Front Side

Back Side

A

B

37.5

450 mm (H)

D

C

140 mm (L)

Leaflet Size: 450 (H) x 140 (L) mm

Claudia Law - Approved - 03.11.2022

SCHEDULING STATUS: S2

XYLEVE ODT Orodispersible Tablets
Levocetirizine dihydrochloride
Contains sugar
Each XYLEVE ODT orodispersible tablet contains 104,00 mg lactose monohydrate, 5,00 mg aspartame (E951), mannitol contained in Pharmaburst B2 (Mannitol (E421), Polyplasdone, Sorbitol (E420) and Syloid)) and 0,018 µg of sulphite ammonia caramel (E150d). Each XYLEVE ODT contains 39 mg of potassium.

Read all of this leaflet carefully because it contains important information for you
XYLEVE ODT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use XYLEVE ODT carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share XYLEVE ODT 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 5 days.

What is in this leaflet

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

1. What XYLEVE ODT is and what it is used for
Levocetirizine dihydrochloride is the active ingredient of XYLEVE ODT. XYLEVE ODT is an antihistamine for systemic use. It is used for the treatment of signs of illness (symptoms) associated with:
- allergic rhinitis (including persistent allergic rhinitis);
- chronic nettle rash of unknown origin (chronic idiopathic urticaria).

2. What you need to know before you take XYLEVE ODT
Do not take XYLEVE ODT
- if you are hypersensitive (allergic) to levocetirizine dihydrochloride or any of the other ingredients of XYLEVE ODT (listed in section 6);
- if you or your child have a severe impairment of kidney function (severe renal failure with creatinine clearance below 10 mL/min);
- if you are pregnant or breastfeeding your baby.

Warnings and precautions
Talk to your doctor or pharmacist before taking XYLEVE ODT. Take special care with XYLEVE ODT:
- If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice;
- If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of XYLEVE ODT may cause seizure aggravation;
- If you are scheduled for allergy testing, ask your doctor if you should stop taking XYLEVE ODT for several days before testing. This medicine may affect your allergy test results.

Children
The use of XYLEVE ODT is not recommended in children less than 6 years since the orodispersible tablets do not allow for dose adaptation.

Other medicines and XYLEVE ODT
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

XYLEVE ODT with food and, drink and alcohol
Caution is advised if XYLEVE ODT is taken at the same time as alcohol or other medicines acting on the brain. In sensitive patients, the concurrent administration of XYLEVE ODT and alcohol or other medicines acting on the brain may cause additional reductions in alertness and impairment of performance.

XYLEVE ODT can be taken with or without food.

Pregnancy and, breastfeeding and fertility
You should not take XYLEVE ODT 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.

Driving and using machines
It is not always possible to predict to what extent XYLEVE ODT 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 XYLEVE ODT affects them. Some patients being treated with XYLEVE ODT may experience somnolence/drowsiness, tiredness and exhaustion. Use caution when driving or operating machinery until you know how this medicine affects you. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy test persons after taking levocetirizine in the recommended dosage.

XYLEVE ODT contains lactose monohydrate, aspartame, sulphite ammonia caramel, sorbitol and potassium
XYLEVE ODT contain a sugar called lactose and caramel. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
XYLEVE ODT contains aspartame (an artificial sweetener). Caution is advised in patients with phenylketonuria, an inherited inability to metabolize phenylalanine which, if untreated, causes brain and nerve damage.
XYLEVE ODT contains "sulphites" and may rarely cause severe hypersensitivity (allergic) reactions and bronchospasm (when the muscles in the lungs tighten, causing restricted airflow).
XYLEVE ODT contains less than 1 mmol (39 mg) potassium per orodispersible tablet, which makes it essentially "potassium-free".

3. How to take XYLEVE ODT
Always take XYLEVE ODT exactly as your doctor or pharmacist has instructed you. Check with your doctor or pharmacist if you are not sure.

Adults or children aged 6 years and older:
The daily recommended dose is one orodispersible tablet.

