Professional Information for XYLEVE 5

SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE
XYLEVE 5 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
XYLEVE 5 mg film-coated tablets.
Each tablet contains 5 mg levocetirizine dihydrochloride.

Contains sugar:
Each XYLEVE tablet contains 58 mg lactose monohydrate.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Film-coated tablets.
White modified capsule-shaped biconvex film-coated tablets debossed with 'U' on one side and plain on the other side.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
XYLEVE is indicated for the relief of symptoms associated with the following allergic conditions:
- seasonal allergic rhinitis
- perennial allergic rhinitis
- chronic idiopathic urticaria.

4.2 Posology and method of administration
Posology
Adults and adolescents 12 years of age and older
The daily recommended dose is one 5 mg tablet.

Children
For children aged 2 – 6 years no adjusted dosage is possible with the film-coated tablet formulation.
Children aged 6 – 12 years:
The daily recommended dose is one 5 mg tablet.

Special populations
Elderly
Adjustment of the dose is recommended in elderly patients with moderate to severe renal impairment (see "Renal impairment" below).

Renal impairment
Adults with renal impairment
The dosing interval must be individualised according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (CL_{cr}) in mL/min is needed.
The CL_{cr} (mL/min) may be estimated from serum creatinine (µmol/L) determination using the following formula:

$$Cl_{cr} = \frac{[140 - \text{age (years)}] \times \text{weight (kg)}}{\text{Serum creatinine (µmol/L)}} \times (0{,}85 \text{ for women})$$

Dosing adjustments for patients with impaired renal function:

Group	Creatinine clearance (mL/min)	Dosage and frequency
Normal	≥ 80	5 mg once daily
Mild	50 – 79	5 mg once daily
Moderate	30 – 49	5 mg once every 2 days
Severe	< 30	5 mg once every 3 days
End-stage renal disease – patients undergoing dialysis	< 10	Contraindicated

Paediatric patients with renal impairment:
The dose will have to be adjusted on an individual basis taking into account the renal clearance of the patient and his/her body weight. There are no specific data for children with renal impairment.

Hepatic impairment
No dose adjustment is needed in patients with solely hepatic impairment. In patients with hepatic impairment and renal impairment, adjustment of the dose is recommended (see "Renal impairment" above).

Duration of use
Intermittent allergic rhinitis (symptoms < 4 days/week or during less than 4 weeks) has to be treated according to the disease and its history; it can be stopped once the symptoms have disappeared and can be restarted again when symptoms reappear. In case of persistent allergic rhinitis (symptoms > 4 days/week or during more than 4 weeks), continuous therapy can be proposed to the patient during the period of exposure to allergens.

Method of administration
The film-coated tablet must be taken orally, swallowed with liquid and may be taken with or without food. It is recommended to take the daily dose in one single intake.

4.3 Contraindications
XYLEVE is contraindicated in:
- Hypersensitivity to levocetirizine, to any piperazine derivative or to any of the excipients listed in section 6.1.
- Infants and toddlers aged less than two years, as safety and efficacy have not been demonstrated.
- During breastfeeding of infants and while pregnant (see section 4.6).
- Patients with end stage renal disease, at less than 10 mL/min creatinine clearance.

4.4 Special warnings and precautions for use
Alcohol
Precaution is recommended with concurrent intake of alcohol. XYLEVE lacks significant sedative effects. Patients should, however, be warned that a small number of individuals may experience sedation. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants (see section 4.5).

Risk of urinary retention
Caution should be taken in patients with predisposing factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as levocetirizine may increase the risk of urinary retention.

Epilepsy and convulsion risk patients
Caution should be taken in patients with epilepsy and patients at risk of convulsion as levocetirizine may cause seizure aggravation.

Allergy skin tests
Response to allergy skin tests are inhibited by antihistamines and a wash-out period (of 3 days) is required before performing them.

Pruritus
Pruritus may occur when levocetirizine is stopped 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 (see section 4.8).

