Patient Information Leaflet for XYLEVE 5

PATIENT INFORMATION LEAFLET

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

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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 the above 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 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 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 daily 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;
- 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.

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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