Method of administration
The orodispersible tablet should be placed on the tongue and should be sucked, not chewed, until completely disintegrated. The resulting suspension must be swallowed with saliva. The orodispersible tablet can be taken with or without water and may be taken with or without food. You can take XYLEVE ODT with meals, or independently of meals. If you have a sensitive stomach, you should best take XYLEVE ODT after meals.

If you take more XYLEVE ODT than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Symptoms of overdose may include:
- sleepiness can occur in adults;
- children may initially show a sense of excitation and restlessness followed by somnolence (sleepiness).

If you forget to take XYLEVE ODT
Do not take a double dose to make up for forgotten individual doses, just continue taking the amounts stated in the dosage instructions.

If you stop taking XYLEVE ODT
Stopping treatment with XYLEVE ODT earlier than foreseen should have no detrimental effects. However, less frequently pruritus (intense itching) may occur if you stop taking XYLEVE ODT even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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

If any of the following happens, stop taking/using XYLEVE ODT and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

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

Tell your doctor if you notice any of the following:
Frequent side effects:
- dry mouth;
- headache;
- tiredness;
- somnolence/drowsiness.

Less frequent side effects:
- exhaustion;
- abdominal pain.

Side effects with frequency unknown:
- palpitations, increased heart rate;
- fits, pins and needles, dizziness, syncope, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement;
- visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements);
- painful or difficult urination, inability to completely empty the bladder, oedema;
- pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption;
- shortness of breath;
- weight increase, muscular pain, joint pain, aggressive or agitated behaviour;
- hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmare;
- hepatitis, abnormal liver function;
- vomiting, increased appetite, nausea, diarrhoea;
- pruritus (intense itching) upon discontinuation.

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 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 XYLEVE ODT.

5. How to store XYLEVE ODT
Store all medicines out of sight and reach of children.
Store at or below 25 ºC (room temperature).
Store in the original package.
Keep the blisters in the outer carton.
Do not store in a bathroom.
Do not use XYLEVE ODT after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.
Return all unused medicines 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 XYLEVE ODT contains
- Each orodispersible tablet contains 5 levocetirizine dihydrochloride.
- The other ingredients are polacrilin potassium, lactose monohydrate, Aspartame (E951), silica (colloidal anhydrous), magnesium stearate, blackcurrant flavour (contains flavouring substances, flavouring preparations, natural flavouring substances, maize maltodextrin, E1518 glyceryl triacetate, E1505 triethyl citrate, E150d sulphite ammonia caramel and moisture) and Pharmaburst B2 (contains mannitol (E421), polyplasdone, sorbitol (E420) and syloid).

What XYLEVE ODT looks like and contents of the pack
XYLEVE ODT are white to off-white, round, flat, bevelled edged orodispersible tablets and plain on both the sides.
XYLEVE ODT is packed in Aluminium-Aluminium blister packs. XYLEVE ODT is available in pack sizes of 1, 2, 4, 5, 7, 10, 2 x 10, 10 x 10, 14, 15, 20, 21, 28, 30, 40, 50, 60, 70, 90 or 100 orodispersible tablets.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
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www.trinitypharma.co.za

SKEDULERINGSTATUS: S2

XYLEVE ODT Oraal-oplosbare Tablette
Levosetirisiendihidrochloried
Bevat suiker
Elke XYLEVE ODT oraal-oplosbare tablet bevat 104,00 mg laktosemonohidraat, 5,00 mg aspartaam (E951), mannitol bevat in Pharmaburst B2 (Mannitol (E421), Poliplasdoon, Sorbitol (E420) en Siloied)) en 0,018 µg sulfietammoniakkaramel (E150d). Elke XYLEVE ODT bevat 39 mg kalium.