Paediatric population
The use of the film-coated tablet formulation is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation. It is recommended to use a paediatric formulation of levocetirizine.

Excipients: lactose monohydrate
XYLEVE contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction
No interaction studies have been performed with levocetirizine (including no studies with CYP3A4 inducers); studies with the racemate compound cetirizine demonstrated that there were no clinically relevant adverse interactions (with antipyrine, azithromycin, cimetidine, diazepam, erythromycin, glipizide, ketoconazole and pseudoephedrine). A small decrease in the clearance of cetirizine (16 %) was observed in a multiple dose study with theophylline (400 mg once a day); while the disposition of theophylline was not altered by concomitant cetirizine administration.
In a multiple dose study of ritonavir (600 mg twice daily) and cetirizine (10 mg daily), the extent of exposure to cetirizine was increased by about 40 % while the disposition of ritonavir was slightly altered (-11 %) further to concomitant cetirizine administration.
The extent of absorption of levocetirizine is not reduced with food, although the rate of absorption is decreased.
In sensitive patients, the concurrent administration of cetirizine or levocetirizine and alcohol or other central nervous system (CNS) depressants may cause additional reductions in alertness and impairment of performance.

4.6 Fertility, pregnancy and lactation
Pregnancy
XYLEVE is contraindicated in pregnancy as safety has not been demonstrated (see section 4.3).

Breastfeeding
XYLEVE is contraindicated in breastfeeding (see section 4.3). Levocetirizine is excreted in human milk.

Fertility
No clinical data are available.

4.7 Effects on ability to drive and use machines
Comparative clinical trials have revealed no evidence that levocetirizine at the recommended dose impairs mental alertness, reactivity or the ability to drive.
Nevertheless, some patients could experience somnolence, fatigue and asthenia during therapy with levocetirizine. Therefore, patients intending to drive, engage in potentially hazardous activities or operate machinery should take their response to the medicine into account.

4.8 Undesirable effects
a) Tabulated list of adverse reactions

System Organ Class	Frequency		
	Frequent	Less Frequent	Not known
Immune system disorders			hypersensitivity including anaphylaxis, angioedema
Metabolism and nutrition disorders			increased appetite, increased weight
Psychiatric disorders			aggression, agitation, hallucination, depression, insomnia, suicidal ideation, nightmare
Nervous system disorders	headache, somnolence		convulsion, paraesthesia, dizziness, syncope, tremor, dysgeusia
Eye disorders			visual disturbances, blurred vision, oculogyration
Ear and labyrinth disorders			vertigo
Cardiac disorders			palpitations, tachycardia
Respiratory, thoracic and mediastinal disorders			dyspnoea
Gastrointestinal disorders	dry mouth	gastrointestinal discomfort, abdominal pain	nausea, vomiting, diarrhoea
Hepatobiliary disorders			hepatitis
Skin and subcutaneous tissue disorders			fixed drug eruption, pruritus, rash, urticaria
Musculoskeletal and connective tissue disorders			myalgia, arthralgia
Renal and urinary disorders			dysuria, urinary retention
General disorders and administration site conditions			oedema
Investigations			abnormal liver function tests.

b. Description of selected adverse reactions
After levocetirizine discontinuation, pruritus has been reported (see section 4.4 above).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose
Symptoms
Symptoms of overdose may include drowsiness in adults. In children, agitation and restlessness may initially occur, followed by drowsiness.

Management of overdoses
There is no known specific antidote to XYLEVE. Should overdose occur, symptomatic or supportive treatment is recommended. Levocetirizine is not effectively removed by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacological Classification / Category and class: A 5.7.1 Antihistaminics
Pharmacotherapeutic group: Antihistamines for systemic use, piperazine derivatives
ATC code: R06A E09

Mechanism of action
Levocetirizine, the (R) enantiomer of cetirizine, is a histamine H_1 receptor antagonist.

