PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

LEVESEIZE XR 500 extended-release tablets

LEVESEIZE XR 750 extended-release tablets

LEVESEIZE XR 1 000 extended-release tablets

LEVESEIZE XR 1 500 extended-release tablets

Levetiracetam

Sugar free

Read all of this leaflet carefully before you start taking LEVESEIZE XR:

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- LEVESEIZE XR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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

1. What LEVESEIZE XR is and what it is used for

LEVESEIZE XR contains the active substance levetiracetam which belongs to a group of medicines called anticonvulsant or antiepileptic medicines used to treat seizures (fits) in epilepsy.

LEVESEIZE XR is used:

- On its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat a certain form of epilepsy. LEVESEIZE XR is used for the epilepsy form in which the fits initially affect only one side of the brain but could thereafter extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalisation).
- As an add-on to other antiepileptic medicines to treat:

– Partial onset seizures with or without generalisation in adults and children over 16 years of age.

– Myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy

– Primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 16 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. What you need to know before you take LEVESEIZE XR

Do not take LEVESEIZE XR:

- If you are hypersensitive (allergic) to levetoracetam, other pyrrolidone derivatives or any of the other ingredients of LEVESEIZE XR listed in section 6 of this leaflet.
- If you are pregnant or breastfeeding.

Warnings and precautions:

Thoughts of harming yourself

LEVESEIZE XR may cause suicidal thoughts or actions. Tell your doctor if you have or previously had thoughts of harming or killing yourself.

If you have thoughts of harming or killing yourself or experience a worsening of your depressive symptoms, tell your doctor or caregiver immediately or go to a hospital. You may find it helpful to tell a relative or close friend that you are taking LEVESEIZE XR and ask them to read this leaflet. They may help to recognise when you experience changes in your behaviour.

Tell your doctor immediately If your seizures become worse after taking LEVESEIZE XR.

Take special care with LEVESEIZE XR:

- If you suffer from kidney problems.
- If you suffer from liver problems.
- If you are 65 years or older.
- If you suffer from any mental disorders as you may experience a change in behaviour while taking LEVESEISE XR
- If you suffer from heart conditions

Children and adolescents

LEVESEIZE XR should not be given to children under the age of 12 years, as safety and efficacy have not been established. The long-term effects of LEVESEIXE XR on learning abilities, growth, puberty and childbearing potential remains unknown.

Other medicines and LEVESEIZE XR:

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

It is especially important to inform your doctor if you are taking methotrexate (a medicine

for psoriasis, inflammation and some cancers) as simultaneous use of LEVESEIZE XR and methotrexate may lead to toxic levels of methotrexate in the blood. Blood levels of methotrexate and levetiracetam must be monitored.

Do not take macrogol (a medicine used as laxative) for one hour before and one hour after taking LEVESEIZE XR as this may result in a loss of its effect.

LEVESEIZE XR with food or drink

Food can cause a delay in the absorption of LEVESEIZE XR thus delaying the onset of action LEVESEIZE XR**.**

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking LEVESEIZE XR.

You should not take LEVESEIZE XR if you are pregnant or breastfeeding. If you get pregnant while taking LEVESEIZE XR, stop taking it immediately and tell your healthcare provider.

Driving and using machines:

LEVESEIZE XR can cause sleepiness or tiredness, especially at the beginning of treatment or following a dosage increase. Take special care before driving or operating machinery until you know how LEVESEIZE XR affects you.

3. How to take LEVESEIZE XR

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

Always take LEVESEIZE XR exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor may start you on a low dose (500 mg or 1 000 mg once a day) and increase your dose every two weeks to a maximum of 3 000 mg once daily. Your dose will depend on your condition or your age and weight if you are a child of 12 years and older.

LEVESEIZE XR tablets can be taken with or without food.

The tablets should be swallowed whole and should not be chewed, broken or crushed.

Your doctor will tell you how long your treatment with LEVESEIZE XR will last. If you have the impression that the effect of LEVESEIZE XR is too strong or too weak, tell your doctor or pharmacist.

Also tell your doctor, pharmacist or other healthcare provider if your seizures (fits) get worse or if you have any new types of seizures.

Patients with kidney disease:

Your doctor may adjust your dose based on your kidney function.

If you take more LEVESEIZE XR than you should:

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton, so that the hospital staff can easily tell what you have taken.

