PROFESSIONAL INFORMATION

SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE
XEVOLCIN™ FC, 5 mg tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
XEVOLCIN FC, 5 mg tablets
Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.
Contains sugar.
Each XEVOLCIN FC 5 mg tablet contains 68,20 mg lactose monohydrate.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Film-coated tablets
XEVOLCIN FC, 5 mg tablets
White, oblong, biconvex, film-coated tablets with '^ 11' engraved on the one side.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
XEVOLCIN FC 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 dose 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 function impairment (see "Renal impairment" below).

Renal impairment
Adults with renal impairment:
The dosing interval must be individualised according to renal function. Refer to the table below 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:

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

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 be taken with or without food. It is recommended to take the daily dose in one single intake.

4.3 Contraindications
XEVOLCIN FC is contraindicated:
- in hypersensitivity to levocetirizine, to any piperazine derivative or to any of the excipients listed in section 6.1
- in infants and toddlers less than two years, as safety and efficacy have not been demonstrated
- during breastfeeding of infants and while pregnant (see section 4.6);
- in 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. XEVOLCIN FC 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 is 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 intolerance
This medicine 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 showed 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 as in XEVOLCIN FC 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
XEVOLCIN FC is contraindicated in pregnancy as safety has not been demonstrated (see section 4.3).
Lactation
Levocetirizine 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 under 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
The table below shows all adverse drug reactions (ADRs) observed during post-market spontaneous reports with Levocetirizine dihydrochloride.

System Organ Class	Frequency		
	Frequent	Less frequent	Not known
Immune system disorders			hypersensitivity including anaphylaxis, angioedema
Metabolism and nutrition disorders			increased appetite, increased weight
Psychiartric 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**	**gastro-intestinal 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. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions 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 XEVOLCIN FC.
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: Antihistamine for systemic use, piperazine derivatives.
ATC code: R06A E09.
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 predominantly (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
Tablet core:
Microcrystalline cellulose (type 102)
Lactose monohydrate
Magnesium stearate

Film-coating:
Hypromellose E464 (type 2910)
Macrogol (type 400)
Titanium dioxide (E171)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
This medicine does not require any special storage conditions.
Store at or below 25 °C.
Keep blister in carton until required for use.

6.5 Nature and contents of container
PA-Aluminium-PVC laminate and aluminium foil (PA/Aluminium/PVC//Aluminium) blisters; 7 or 10 tablets per blister strip, packed in cartons in 7's, 10's or 30's.
Not all pack sizes are necessarily marketed.

6.6 Special precautions for disposal and other handling
No special requirements for disposal. Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Abex Pharmaceutica (Pty) Ltd
Suite C, Rubenstein Ridge
617 Rubenstein Drive
Moreleta Park
0181
South Africa

8. REGISTRATION NUMBER
Xevolcin FC: 47/5.7.1/0951

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
01 February 2022

10. DATE OF REVISION OF THE TEXT
February 2022

XEF PI V1:2022

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
5. How to store XEVOLCIN FC
6. Contents of the pack and other information

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 holpitalisation.
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, 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 25 °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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Registration number
Xevolcin FC: 47/5.7.1/0951

Access to the corresponding Professional Information
www.astralpharma.co.za

XEF PIL V1:2022

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S2

XEVOLCIN™ FC, 5 mg tablette
Levosetirisien dihidrochloried
Bevat suiker: laktose monohieraat(68,2 mg per tablet)

Lees die hele voubiljet sorgvuldig deur, want dit bevat belangrike inligting vir jou
XEVOLCIN FC is beskikbaar sonder voorskrif van 'n dokter, sodat jy 'n ligte siekte kan behandel. Jy sal XEVOLCIN FC nogtans met sorg moet gebruik om die beste resultate daarmee te behaal.
- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer wil lees.
- Moenie XEVOLCIN FC met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy nog inligting of raad benodig.
- Jy moet 'n dokter spreek as jou simptome vererger of nie na 5 dae verbeter nie.

Wat is in hierdie voubiljet
1. Wat XEVOLCIN FC is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy XEVOLCIN FC neem
3. Hoe om XEVOLCIN FC te neem
4. Moontlike newe-effekte
5. Hoe om XEVOLCIN FC te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat XEVOLCIN FC is en waarvoor dit gebruik word
Levosetirisien dihidrochloried is die aktiewe bestanddeel van XEVOLCIN FC. XEVOLCIN FC is 'n antihistamien vir sistemiese gebruik.
Dit word gebruik vir tekens van siekte (simptome) geassosieer met:
- allergiese rinitis (waaronder volgehoue allergiese rinitis);
- chroniese netelroos van onbekende oorsprong (chroniese idiopatiese urtikarie).