Lees die hele pamflet sorgvuldig deur want dit bevat belangrike inligting vir u
XYLEVE ODT is beskikbaar sonder 'n doktersvoorskrif om 'n ligte siektetoestand te behandel. Nietemin, u moet nogsteeds XYLEVE ODT met omsigtigheid gebruik om die beste resultate daaruit te kry.
- Hou hierdie pamflet. U mag dit dalk later weer moet lees.
- Moet nie XYLEVE ODT met enige ander persoon deel nie.
- Raadpleeg u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- U moet 'n dokter besoek indien u simptome vererger of nie verbeter na 5 dae nie.

Wat is in hierdie pamflet

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

1. Wat XYLEVE ODT is en waarvoor dit gebruik word
Levosetirisiendihidrochloried is die aktiewe bestanddeel in XYLEVE ODT. XYLEVE ODT is 'n antihistamien vir sistemiese gebruik. Dit word gebruik vir die behandeling van siektetoestande (simptome) wat verband hou met:
- allergiese rinitis (insluitend aanhoudende allergiese rinitis);
- chroniese brandneteluitslag van onbekende oorsprong (chroniese idiopatiese urtikariee).

2. Wat u moet weet voordat u XYLEVE ODT neem
Moet nie XYLEVE ODT neem:
- indien u hipersensitief (allergies) is vir levosetirisiendihidrochloried of enige van die ander bestanddele van XYLEVE ODT (gelys in afdeling 6);
- indien u of u kind aan ernstige ingekorte nierfunksie ly (ernstige nierversaking met kreatinienopruimingsvlakke onder 10 mL/min);
- indien u swanger is of u baba borsvoed.

Waarskuwings en voorsorgmaatreëls
Raadpleeg u dokter of apteker voordat u XYLEVE ODT neem. Wees veral versigtig met XYLEVE ODT:
- Indien u nie in staat is om u blaas leeg te maak nie (as gevolg van toestande soos rugmurgbesering of vergrote prostaat), raadpleeg u dokter vir advies;
- Indien u aan epilepsie ly of op risiko is vir konvulsies, moet u asseblief u dokter raadpleeg vir advies, aangesien die gebruik van XYLEVE ODT aanval kan vererger;
- Indien u geskeduleerd is vir allergietoetse, raadpleeg u dokter of u vir 'n paar dae moet stop om XYLEVE ODT te neem voordat u die toetse laat doen. Hierdie medisyne kan u allergietoetsresultate beïnvloed.

Kinders
Die gebruik van XYLEVE ODT word nie aanbeveel in kinders jonger as 6 jaar nie, aangesien die oraal-oplosbare tablette nie dosisaanpassings moontlik maak nie

Ander medisyne en XYLEVE ODT
Noem altyd aan u gesondheidsorgverskaffer indien u enige ander medisyne neem. (Dit sluit alle komplimentêre of tradisionele medisyne in.)

XYLEVE ODT saam met voedsel, drank en alkohol
Wees versigtig indien u XYLEVE ODT gelyktydig met alkohol of ander medisyne wat op die brein werk, neem. In sensitiewe pasiënte kan die gelyktydige toediening van XYLEVE ODT en alkohol of ander medisyne wat op die brein werk, addisionele afname in waaksaamheid en werksverrigting veroorsaak.

XYLEVE ODT kan met of sonder voedsel geneem word.

Swangerskap, borsvoeding en vrugbaarheid
U moet nie XYLEVE ODT neem indien u swanger is of u baba borsvoed nie. Indien u swanger is of borsvoed, vermoed dat u swanger kan wees of beplan om swanger te raak, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne neem.

Bestuur en gebruik masjiene
Dit is nie altyd moontlik om te voorspel tot watter mate XYLEVE ODT die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet toesien dat hulle nie aan die bogenoemde aktiwiteite deelneem totdat hulle nie ten volle bewus is van die mate waarin XYLEVE ODT hulle affekteer nie. Sommige pasiënte wat met XYLEVE ODT behandel word, kan slaperigheid/lomerigheid, moegheid en uitputting ervaar. Wees dus versigtig wanneer u bestuur of masjinerie gebruik. Spesiale studies het egter getoon dat levosetirisien, in die aanbevole dosis, geen effek op die verstandelike waaksaamheid, die vermoë om te reageer of die vermoë om te bestuur in gesonde proefpersone gehad het nie.