Signs of taking too much LEVESEIZE XR are increased sleepiness, aggression, feeling agitated, decreased consciousness and difficulty breathing.

If you forget to take LEVESEIZE XR:

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take LEVESEIZE XR at the next regularly scheduled time.

Do not take a double dose to make up for the forgotten individual doses.

If you stop taking LEVESEIZE XR:

Do not stop your treatment without your doctor's advice as this could increase your seizures (fits).

Should your doctor decide to stop your LEVESEIZE XR treatment, he/she will instruct you about the gradual withdrawal of LEVESEIZE XR.

4. Possible side effects

LEVESEIZE XR can have side effects.

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

If any of the following happens, stop taking LEVESEIZE XR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis;
- thoughts about harming yourself (suicidal thoughts) or attempting to kill yourself (suicide attempt);
- bleeding or bruising more easily than normal;

- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- liver diseases or liver failure (stomach pain, clay coloured stool, dark urine), unpleasant breath odour, unusual tiredness, nausea (feeling sick), vomiting (being sick of blood, yellowing of skin or eyes);
- pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back).
- respiratory failure (coughing, shortness of breath, wheezing, rapid breathing and feeling tired);
- erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea);
- kidney problems (drowsiness, shortness of breath, fatigue, confusion, nausea, fits, passing less urine than is normal for you);
- seizures (fits).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- changes in your mood, feeling agitated or feeling hostile,
- memory loss or impairment;
- anorexia (decreased appetite), increased weight;
- pain in a muscle or group of muscles, muscle spasm;
- headache or dizziness;
- difficulty sleeping or sleepiness;
- vertigo (sensation of spinning or swaying);
- tremors (involuntary trembling or shaking of hands and feet);

- feeling depressed, nervous, anxious or irritable;
- tingling or numbness of your hands and feet (pins and needles);
- blurred or double vision;
- nausea (feeling sick), vomiting (being sick), diarrhoea, pain in your stomach, indigestion;
- abnormal physical weakness or lack of energy, pain, feeling tired;
- nasopharyngitis (sore throat, runny or blocked nose, sneezing, muscle pains, headache);
- influenza (fever, cough, general feeling of discomfort or illness, headache, joint pain, muscle aches and pains, loss of appetite, sweating), runny nose, cough, sinusitis;
- infections;
- Balance, speech or co-ordination problems;
- accidental injury.

Less frequent side effects:

- weight loss.
- abnormal electrocardiogram results (QT prolongation)

Side effects with an unknown frequency:

- upper respiratory tract infection (sneezing, cough, runny nose, scratchy or sore throat, fever);
- common cold (runny nose, sneezing and nasal congestion);
- seeing or hearing things that does not exist;
- hair loss (temporary);
- mouth ulcers (sores and around the mouth);
- too low levels of sodium in your blood (nausea (feeling sick), vomiting (being sick), shortness of breath, headache, dizziness, confusion, convulsions (fits), coma);
- feeling angry or confused;

- uncontrollable twitching or jerking movements, muscle weakness;
- panic attacks (feeling fear for loss of control, sweating, increased heart rate, shaking);
- abnormal liver test results when blood tests are done.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects 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 LEVESEIZE XR.

5. How to store LEVESEIZE XR

- Store at or below 25 °C.
- Protect from light and moisture.
- Keep the tablets in the original container until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton / blister.
- 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 LEVESEIZE XR contains:

The active substance in LEVESEIZE XR is levetiracetam.

LEVESEIZE XR 500 Each extended-release tablet contains 500 mg levetiracetam.

LEVESEIZE XR 750: Each extended-release tablet contains 750 mg levetiracetam.

LEVESEIZE XR 1 000: Each extended-release tablet contains 1 000 mg levetiracetam.

LEVESEIZE XR 1 500: Each extended-release tablet contains 1 500 mg levetiracetam.

The other ingredients are amino methacrylate copolymer, colloidal silicon dioxide, crospovidone (E1202), dibutyl sebacate, ethyl cellulose aqueous dispersion, FD&C aluminium lake blue No. 1 (colourant), hypromellose (E464), magnesium stearate (E572), microcrystalline cellulose, silicified, Opadry II Clear (containing macrogol (E1521), polysorbate 80 (E433) and talc (E553b)), Opacode Black (containing ammonium hydroxide (E527), iron oxide black (E172) and propylene glycol (E1520)), polysorbate 20 (E432), povidone (E1201), sodium laurilsulfate (E487), talc (E553b) and triethyl citrate (E1505).