5.2 Pharmacokinetic properties
Absorption
Levocetirizine is absorbed after oral administration with peak blood levels reached 0,9 hours after oral administration. Plasma levels are linearly related between 2,5 mg and 20 mg.

Distribution
Levocetirizine is 90 % bound to human plasma proteins.

Biotransformation
The extent of metabolism is less than 14 % of the dose. The plasma half-life is approximately 8 hours in adults.

Elimination
The main route of excretion is via urine, accounting for approximately 85 % of the dose. Approximately 13 % is excreted in the faeces.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Colloidal silica, anhydrous
Lactose monohydrate
Magnesium stearate (E572)
Maize starch
Microcrystalline cellulose (E460a)

Film-coating
Hypromellose
Polyethylene glycol
Titanium dioxide (E171).

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years.

6.4 Special precautions for storage
Store at or below 25 °C.
Keep the blister strips in the outer carton until required for use.

6.5 Nature and contents of container
Silver aluminium/aluminium foil blister strips placed in an outer carton.
Pack size: 10 or 30 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Unichem SA (Pty) Ltd
San Domenico
Ground Floor, Unit G4
10 Church Street
Durbanville
Cape Town
7551

8. REGISTRATION NUMBER
48/5.7.1/0744

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
23 August 2022

10. DATE OF REVISION OF THE TEXT
Not yet revised.

APPROVED
05/10/2022

360 mm

420 mm

Patient Information Leaflet for XYLEVE 5

SCHEDULING STATUS: S2

XYLEVE 5 mg film-coated tablets
Levocetirizine dihydrochloride.
Contains sugar: Lactose monohydrate (58 mg per tablet).

Read all of this leaflet carefully because it contains important information for you
XYLEVE is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use XYLEVE carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share XYLEVE 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 XYLEVE is and what it is used for
2. What you need to know before you take XYLEVE
3. How to take XYLEVE
4. Possible side effects
5. How to store XYLEVE
6. Contents of the pack and other information.

1. What XYLEVE is and what it is used for
Levocetirizine dihydrochloride is the active ingredient of XYLEVE.
XYLEVE 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
Do not take XYLEVE:
- If you are hypersensitive (allergic) to levocetirizine dihydrochloride or any of the other ingredients of XYLEVE (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. Take special care with XYLEVE:
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 may cause seizure aggravation.
If you are scheduled for allergy testing, ask your doctor if you should stop taking XYLEVE for several days before testing. XYLEVE may affect your allergy test results.

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

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

XYLEVE with food, drink and alcohol
Caution is advised if XYLEVE is taken at the same time as alcohol or other medicines acting on the brain. In sensitive patients, the concurrent administration of XYLEVE and alcohol or other medicines acting on the brain may cause additional reductions in alertness and impairment of performance.
XYLEVE can be taken with or without food.

Pregnancy and breastfeeding
You should not take XYLEVE 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 XYLEVE may interfere with the daily activities of the patients. Patients should ensure that they do not engage in potentially dangerous activities until they are aware of the measure to which XYLEVE affects them.
Some patients being treated with XYLEVE may experience somnolence/drowsiness, tiredness and exhaustion. Use with 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 regimen.

XYLEVE contains lactose monohydrate
XYLEVE contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking XYLEVE.

3. How to take XYLEVE
Do not share medicines prescribed for you with any other person.
Always take XYLEVE exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

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

Method of administration
XYLEVE tablets should be swallowed whole with water and may be taken with or without food.
If you have a sensitive stomach, you should best take XYLEVE after meals.

If you take more XYLEVE 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.

If you forget to take XYLEVE
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
Stopping treatment with XYLEVE earlier than foreseen should have no detrimental effects. However, less frequently pruritus (intense itching) may occur if you stop taking XYLEVE 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 can have side effects.
Not all side effects reported for XYLEVE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XYLEVE, please consult your health care provider for advice.

If any of the following happens, stop taking XYLEVE 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 all very serious side effects. If you have them, you may have had a serious reaction to XYLEVE. 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,
- hallucinations, 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.

