvoeding en vrugbaarheid

Swangerskap:

Die veiligheid van levosetirisien is nie tydens swangerskap vasgestel nie en daarom moet LEVOGEX nie tydens swangerskap gebruik word nie.

Borsvoeding:

Levosetirisien word vrygestel in borsmelk en daarom moet LEVOGEX nie deur vroue wat borsvoed gebruik word nie.

Vrugbaarheid:

Geen data op vrugbaarheid is beskikbaar nie.

Indien u swanger is of borsvoed terwyl u LEVOGEX tablette neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir advies

Bestuur en hantering van masjinerie

LEVOGEX het nie beduidende sederende effekte nie. Pasiënte moet egter in kennis gestel word dat sekere individue 'n toestand van kalmte, lomerigheid en moegheid kan ervaar, en daarom moet pasiënte versigtig wees wanneer hulle LEVOGEX neem terwyl hulle bestuur of gevaarlike take verrig, aangesien hulle hul individuele reaksie op die medikasie moet bepaal. Die sederende effek kan vererger word deur die gelyktydige inname van alkohol of ander sentrale senuweestelsel-onderdrukkers.

Dit is nie altyd moontlik om te voorspel tot watter mate LEVOGEX met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie bogenoemde aktiwiteite verrig totdat hulle bewus is van die mate waarin LEVOGEX hulle aantas nie.

Belangrike inligting oor sommige van die bestanddele van LEVOGEX tablette:

LEVOGEX bevat laktosemonohidraat wat 'n uitwerking op die beheer van u bloedsuiker kan hê indien u aan diabetes mellitus lei.

Indien u dokter u ingelig het dat u'n onverdraagsaamheid teenoor sekere suikers het, moet u nie LEVOGEX tablette neem nie.

3. HOE OM LEVOGEX TABLETTE TE NEEM

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.

Neem LEVOGEX tablette altyd presies soos beskryf in hierdie voubiljet of soos u gesondheidsorgkundige u ingelig het. U moet u gesondheidsorgkundige raadpleeg indien u onseker is.

Hoe om LEVOGEX tablette te neem:

- LEVOGEX tablette moet mondeliks ingeneem word, d.w.s. gedrink word.

- LEVOGEX tablette moet gesluk word met 'n glas water.
- LEVOGEX tablette kan met of sonder voedsel geneem word.
- Neem LEVOGEX tablette een keer per dag, ongeveer dieselfde tyd elke dag.

Doserings vir LEVOGEX tablette:

Volwassenes of kinders 6 jaar of ouer:

Die daaglikse aanbevole dosis is een 5 mg tablet.

Pasiënte met verminderde lewerfunksie:

Geen dosisaanpassing is nodig by pasiënte met ingeperkte lewerfunksie nie.

Pasiënte met verminderde nierfunksie:

Doserings in pasiënte met verminderde nierfunksie:		
Nierstatus	**Kreatinien opruiming (CLcr)**	**Dosis**
Matige inperking	30 to 49 ml/min	5 mg elke tweede dag
Ernstige inperking	< 30 ml/min	5 mg elke derde dag
Eindstadium niersiekte of ontvang dialise	< 10 ml/min	Teenaangedui

Hoe lank mag LEVOGEX tablette geneem word:

LEVOGEX tablette kan gestaak word sodra die simptome verdwyn het en kan weer begin word wanneer die simptome weer verskyn.

Moenie LEVOGEX tablette vir langer as ses weke neem nie.

Indien u die indruk het dat die effek van LEVOGEX tablette te sterk of te swak is, raadpleeg u dokter of apteker.

Indien u meer LEVOGEX tablette neem as wat u moes:

In die geval van ‘n oordosering van LEVOGEX tablette, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, gaan na die naaste hospitaal of gifhulpsentrum vir hulp.

Indien u vergeet om LEVOGEX tablette te neem:

- Neem u volgende dosis op u gewone tyd.
- Moenie 'n dubbele dosis neem om vergete individuele dosisse om te maak nie.