What LEVESEIZE XR looks like and contents of the pack:

LEVESEIZE XR 500 Oval, biconvex, coated, bilayer tablet with blue layer having laser drill and a white to off-white layer, imprinted with “573” with black ink on one side and plain on the other side.

LEVESEIZE XR 750 : Oval, biconvex, coated, bilayer tablet with blue layer having laser drill and white to off-white layer, imprinted with “576” with black ink on one side and plain on the other side.

LEVESEIZE XR 1 000 Oval, biconvex, coated, bilayer tablet with blue layer and white to off-white layer, having laser drill on blue layer and imprinted with "574" with black ink on one side and plain on the other side.

LEVESEIZE XR 1 500 : Oval, biconvex, coated, bilayer tablet with blue layer and white to off-white layer, having laser drill on blue layer and imprinted with "575" with black ink on one side and plain on the other side.

LEVESEIZE XR 500 and LEVESEIZE XR 750 :

White, HDPE screw neck bottle with a white polypropylene child-resistant cap, a silica gel desiccant and a white to off-white low moister polyester coil.

Pack size: 60 tablets.

The container is packed in an outer carton.

Not all pack sizes may be marketed.

LEVESEIZE XR 1 000 and LEVESEIZE XR 1 500 :

White, HDPE screw neck bottle with a white polypropylene child-resistant cap, a silica gel desiccant and a white to off-white low moister polyester coil.

Pack size: 30 tablets.

OR

White opaque PVC and aluminium foil blister strips, placed in an outer carton.

Pack size: 28 tablets.

The container is packed in an outer carton.

Not all pack sizes may be marketed.

Holder of certificate of registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road

Stormill, Ext.1, Roodepoort

Johannesburg

1724

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LEVESEIZE XR 500: 52/2.5/0256

LEVESEIZE XR 750: 52/2.5/0257

LEVESEIZE XR 1 000 : 52/2.5/0258

LEVESEIZE XR 1 500 : 52/2.5/0259

Date of registration:

12 July 2022

PASIËNT INLIGTINGSPAMFLET

SKEDULARINGSTATUS

S3

LEVESEIZE XR 500 tablette met verlengde vrystelling
LEVESEIZE XR 750 tablette met verlengde vrystelling
LEVESEIZE XR 1 000 tablette met verlengde vrystelling
LEVESEIZE XR 1 500 tablette met verlengde vrystelling
Levetirasetam
Suikervry

Lees die hele pamflet noukeurig deur voordat jy LEVESEIZE XR begin neem:

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- As jy enige verdere vrae het, vra jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- LEVESEIZE XR is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie pamflet:

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

1. Wat LEVESEIZE XR is en waarvoor dit gebruik word

LEVESEIZE XR bevat die aktiewe bestanddeel levetirasetam wat behoort aan 'n groep medisyne genaamd antikonvulsiewe of anti-epileptiese medisyne wat gebruik word om aanvalle (konvulsies) in epilepsie te behandel.

LEVESEIZE XR word gebruik:

- Op sy eie by volwassenes en adolessente vanaf 16 jaar oud met nuut gediagnoseerde epilepsie, om 'n sekere vorm van epilepsie te behandel. LEVESEIZE XR word gebruik vir die epilepsievorm waarin die aanvalle aanvanklik slegs een kant van die brein affekteer, maar daarna kan uitbrei na groter areas aan beide kante van die brein (gedeeltelike aanvangsaanvalle met of sonder sekondêre veralgemening).
- As 'n byvoeging tot ander anti-epileptiese medisyne om die volgende te behandel:
  - Gedeeltelike aanvalle met of sonder veralgemening by volwassenes en kinders ouer as 16 jaar.
  - Miokloniese aanvalle (kort, skokagtige rukke van 'n spier of groep spiere) by volwassenes en adolessente vanaf 12 jaar met jeugdige miokloniese epilepsie
  - Primêre veralgemeende tonies-kloniese aanvalle (ernstige aanvalle, insluitend verlies van bewussyn) by volwassenes en adolessente vanaf 16 jaar met idiopatiese algemene epilepsie (die tipe epilepsie wat vermoedelik 'n genetiese oorsaak het).