2. Wat jy moet weet voordat jy XEVOLCIN FC neem
Moenie XEVOLCIN FC neem nie
- as jy hipersensitief (allergies) is vir levosetirisien dihidrochloried of vir enige van die ander bestanddele van XEVOLCIN FC (gelys in afdeling 6)
- as jy of jou kind 'n erg verswakte nierfunksie het (erge nierversaking met kreatinienopruiming onder 10 mL/min)
- as jy swanger is of jou baba borsvoed.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of apteker voordat jy XEVOLCIN FC neem. Wees versigtig met XEVOLCIN FC:
As jy waarskynlik nie in staat sal wees om jou blaas te ledig nie (met aandoeninge soos 'n rugmurgbesering of 'n vergrote prostaat), raadpleeg dan asseblief jou dokter vir advies.

As jy aan epilepsie ly of die risiko loop om konvulsies te kry, raadpleeg asseblief jou dokter vir advies, aangesien die gebruik van XEVOLCIN FC die aanvalle kan vererger.
As jy geskeduleer is vir allergietoetse, wra jou dokter of jy vir 'n paar dae voor die toetse moet ophou om XEVOLCIN FC te neem. Hierdie medisyne kan jou allergietoetsresultate beïnvloed.

Kinders
Die gebruik van XEVOLCIN FC word nie aanbeveel by kinders jonger as 6 jaar nie, aangesien die filmbedekte tablette nie 'n dosisaanpassing toelaat nie.

Ander medisyne en XEVOLCIN FC
Lig altyd jou gesondheidsorgverskaffer in as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

XEVOLCIN FC met voedsel, drankies en alkohol
Waaksaamheid word aangeraai as XEVOLCIN FC gelyktydig met alkohol of ander medisyne wat op die brein inwerk geneem word.
By gevoelige pasiënte kan die gelyktydige toediening van XEVOLCIN FC en alkohol of ander medisyne wat op die brein inwerk, lei tot bykomende vermindering van bewustheid en verminderde prestasie.
XEVOLCIN FC kan met of sonder kos geneem word.

Swangerskap, borsvoeding en vrugbaarheid
Jy moet nie XEVOLCIN FC neem as jy swanger is of as jy jou baba borsvoed nie.
As jy swanger is of borsvoed, dink jy is dalk swanger, of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne neem.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel tot hoe 'n mate XEVOLCIN FC die daaglikse aktwiteite van 'n pasiënt kan beïnvloed nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem voordat hulle nie bewus is tot hoe 'n mate XEVOLCIN FC hulle aantas nie.
Sommige pasiënte wat behandel word kan slaperigheid/lomerigheid, moegheid en uitputting ervaar. Wees veral versigtig wanneer jy 'n kar bestuur of masjinerie hanteer, totdat jy weet hoe hierdie medisyne jou aantas. Spesiale toetse het egter by gesonde persone geen belemmering van verstandelike bewustheid, vermoë om te reageer of vermoë om te bestuur getoon na die inname van die aanbevole dosis levosetirisien nie.

XEVOLCIN FC bevat laktose monohidraat
XEVOLCIN FC bevat 'n suiker genaamd laktose. Indien jou dokter jou voorheen meegedeel het dat jy sekere suikers nie kan verdra nie, kontak jou dokter voordat jy hierdie medisyne neem.

3. Hoe om XEVOLCIN FC te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem XEVOLCIN FC altyd presies soos jou dokter of apteker jou aangeraai het. Kontroleer met jou dokter of apteker as jy nie seker is nie.

Volwassenes en kinders 6 jaar en ouer:
Die aanbevole daaglikse dosis is een tablet. Die tablette moet heel ingesluk word, met water, en kan met of sonder voedsel geneem word.

Metode van toediening
XEVOLCIN FC tablette moet heel ingesluk word met water en kan met of sonder voedsel geneem word.
Jy kan XEVOLCIN FC met maaltye, of sonder inagneming van maaltye, neem. Indien jy 'n gevoelige maag het, moet jy liewers XEVOLCIN FC na etes neem.

Indien jy meer XEVOLCIN FC neem as wat jy moes
In die geval van 'n oordoseering, raadpleeg jou dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of giftebeersentrum.
Simptome van oordosering kan insluit:
- slaperigheid kan by volwassenes voorkom
- kinders kan aanvanklik 'n gevoel van opgewondenheid en rusteloosheid vertoon met slaperigheid daarna.