4. MOONTLIKE NEWE-EFFEKTE

LEVOGEX tablette kan newe-effekte hê.

Nie alle newe-effekte wat vir LEVOGEX tablette aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak terwyl u LEVOGEX tablette neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgkundige vir advies.

Lig u dokter dadelik in of gaan na die ongevalle-afdeling by u naaste hospitaal as u enige van die volgende opmerk:

- Hipersensitiwiteit (allergiese) reaksies saam met velreaksies.
- Urtikaria (galbulte, opgehewe dele van die vel wat dikwels rooi, warm en jeukerig is en wat skielik verskyn en dan spoorloos verdwyn).
- Pruritus (erge jeukerigheid, veral van onbeskadigde vel).
- Angio-edeem (swelling van die dieper lae van die vel, kom soms voor met galbulte. Dit is nie rooi of jeukerig nie. Dit kom gewoonlik voor in sagte weefsel soos ooglede, lippe, tong, keel, mond of geslagsdele).

Lig u dokter in indien u enige van die volgende opmerk:

Algemene newe-effekte:

- Hoofpyn
- Lomerigheid
- Droë mond

- Naarheid
- Moegheid
- Spierpyn

Minder algemene newe-effekte:

- Ongemak van die maag
- Naarheid
- Gebrek aan energie
- Algemene gevoel van siek wees

Onbekende newe-effekte:

- Hipersensitiwiteitsreaksies saam met velreaksies
- Swelling van die vel
- Ernstige allergiese reaksies
- Stuipaanvalle
- Visuele versteurings
- Geklop van die hart
- Versnelde hartklop
- Kortasem
- Swelling van die lewer
- Abnormale lewerfunksie
- Jeukerige veluitslag
- Herhalende velafwykings
- Gewigstoename

Indien u enige newe-effekte ervaar wat nie in hierdie voubiljet genoem is nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u enige newe-effekte ervaar, raadpleeg u gesondheidsorgkundige.

U kan newe-effekte by die **Adcock Ingram Pharmacovigilance** departement aanmeld via ‘n epos te stuur na Adcock.Aereports@adcock.com, te faks na +27 86 553 0128 of te bel op 011 635 0314.
U kan ook newe-effekte by SAHPRA aanmeld via die vorm “**6.04 Adverse Drug Reaction Reporting Form”,** wat op die internet onder SAHPRA se publikasies gevind kan word: https://www.sahpra.org.za/Publications/Index/8.

Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf aangaande die veiligheid van LEVOGEX.

5. Hoe om LEVOGEX TABLETTE te bêre:

- Bêre alle medisyne buite bereik van kinders.
- Bêre teen of benede 25 °C.
- Beskerm teen vog.
- Moet nie gebruik ná die vervaldatum wat op die etiket aangedui nie.
- Bêre in stulpstroke binne-in buitekarton totdat dit benodig word vir gebruik.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting:

Wat LEVOGEX bevat:

Die aktiewe bestanddeel is Levosetirisien dihidrochloried 5 mg.

Bevat suiker: Laktosemonohidraat 64 mg

Die ander bestanddele is: Laktosemonohidraat, mikrokristallyne sellulose, magnesiumstearaat, hipromellose, titaniumdioksied, makrogol 400.

Hoe LEVOGEX lyk en die inhoud van die verpakking:

Wit tot naaswit, ovaal, bikonvekse tablette gegraveer met “L9CZ” aan die een kant en “5” aan die ander kant.

Die tablette is beskikbaar in deursigtige of wit ondeursigtige PVC/PVDC of oPA/Al/PVC met aluminium oortrek-foelie stulpverpakkings, met 10 tablette per stulpstrook. Stulpstroke word in 'n enkele kartondosie verpak, in verpakkings van 10 of 30 tablette.

Houer van Sertifikaat van Registrasie:

ADCOCK INGRAM LIMITED

New Road 1

Erand Gardens

Midrand, 1685

Kliëntediens: 0860 ADCOCK / 232625

Hierdie voubiljet is mees onlangs hersien op:

7 Desember 2023

Registrasienommer:

46/5.7.1/0300