2. Wat jy moet weet voordat jy LEVESEIZE XR neem

Moenie LEVESEIZE XR neem nie:

- As jy hipersensitief (allergies) is vir levetorasetam, ander pirrolidoonderivate of enige van die ander bestanddele van LEVESEIZE XR wat in afdeling 6 van hierdie pamflet gelys word.
- As jy swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls:
Gedagtes om jouself te beseer
LEVESEIZE XR kan selfmoordgedagtes of -aksies veroorsaak. Vertel jou dokter as jy gedink het of voorheen daaraan gedink het om jouself te beseer of dood te maak.
As jy gedagtes het om jouself seer te maak of dood te maak of 'n verergering ervaar van jou depressiewe simptome, vertel jou dokter of versorger dadelik of gaan na 'n hospitaal. Jy sal dit dalk nuttig vind om 'n familielid of goeie vriend te vertel dat jy LEVESEIZE XR neem en hulle te vra om hierdie pamflet te lees. Hulle kan help om dit te herken wanneer jy veranderinge in jou gedrag ervaar.
Wees veral versigtig met LEVESEIZE XR:

- As jy aan nierprobleme ly.
- As jy aan lewerprobleme ly.
- As jy 65 jaar of ouer is.

Kinders en adolessente
LEVESEIZE XR moet nie aan kinders onder die ouderdom van 12 jaar gegee word nie, aangesien veiligheid en doeltreffendheid nie vasgestel is nie.

Ander medisyne en LEVESEIZE XR:
Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)

Swangerskap en borsvoeding:
As jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy LEVESEIZE XR neem.
Jy moet nie LEVESEIZE XR neem as jy swanger is of borsvoed nie. As jy swanger raak terwyl jy LEVESEIZE XR neem, hou dadelik op om dit te neem en vertel jou gesondheidsorgverskaffer.

Bestuur en gebruik van masjiene:
LEVESEIZE XR kan slaperigheid of moegheid veroorsaak, veral aan die begin van behandeling of na 'n dosisverhoging. Wees veral versigtig voordat jy bestuur of masjinerie gebruik totdat jy weet hoe LEVESEIZE XR jou affekteer.

3. Hoe om LEVESEIZE XR te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd LEVESEIZE XR presies soos jou dokter vir jou gesê het. Raadpleeg jou dokter of apteker as jy nie seker is nie.

Jou dokter kan jou met 'n lae dosis (500 mg of 1 000 mg een keer per dag) begin en jou dosis elke twee weke verhoog tot 'n maksimum van 3 000 mg een keer per dag. Jou dosis sal afhang van jou toestand of jou ouderdom en gewig as jy 'n kind van 12 jaar en ouer is.

LEVESEIZE XR tablette kan met of sonder kos geneem word.
Die tablette moet heel ingesluk word en moet nie gekou, gebreek of fyngedruk word nie.

Jou dokter sal jou vertel hoe lank jou behandeling met LEVESEIZE XR sal duur. As jy ondervind dat die effek van LEVESEIZE XR te sterk of te swak is, vertel jou dokter of apteker.

Vertel ook jou dokter, apteker of ander gesondheidsorgverskaffer as jou aanvalle erger word of as jy enige nuwe soorte aanvalle het.

Pasiënte met niersiekte:
Jou dokter kan jou dosis aanpas op grond van jou nierfunksie.

As jy meer LEVESEIZE XR neem as wat jy behoort te doen:
In die geval van oordosis, raadpleeg jou dokter of apteker sonder versuim. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Neem enige tablette wat oorbly, insluitend die karton saam, sodat die hospitaalpersoneel maklik kan sien wat jy geneem het. Tekens van die neem van te veel LEVESEIZE XR is verhoogde slaperigheid, aggressie, opgewondenheid, afname in bewussyn en moeilike asemhaling.

As jy vergeet het om LEVESEIZE XR te neem:
As jy jou dosis net 'n paar uur gemis het, neem die gemiste dosis sodra jy onthou. As dit amper tyd is vir jou volgende dosis, slaan die gemiste dosis oor en neem LEVESEIZE XR op die volgende gereelde geskeduleerde tyd.
Moenie 'n dubbele dosis neem om die vergete individuele dosisse op te maak nie.

As jy ophou om LEVESEIZE XR te neem:
Moenie jou behandeling staak sonder jou dokter se advies nie, aangesien dit jou aanvalle (konvulsies) kan verhoog. Indien jou dokter besluit om jou LEVESEIZE XR-behandeling te staak, sal hy/sy jou aanwysings gee oor die geleidelike onttrekking van LEVESEIZE XR.