XYLEVE ODT bevat laktosemonohidraat, aspartaam, sulfietammoniakkaramel, sorbitol en kalium
XYLEVE ODT bevat 'n suiker wat laktose en karamel genoem word. Indien u dokter u ingelig het dat u 'n intoleransie het vir sommige suikers, kontak u dokter voordat u hierdie medisyne gebruik.
XYLEVE ODT bevat aspartaam ('n kunsmatige versoeter). Sorg word aanbeveel by pasiënte met fenielketonurie, 'n oorerflike onvermoë om fenielalanien te metaboliseer, wat indien dit nie behandel word nie, kan lei tot brein- en senuweeskade.
XYLEVE ODT bevat "sulfiete" en kan selde ernstige hipersensitiwiteitsreaksies (allergiese) en brongospasma veroorsaak (wanneer die spiere in die longe styf trek, wat beperkte lugvloei veroorsaak).
XYLEVE ODT bevat minder as 1 mmol (39 mg) kalium per oraal-oplosbare tablet, wat dit in wese "kaliumvry" maak.

3. Hoe om XYLEVE ODT te neem
Neem XYLEVE ODT altyd presies soos u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker indien u nie seker is nie.

Volwassenes of kinders van 6 jaar en ouer:
Die daaglikse aanbevole dosis is een oraal-oplosbare tablet.

Metode van toediening
Die oraal-oplosbare tablet moet op die tong geplaas word en gesuig word, en nie gekou word nie, totdat dit heeltemal opgelos is. Die resulterende suspensie moet dan met die speeksel ingesluk word. Die oraal-oplosbare tablet kan met of sonder water geneem word en kan met of sonder voedsel geneem word. U kan XYLEVE ODT met etes, of onafhanklik van etes neem. Indien u 'n sensitiewe maag het, moet u XYLEVE ODT eerder na etes neem.

Indien u meer XYLEVE ODT neem as wat u moet
In geval van oordosering, raadpleeg u dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.
Simptome van oordosering kan insluit:
- slaperigheid mag by volwassenes voorkom;
- kinders mag aanvanklik 'n gevoel van opgewondenheid en onrustigheid ervaar, gevolg deur somnolensie (slaperigheid).

Indien u vergeet om XYLEVE ODT te neem
Moet nie 'n dubbele dosering neem om op te maak vir die vergete individuele dosis nie, gaan slegs voort met die normale inname van die hoeveelheid soos gemeld in die doseringsinstruksies.

Indien u ophou om XYLEVE ODT te neem
Staking van behandeling met XYLEVE ODT, vroeër as wat voorsien is, behoort geen nadelige effekte tot gevolg te hê nie. Pruritus (intense jeuk) kan egter minder gereeld voorkom indien u ophou om XYLEVE ODT te neem, selfs al was die simptome nie voor die aanvang van die behandeling teenwoordig nie. Die simptome kan spontaan opklaar. In sommige gevalle kan die simptome intens wees en kan dit noodsaaklik wees om weer met behandeling te begin. Die simptome behoort op te klaar sodra behandeling weer begin word.

Indien u enige verdere vrae het oor die gebruik van hierdie medisyne, raadpleeg u dokter of apteker.

4. Moontlike newe-effekte
XYLEVE ODT kan newe-effekte hê.
Nie alle newe-effekte wat vir XYLEVE ODT aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige onaangename gevolge ervaar tydens die gebruik van XYLEVE ODT, raadpleeg asseblief gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou dadelik op om XYLEVE ODT te neem/gebruik en raadpleeg u dokter onmiddellik of gaan na die ongevalle-afdeling in u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme met sluk of asemhaling kan veroorsaak;
- uitslag of jeuk;
- floute.

Hierdie is baie ernstige newe-effekte. Indien u dit het, het u moontlik 'n ernstige reaksie op XYLEVE ODT gehad. U mag dalk dringend mediese hulp of hospitalisasie benodig.

