

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

XEVOLCIN™ FC, 5 mg tablets

Levocetirizine dihydrochloride

Contains sugar: Lactose monohydrate (68,2 mg per tablet)

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

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

- Keep this leaflet. You may need to read it again.
- Do not share XEVOLCIN FC 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 XEVOLCIN FC is and what it is used for
 2. What you need to know before you take XEVOLCIN FC
 3. How to take XEVOLCIN FC
 4. Possible side effects
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 6. Contents of the pack and other information
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1. What XEVOLCIN FC is and what it is used for

Levocetirizine dihydrochloride is the active ingredient of XEVOLCIN FC. XEVOLCIN FC 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 XEVOLCIN FC

Do not take XEVOLCIN FC

- if you are hypersensitive (allergic) to levocetirizine dihydrochloride or to any of the other ingredients of XEVOLCIN FC (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 XEVOLCIN FC. Take special care with XEVOLCIN FC:

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 XEVOLCIN FC may cause seizure aggravation.

If you are scheduled for allergy testing, ask your doctor if you should stop taking XEVOLCIN FC for several days before testing. This medicine may affect your allergy test results.

Children

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

Other medicines and XEVOLCIN FC

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

XEVOLCIN FC with food, drink and alcohol

Caution is advised if XEVOLCIN FC is taken at the same time as alcohol or other medicines acting on the brain.

In sensitive patients, the concurrent administration of XEVOLCIN FC and alcohol or other medicines acting on the brain may cause additional reductions in alertness and impairment of performance.

XEVOLCIN FC can be taken with or without food.

Pregnancy, breastfeeding and fertility

You should not take XEVOLCIN FC 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 XEVOLCIN FC 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 XEVOLCIN FC affects them.

Some patients being treated with 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.

XEVOLCIN FC contains lactose monohydrate

XEVOLCIN FC 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 this medicinal product.

3. How to take XEVOLCIN FC

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

Always take use XEVOLCIN FC exactly as your doctor or pharmacist has 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. The tablets should be swallowed whole with water and may be taken with or without food.

Method of administration

XEVOLCIN FC tablets should be swallowed whole with water and may be taken with or without food.

You can take XEVOLCIN FC with meals, or independently of meals. If you have a sensitive stomach, you should best take XEVOLCIN FC after meals.

If you take more XEVOLCIN FC 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 XEVOLCIN FC

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 XEVOLCIN FC

Stopping treatment with XEVOLCIN FC earlier than foreseen should have no detrimental effects. However, less frequently pruritus (intense itching) may occur if you stop taking XEVOLCIN FC 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

XEVOLCIN FC can have side effects.

Not all side effects reported for XEVOLCIN FC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking XEVOLCIN FC, please consult your healthcare provider for advice.

If any of the following happens, stop taking XEVOLCIN FC 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 XEVOLCIN FC. 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,
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- shortness of breath,
- weight increase, muscular pain, joint pain, aggressive or agitated behaviour,
- hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmares,
- 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, pharmacist or nurse. 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 XEVOLCIN FC.

5. How to store XEVOLCIN FC

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

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 XEVOLCIN FC contains

The active substance is levocetirizine dihydrochloride. Each film-coated tablet contains 5 mg of levocetirizine dihydrochloride.

The other ingredients are: microcrystalline cellulose (type 102), lactose monohydrate and magnesium stearate; the film-coating consists of hypromellose E464 (type 2910), titanium dioxide (E171) and macrogol (type 400).

What XEVOLCIN FC looks like and contents of the pack

Film-coated tablets are white, oblong, biconvex, film-coated tablet with '^ 11' engraved on the one side.

XEVOLCIN FC tablets are packed in PA-Aluminium-PVC laminate and aluminium foil (PA/Aluminium/PVC//Aluminium) blisters; 7 or 10 tablets per strip, packed in cartons in 7's, 10's or 30's.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

www.astralpharma.co.za

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