5. How to store XYLEVE
- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton or blister strips.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What XYLEVE contains
The active substance in XYLEVE is levocetirizine dihydrochloride.
Each tablet contains 5 mg levocetirizine dihydrochloride.
The other ingredients are colloidal silica (anhydrous), hypromellose, lactose monohydrate, magnesium stearate (E572), maize starch, microcrystalline cellulose (E460a), polyethylene glycol and titanium dioxide (E171).

What XYLEVE looks like and contents of the pack
White, modified capsule-shaped, biconvex, film-coated tablets debossed with "U" on one side and plain on the other side.
Silver aluminium/aluminium foil blister strips placed in an outer carton.
Pack size:10 or 30 tablets. Not all pack sizes may be marketed.

Holder of certificate of registration
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Pasiëntinligtingsblad vir XYLEVE 5

SKEDULERINGSTATUS: S2

XYLEVE 5 mg filmbedekte tablette
Levosetirisiendihidrochloried.
Bevat suiker: Laktosemonohidraat (58 mg per tablet).

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.
XYLEVE is beskikbaar sonder 'n dokter se voorskrif, sodat jy 'n geringe aandoening kan behandel. Jy moet XYLEVE nogtans met sorg gebruik om die beste resultate te kry.
- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie XYLEVE met iemand anders deel nie.
- Vra jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig.
- Jy moet 'n dokter gaan spreek indien jou simptome vererger of nie binne 5 dae verbeter nie.

Wat is in hierdie inligtingsblad

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

1. Wat is XYLEVE en waarvoor word dit gebruik
Levosetirisiendihidrochloried is die aktiewe bestanddeel van XYLEVE.
XYLEVE is 'n antihistamien vir sistemiese gebruik.

Dit word gebruik vir die behandeling van tekens en simptome geassosieer met:
- Allergiese rinitis (insluitend aanhoudende allergiese rinitis).
- Chroniese netelroos waarvan die oorsprong onbekend is (chroniese idiopatiese urtikarie).

2. Wat jy moet weet voordat jy XYLEVE neem
Moenie XYLEVE neem nie:
- Indien jy allergies (hipersensitief) vir levosetirisiendihidrochloried of vir enige van die ander bestanddele van XYLEVE is (gelys by afdeling 6).
- Indien jou of jou kind se nierfunksie erg belemmer is (erge nierversaking met kreatinienopruiming laer as 10 mL/min).
- Indien jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls
Bespreek dit met jou dokter of apteker voordat jy XYLEVE neem. Neem spesiale sorg met XYLEVE:
Indien jy waarskynlik nie jou blaas sal kan ledig nie (weens mediese toestande soos rugmurgbesering of vergrote prostaat), vra asseblief jou dokter se raad.
Indien jy aan epilepsie ly of 'n risiko vir stuiptrekkings het, konsulteer asseblief jou dokter, aangesien XYLEVE die toevalle kan vererger.
Indien jy geskeduleer is om allergietoetse te ondergaan, vra jou dokter of jy vir 'n paar dae voor die toetse moet ophou om XYLEVE te neem. XYLEVE mag die resultate van jou allergietoetse beïnvloed.

Kinders
XYLEVE moenie gebruik word deur kinders onder die ouderdom van 6 jaar nie, aangesien die filmbedekte tablet nie gemanipuleer kan word vir aangepaste doserings nie.

Ander medisyne en XYLEVE
Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

XYLEVE met kos, drinkgoed en alkohol
Jy word aangeraai om versigtig te wees indien jy alkohol of ander medisyne wat inwerk op die brein, terselfdertyd inneem. By sensitiewe pasiënte kan die gepaardgaande toediening van XYLEVE en alkohol of ander medisynes wat op die brein inwerk, bykomende vermindering in waaksaamheid en belemmerde vermoëns veroorsaak.
XYLEVE kan met of sonder kos geneem word.