Stel u dokter in kennis indien u enige van die volgende opmerk:
Gereelde newe-effekte:
- droë mond;
- hoofpyn;
- moegheid;
- somnolensie/lomerigheid.

Minder gereelde newe-effekte
- uitputting;
- abdominale pyn.

Newe-effekte met 'n onbekende frekwensie:
- palpitasies, verhoogde hartspoed;
- stuiptrekkings, naalde en spelde, duiseligheid, sinkopee, tremor, disgeusie (afwyking van smaaksintuig), sensasie van rotasie of beweging;
- visuele versteurings, dowwe visie, okulogirasie (oë met onbeheerde sirkelbewegings);
- pynlike of moeilike urinering, onvermoë om die blaas heeltemal leeg te maak, edeem;
- pruritus (jeukerigheid), uitslag, urtikarieë (swelling, rooiheid en jeukerigheid van die vel), veluitbarstings;
- kort van asem;
- gewigstoename, spierpyn, gewrigspyn, aggressiewe gedrag of gevoel van agitasie;
- hallusinasie, depressie, slapeloosheid, herhalende gedagtes oor of beheptheid met selfmoord, nagmerrie;
- hepatitis, abnormale lewerfunksie;
- braking, verhoogde eetlus, naarheid, diarree;
- pruritus (intense jeuk) met staking van medikasie.

Indien u enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet u u dokter of apteker daarvan in kennis stel.

Rapportering van newe-effekte
Indien u newe-effekte ervaar, moet u u dokter of apteker in kennis stel. U kan ook newe-effekte aan SAHPRA rapporteer via die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn onder SAHPRA se publikasies beskikbaar is: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting in te win oor die veiligheid van XYLEVE ODT.

5. Hoe om XYLEVE ODT te stoor
Stoor alle medisyne buite sig en bereik van kinders.
Stoor teen of benede 25 ºC (kamertemperatuur).
Stoor in die oorspronklike verpakking.
Hou die stolpverpakkings in die buitenste karton.
Moet nie in die badkamer stoor nie.
Moet nie XYLEVE ODT gebruik na die vervaldatum wat op die etiket of karton aangedui word nie. Die vervaldatum verwys na die laaste dag van daardie maand.
Neem alle ongebruikte medisyne terug na u apteker.
Moet nie ongebruikte medisyne weggooi in riool of rioolstelsels (bv. toilette) nie.

6. Inhoud van die verpakking en ander inligting
Wat XYLEVE ODT bevat
- Elke oraal-oplosbare tablet bevat 5 mg levosetirisiendihidrochloried.
- Die ander bestanddele is polakrilien kalium, laktosemonohidraat, Aspartaam (E951), silika (anhedriese kolloïede), magnesiumstearaat, swartbessiegeur (bevat geurstowwe, geurmiddelpreparate, natuurlike geurstowwe, mielie maltodekstrien, E1518 gliserientriasetaat, E1505 trietielsitraat, E150d sulfietammoniakkaramel en vog) en Pharmaburst B2 (bevat mannitol (E421), poliplasdoon, sorbitol (E420) en siloïed).

Hoe XYLEVE ODT lyk en die inhoud van die verpakking
XYLEVE ODT is wit tot naaswit, ronde, plat, afgekante oraal-oplosbare tablette wat plein is aan beide kante.
XYLEVE ODT word verpak in Aluminium-Aluminium stolpverpakkings.
XYLEVE ODT is beskikbaar in verpakkingsgroottes van 1, 2, 4, 5, 7, 10, 2 x 10, 10 x 10, 14, 15, 20, 21, 28, 30, 40, 50, 60, 70, 90 of 100 oraal-oplosbare tablette.
Nie alle verpakkingsgroottes word moontlik bemark nie.

Houer van Registrasiesertifikaat
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Hierdie pamflet is laas hersien in
N.A

Registrasienommer
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Toegang tot die ooreenstemmende Professionele Inligting:
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Sharon Item & Artwork code