Indien jy vergeet om XEVOLCIN FC te neem
Moenie 'n dubbeldosis neem om 'n vergete dosis in te haal nie, maar gaan gewoonweg aan met die hoeveelheid vermeld in die gebruiksaanwysings.

Indien jy ophou om XEVOLCIN FC te neem
Om behandeling met XEVOLCIN FC vroeër te staak as wat voorsien is, behoort geen nadelige uitwerking te hê nie. Jeuk (intense jeuk) kan egter minder gereeld voorkom as jy ophou om XEVOLCIN FC te neem, selfs al was daardie simptome nie teenwoordig voor die aanvang van behandeling nie. Die simptome kan spontaan opklaar. In sommige gevalle kan die simptome erg wees en dit kan nodig wees om die behandeling te hervat. Die simptome behoort op te klaar as die behandeling hervat word.
Indien jy enige verder vrae het oor die gebruik van hierdie medisyne, vra jou dokter of apteker.

4. Moontlike newe-effekte
XEVOLCIN FC kan newe-effekte hê.
Nie alle newe-effekte wat vir XEVOLCIN FC aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy XEVOLCIN FC neem, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, staak XEVOLCIN FC, lig jou dokter dadelik daarvan in, of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme om te sluk of asem te haal kan veroorsaak
- uitslag of jeuk
- floute.

Hierdie is almal baie ernstige newe-effekte. Indien jy hulle het, het jy moontlik 'n ernstige reaksie gehad op XEVOLCIN FC. Jy kan dringende mediese aandag of hospitalisering benodig.

Lig jou dokter in as jy enige van die volgende waarneem:

Gereelde newe-effekte:
- droë mond
- hoofpyn
- moegheid
- slaperigheid /lomerigheid

Minder gereelde newe-effekte:
- moegheid
- buikpyn

Newe-effekte met onbekende frekwensie:
- hartkloppings, toename in harttempo,
- stuipe, speld-en-naaldprikkels, duiseligheid, sinkopee, bewing, disgeusie (afwyking van die smaaksintuig), sensasie van rotasie of beweging,
- visuele versteurings, dowwe sig, okulogirasie (oë met ongekontroleerde sirkelbeweging),
- pynlike of moeilike urinering, onvermoë om die blaas heeltemal leeg te maak, edeem,
- pruritus (jeuk), uitslag, urtikaria (swelling, rooiheid en jeuking van die vel), veluitslag,
- kortasemheid,
- gewigstoename, spierpyn, gewrigspyn, aggressiewe of onrustige gedrag,
- hallusinasie, depressie, slapeloosheid, herhalende gedagtes van selfdood of beheptheid daarmee, nagmerries,
- hepatitis, abnormale lewerfunksie,
- braking, verhoogde eetlus, naarheid, diarree,
- pruritus (intense gejeuk) met staking.

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

Aanmelding van newe-effekte
Indien jy newe-effekte ondervind, bespreek dit met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die "**6.04 Adverse Drug Reaction Reporting Form**", wat aanlyn onder SAHPRA se publikasies verskyn: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy meer inligting verskaf oor die veiligheid van XEVOLCIN FC.

5. Hoe om XEVOLCIN FC te bewaar
Bewaar alle medisyne buite bereik van kinders.
Bewaar by of benede 25 °C.
Moenie in 'n badkamer bewaar nie.
Moenie na die vervaldatum, wat op die etiket/karton/bottel aangedui word, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting
Wat XEVOLCIN FC bevat
Die aktiewe bestanddeel is levosetirisien dihidrochloried. Elke filmbedekte tablet bevat 5 mg levosetirisien dihidrochloried.
Die ander bestanddele is: mikrokristallyne sellulose (tipe 102), laktose monohidraat en magnesiumstearaat; die filmbedekking bestaan uit hipromellose E464 (tipe 2910), titaandioksied (E171) en makrogol (tipe 400).

Hoe XEVOLCIN FC lyk en wat die inhoud van die pakkie is
Filmbedekte tablette: 'n wit, langwerpige, bikonvekse, filmbedekte tablet met '^ 11' aan die een kant gegraveer.
XEVOLCIN FC tablette is verpak in PA-Aluminium-PVC laminaat en aluminiumfoelie (PA-Aluminium-PVC/Aluminium) stulpstroke; 7 of 10 tablette per strokie, verpak in kartonne met 7, 10 of 30 tablette.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van die registrasiesertifikaat
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