4. Moontlike newe-effekte
LEVESEIZE XR kan newe-effekte hê.
Nie alle newe-effekte wat vir LEVESEIZE XR aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger of as u enige nadelige effekte ervaar terwyl u LEVESEIZE XR neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om LEVESEIZE XR te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal;
- uitslag, galbulte of jeuk;
- flou word.

Dit is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige reaksie op LEVESEIZE XR gehad. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
- pynlike, blase of skilferende veluitslag, soos Stevens-Johnson-sindroom of toksiese epidermale nekrolise;
- gedagtes om jouself te benadeel (selfmoordgedagtes);
- bloeding of kneusing makliker as normaal;
- gereelde infeksies soos koors, erge kouekoors, seer keel of mondsere;
- lewersiektes of lewerversaking (maagpyn, kleikleurige stoelgang, donker urien, onaangename asemreuk, ongewone moegheid, naarheid (siek voel), braking (siek wees van bloed, vergeling van vel of oë);

- pankreatitis (naarheid, braking, koors, pyn in jou maagarea wat na jou rug uitstraal).
- respiratoriese versaking (hoes, kortasem, hyg, vinnige asemhaling en moegheid);
- erythema multiforme (rooi, dikwels jeukerige kolle, soortgelyk aan die uitslag van masels wat op die ledemate begin en soms op die gesig en die res van die liggaam, die kolle kan blase vorm of kan vorder om verhewe, rooi, bleek-gesentreerde merke te vorm , ander simptome sluit in koors, seer keel, hoofpyn en/of diarree);
- nierprobleme (slaperigheid, kortasem, moegheid, verwarring, naarheid, aanvalle, minder urinering as wat vir jou normaal is);
- aanvalle (konvulsies).

Dit is alles ernstige newe-effekte. Jy mag dalk dringende mediese hulp benodig.

Vertel jou dokter as jy enige van die volgende opmerk:
Gereelde newe-effekte:
- veranderinge in jou gemoed, opgewonde voel of vyandig voel,
- geheueverlies of inkorting;
- anoreksie (verminderde eetlus), verhoogde gewig;
- pyn in 'n spier of groep spiere, spierspasma;
- hoofpyn of duiseligheid;
- moeilike slaap of slaperigheid;
- vertigo (sensasie van spin of wieg);
- bewing (onwillekeurige bewing of bewing van hande en voete);
- depressief, senuweeagtig, angstig of geïrriteerd voel;
- tinteling of gevoelloosheid van jou hande en voete (spelde en naalde);
- dowwe of dubbelvisie;
- naarheid (siek voel), braking (siek wees), diarree, pyn in jou maag, spysvertering;
- abnormale fisiese swakheid of gebrek aan energie, pyn, moegheid;
- nasofaringitis (seer keel, loopneus of verstopte neus, nies, spierpyne, hoofpyn);
- griep (koors, hoes, algemene gevoel van ongemak of siekte, hoofpyn, gewrigspyn, spierpyne, verlies aan eetlus, sweet), loopneus, hoes, sinusitis;
- infeksies;
- balansprobleme;
- toevallige besering.

Minder gereelde newe-effekte:
- gewigsverlies.

Newe-effekte met 'n onbekende frekwensie:
- boonste lugweginfeksie (nies, hoes, loopneus, krap of seer keel, koors);
- gewone verkoue (loopneus, nies en neusverstopping);
- dinge sien of hoor wat nie bestaan nie;
- haarverlies (tydelik);
- mondsere (sere in en om die mond);
- te lae vlakke van natrium in jou bloed (naarheid (voel siek), braking (siek wees), kortasem, hoofpyn, duiseligheid, verwarring, stuiptrekkings (konvulsies), koma);
- kwaad of verward voel;
- onbeheerbare ruk- of rukbewegings, spierswakheid;
- paniekaanvalle (voel vrees vir verlies van beheer, sweet, verhoogde hartklop, bewing);
- abnormale lewertoetsresultate wanneer bloedtoetse gedoen word.

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

Rapportering van newe-effekte:
As jy newe-effekte kry, praat met jou dokter of apteker. Dit sluit enige moontlike newe-effekte in wat nie in hierdie pamflet gelys word nie. Jy kan ook newe-effekte rapporteer via die **“6.04 Adverse Drug Reaction Reporting Form”,** wat aanlyn gevind word onder

SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van LEVESEIZE XR te verskaf.