Swangerskap en borsvoeding
Moenie XYLEVE neem indien jy swanger is of jou baba borsvoed nie.
Indien jy swanger is of jou baba borsvoed, vermoed dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne neem.

Bestuur en die gebruik van masjiene
Dit is nie altyd moontlik om te voorspel tot watter mate XYLEVE met jou daaglikse aktiwiteite mag inmeng nie. Pasiënte moet seker maak dat hulle nie goed doen wat moontlik gevaarlik kan wees nie, totdat hulle weet hoe XYLEVE hulle affekteer.
Party pasiënte wat met XYLEVE behandel word kan slaperigheid/lomerigheid, moegheid en uitputting ervaar. Wees versigtig voordat jy 'n voertuig bestuur of masjiene gebruik, totdat jy weet hoe hierdie medisyne jou affekteer. Spesiale toetse het egter geen belemmering van verstandelike wakkerheid, reaksievermoë of vermoë om 'n voertuig te bestuur by gesonde toetspersone ná inname van levosetirisien teen die aanbevole dosis aangedui nie.

XYLEVE bevat laktosemonohidraat
XYLEVE bevat 'n suiker genaamd laktose. Indien jou dokter vir jou gesê het dat jy onverdraagsaam vir sekere suikers is, kontak jou dokter voordat jy XYLEVE neem.

3. Hoe om XYLEVE te neem
Moenie medisyne wat vir jou voorgeskryf is met enigiemand anders deel nie.
Neem XYLEVE altyd presies soos wat in hierdie inligtingsblad verduidelik word of soos wat jou dokter of apteker vir jou aangedui het. Vra gerus jou dokter of apteker indien jy onseker is.

Volwassenes of kinders ouer as 6 jaar
Die aanbevole dosis is een tablet daagliks.

Metode van toediening:
XYLEVE moet heel ingesluk word met water en kan met of sonder kos geneem word.
Indien jy 'n sensitiewe maag het, sal dit beter wees om XYLEVE na etes te neem.

Indien jy meer XYLEVE geneem het as wat jy moet
In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Simptome van oordosis mag die volgende insluit:
- slaperigheid mag voorkom by volwassenes,
- kinders mag aanvanklik opgewonde en rusteloos wees, en dan slaperig raak.

Indien jy vergeet het om XYLEVE te neem
Moenie 'n dubbele dosis neem om te vergoed vir 'n dosis wat oorgeslaan is nie, gaan net voort om die hoeveelheid te gebruik wat by die doseeraanwysings aangedui word.

Indien jy ophou om XYLEVE te neem
Daar behoort geen nadelige effekte te wees wanneer behandeling met XYLEVE vroeër gestaak word as wat beplan is nie. Soms kan pruritus (intense gejeuk) egter voorkom wanneer jy ophou om XYLEVE te neem, selfs al was hierdie simptome nie teenwoordig voordat met behandeling begin is nie. Die simptome kan vanself opklaar. In sommige gevalle mag die simptome intens wees en dit mag nodig wees om die behandeling te hervat. Die simptome behoort op te klaar wanneer behandeling hervat word.
Indien jy enige verdere vrae het rakende die gebruik van XYLEVE, vra jou dokter of apteker.

4. Moontlike newe-effekte
XYLEVE kan newe-effekte hê.
Nie alle newe-effekte wat vir XYLEVE gerapporteer is, word in hierdie inligtingsblad ingesluit nie.
Indien jou algemene gesondheid verswak of indien jy enige ongunstige effekte ondervind terwyl jy XYLEVE neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om XYLEVE te neem en sê dadelik vir jou dokter of gaan na die ongevalleafdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak met sluk of asemhaling,
- uitslag of gejeuk,
- floute.

Hierdie is baie ernstige newe-effekte. Indien jy dit ondervind, mag jy 'n ernstige reaksie op XYLEVE gehad het. Jy mag dringend mediese bystand of hospitalisasie benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:
Newe-effekte wat dikwels voorkom:
- droë mond,
- hoofpyn,
- moegheid,
- slaperigheid/lomerigheid.

Newe-effekte wat minder dikwels voorkom:
- uitputting,
- buikpyn.

Newe-effekte waarvan die frekwensie onbekend is:
- palpitasies, versnelde hartklop,
- toevalle/stuiptrekkings, speldeprik-sensasies, duiseligheid, sinkopee, tremore, disgeusie (distorsie van smaaksintuig), sensasie van draaiing of beweging,
- visuele versteurings, dowwe visie, okulogirasie (oë maak onwillekeurige draaibewegings),
- pynlike of moeilike urinering, onvermoë om die blaas heeltemal te ledig, edeem ,
- pruritus (gejeuk), uitslag, urtikarie (swelling, rooiheid en jeukende vel), uitbarstings op die vel,
- kortasemheid,
- gewigstoename, spierpyn, gewrigspyn, aggressiewe of rustelose gedrag,
- hallusinasies, depressie, slaaploosheid, herhalende gedagtes van of beheptheid met selfdood, nagmerries,
- hepatitis, abnormale lewerfunksie,
- braking, verhoogde aptyt, naarheid, diarree,
- pruritus (erge gejeuk) wat voorkom na die gebruik gestaak is.

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief jou dokter of apteker in.

Rapportering van newe-effekte
Indien jy newe-effekte ondervind, bespreek dit met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die vorm om ongunstige geneesmiddelreaksies te rapporteer, wat aanlyn by SAHPRA se publikasies beskikbaar is: http://www.sahpra.org.za/Publications/Index/8
Deur newe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van XYLEVE te verskaf.

5. Hoe om XYLEVE te bêre
- Bêre by of onder 25 °C.
- Hou die stulpstroke in die buitenste karton tot nodig vir gebruik.
- BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moenie gebruik ná die vervaldatum wat op die karton of stulpstroke gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) wegdoen nie.

6. Inhoud van die pak en ander inligting
Wat XYLEVE bevat
Die aktiewe bestanddeel in XYLEVE is levosetirisiendihidrochloried.
Elke tablet bevat 5 mg levosetirisiendihidrochloried.
Die ander bestanddele is kolloïdale silika (anhidries), hipromellose, laktosemonohidraat, magnesiumstearaat (E572), mieliestysel, mikrokristallyne sellulose (E460a), poliëtileenglikol en titaandioksied (E171).

Hoe XYLEVE lyk en inhoud van die verpakking
Wit, gemodifiseerde kapsulevormige, bikonvekse, filmbedekte tablette met "U" aan die een kant ingepers en glad aan die ander kant.
Silwer aluminium/aluminium-stulpstroke, wat in 'n buitenste karton verpak is.
Verpakkingsgrootte: 10 of 30 tablette. Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die registrasiesertifikaat
Unichem SA (Edms.) Bpk.
San Domenico
Grondvloer, Eenheid G4
Kerkstraat 10
Durbanville
7551 Kaapstad
Tel: 021 531 0436

Hierdie inligtingsblad is hersien
Datum van registrasie: 23 Augustus 2022.
Datum van hersiening: Nog nie hersien nie.

Registrasienommer
48/5.7.1/0744

Applicant: Unichem SA (Pty) Ltd
Manufactured by/ Vervaardig deur:
UNICHEM LABORATORIES LTD.

13014189

360 mm

420 mm

Company Name : UNICHEM LABORATORIES LTD.		**Date:** 29–09–2022
Agency Name: UNICORN CREATION		**Open Size:** 420 x 360 mm
Product: XYLEVE tablets Leaflet	**Packing:** NA	**Folding Size :** 60 x 35 mm (Plain Perforated Tape)
Item Code: 13014189	**Location:** Ghaziabad	**Pharmacode :** NA
Specification: 40 gsm bible paper		**Market:** For South Africa Export (Trinity pharma)
Colour Code: 1, text in Black		
Reason: New artwork.		

APPROVED
05/10/2022