5. Hoe om LEVESEIZE XR te stoor

- Bewaar by of benede 25 °C.
- Beskerm teen lig en vog.
- Hou die tablette in die oorspronklike houer totdat dit benodig word vir gebruik.
- BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Moet nie gebruik na die vervaldatum wat op die karton / stulpverpakking gedruk is nie.
- Gee alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting

Wat LEVESEIZE XR bevat:
Die aktiewe bestanddeel in LEVESEIZE XR is levetirasetam.
LEVESEIZE XR 500 Elke verlengde-vrystellingstablet bevat 500 mg levetirasetam.
LEVESEIZE XR 750: Elke verlengde-vrystellingstablet bevat 750 mg levetirasetam.
LEVESEIZE XR 1 000 Elke verlengde-vrystellingstablet bevat 1 000 mg levetirasetam.
LEVESEIZE XR 1 500 : Elke verlengde-vrystellingstablet bevat 1 500 mg levetirasetam.

Die ander bestanddele is aminometakrilaatkopolimeer, kolloïdale silikondioksied, krospovidoon (E1202), dibutielsebakaat, etielsellulose waterige dispersie, FD&C aluminium lakeblou nr. 1 (kleurstof), hipromellose (E464), magnesiumstearaat (E572), mikrokristallyne sellulose. gesilifiseerd, Opadry II Clear (bevat makrogol (E1521), polisorbaat 80 (E433) en talk (E553b)), Opacode Black (bevat ammoniumhidroksied (E527), ysteroksied swart (E172) en propileenglikol (E1520)), polisorbaat 20 (E432), povidoon (E1201), natriumlaurielsulfaat (E487), talk (E553b) en triëtielsitraat (E1505).

Hoe LEVESEIZE XR lyk en inhoud van die verpakking:
LEVESEIZE XR 500: Ovaal, bikonvekse, bedekte, tweelaag tablet met ‘n blou en ‘n wit tot naaswit laag. Die blou laag met laserboor bedruk "573" met swart ink aan die een kant en effe aan die ander kant.
LEVESEIZE XR 750: Ovaal, bikonvekse, bedekte, tweelaag tablet met ‘n blou en ‘n wit tot naaswit laag. Die blou laag met laserboor bedruk "576" met swart ink aan die een kant en effe aan die ander kant.
LEVESEIZE XR 1 000: Ovaal, bikonvekse, bedekte, tweelaag tablet met ‘n blou en ‘n wit tot naaswit laag. Die blou laag met laserboor bedruk "574" met swart ink aan die een kant en effe aan die ander kant.
LEVESEIZE XR 1 500: Ovaal, bikonvekse, bedekte, tweelaag tablet met ‘n blou en ‘n wit tot naaswit laag. Die blou laag met laserboor bedruk "575" met swart ink aan die een kant en effe aan die ander kant.

LEVESEIZE XR 500 en LEVESEIZE XR 750:
Wit, HDPE-skroefnekbottel met 'n wit polipropileen-kinderbestande doppie, 'n silikagel-droogmiddel en 'n wit tot naaswit lae vogtige poliësterspoel.
Verpakkingsgrootte: 60 tablette.

LEVESEIZE XR 1000 mg en LEVESEIZE XR 1500 mg:
Wit, HDPE-skroefnekbottel met 'n wit polipropileen-kinderbestande doppie, 'n silikagel-droogmiddel en 'n wit tot naaswit lae vogtige poliësterspoel.
Verpakkingsgrootte: 30 tablette.
Of
Wit ondeursigtige PVC en aluminiumfoelie stulpstroke, verpak in 'n buitekarton.
Verpakkingsgrootte: 28 tablette.

Houer van sertifikaat van registrasie
Ranbaxy Pharmaceuticals (Edms.) Bpk
Lautreweg 14
Stormill, Uitbr.1, Roodepoort
Johannesburg
1724

Hierdie pamflet is laas hersien:

Registrasienommers:
LEVESEIZE XR 500: 52/2.5/0256
LEVESEIZE XR 750: 52/2.5/0257
LEVESEIZE XR 1 000 : 52/2.5/0258
LEVESEIZE XR 1 500 : 52/2.5/0259

Datum van of registrasie