INTIRACETAM FILM COATED TABLET

Levetiracetam (250mg, 500mg, 1000mg)

What is in this leaflet

1. What INTIRACETAM is used for
2. How INTIRACETAM works
3. Before you use INTIRACETAM
4. How to use INTIRACETAM
5. While you are using it
6. Side effects
7. Storage and Disposal of INTIRACETAM
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What INTIRACETAM is used for

INTIRACETAM is used:

- on its own in adults and adolescents from 16 years of age with a certain type of newly diagnosed epilepsy. Epilepsy is a condition where the patients have repeated fits (seizures). Levetiracetam 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 seizures with or without secondary generalization).
  INTIRACETAM has been given to you by your doctor to reduce the number of fits.
- as an add-on to other antiepileptic medicines to treat:
  - partial onset seizures with or without secondary generalization in adults and children from 4 years of age with epilepsy.
  - 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 generalized tonic-clonic seizures (major fits, including loss of consciousness) in adults and children from 12 years of age with Idiopathic Generalized Epilepsy.

How INTIRACETAM works

INTIRACETAM is an antiepileptic medicine (amedicine used to treat seizures in epilepsy).

Before you use INTIRACETAM

- *When you must not use it*

Do not take INTIRACETAM

- If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (see section **Product Description**).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
INTIRACETAM can be used during pregnancy, only if after careful assessment it is considered necessary by your doctor. Youshould not stop your treatment without discussing this with your doctor. A risk ofbirth defects for your unborn child cannotbe completely excluded. INTIRACETAM has shown unwanted reproductive effects in animal studies.
Breast-feeding is not recommended during treatment.

Children and adolescents

INTIRACETAM is not indicated in children and adolescents before 16 years on its own(monotherapy).

- *Before you start to use it*

Talk to your doctor before taking INTIRACETAM

- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- If you notice any slowdown in the growth or unexpected puberty development of your child, please contact your doctor.
- A small number of people being treated with anti-epileptics such as INTIRACETAM have had thoughts of harming or killing themselves. If you have any symptoms ofdepression and/or suicidal ideation, please contact your doctor.
- If you notice any abnormal and aggressive behaviours, or if you or your family and friends notice important changes in mood or behaviour, immediately contact your doctor.
- If you have a family or medical history of heart problems, for example disturbance in heart rhythm (visible on an electrocardiogram) or if you are taking any other medicine that makes you prone to have disturbance in heart rhythm or unusual amount of salt in the body.

- *Taking other medicines*

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

How to use INTIRACETAM

- *How much to use*

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take the number of tablets following your doctor's instructions.

Monotherapy:

Dose in adults and adolescents (from 16 years of age):
General dose: between 1000 mg and 3000 mg each day.
When you will first start taking INTIRACETAM, your doctor will prescribe you a lower dose during 2 weeks before giving you thelowest general dose.

Add-on therapy:

Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:
General dose: between 1000 mg and 3000 mg each day.

Dose in children (4 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:

Your doctor will prescribe the most appropriate pharmaceutical form of INTIRACETAM according to the age, weight and dose.

Swallow INTIRACETAM tablets with a sufficient quantity of liquid (e.g. a glass of water). You can take INTIRACETAM tablets with or without food. After oral administration thebitter taste of levetiracetam may be experienced.

- *When to use it*

INTIRACETAM must be taken twice a day, once inthe morning and once in the evening, at about the same time each day. You may take INTIRACETAM with or without food.

- *How long to use it*

INTIRACETAM is used as a chronic treatment. You should continue INTIRACETAM treatment foras long as your doctor has told you.

Do not stop your treatment without your doctor's advice as this could increase yourseizures. If stopping treatment, INTIRACETAM should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your INTIRACETAM treatment, he/she will instruct you aboutthe gradual withdrawal of INTIRACETAM.

- *If you forget to use it*

Contact your doctor if you have missed one or more doses. Do not take a doubledose to make up for a forgotten tablet.

- *If you use too much (overdose)*

The possible side effects of an overdose ofINTIRACETAM are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.
Contact your doctor if you took more tablets than you should. Your doctor willestablish the best possible treatment of overdose.

While you are using it

- *Things you must do*

Take your medicine exactly as yourdoctor has told you.
If you have any further questions on theuse of this medicine, ask your doctor orpharmacist.

- *Things you must not do*

Do not stop taking the medicine unlessadvised by your doctor.
Do not give INTIRACETAM to anyone else, even if they have the same symptoms or condition as you.

- *Things to be careful of*

Driving and using machines
INTIRACETAM may impair your ability to drive oroperate any tools or machinery, as INTIRACETAM may make you sleepy. This is more likely at the beginning of treatment or after an increase in the dose. You should not drive or use machines until it is established that your ability to perform such activities is not affected.
Your seizures may rarely become worse or happen more often, mainly during the first month after starting the treatment orincrease of the dose of INTIRACETAM. If you notice any of these symptoms while taking INTIRACETAM, immediately contact yourdoctor.

Side effects

Like all medicines, this medicine can cause side effects, although not everybodygets them. The most frequently reported side effects are nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness. At the beginning of the treatment or at dose increase side effects like sleepiness, tiredness and dizziness may be more common. These effects should however decrease over time.

Very common:

- nasopharyngitis (common cold);
- somnolence (sleepiness), headache.

Common:

- anorexia (loss appetite);
- depression, hostility or aggression,anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy(lack of energy and enthusiasm), tremor (involuntary trembling);
- vertigo (sensation of rotation);
- cough;
- abdominal pain, diarrhea, dyspepsia(indigestion), vomiting, nausea;
- rash;
- asthenia/fatigue (tiredness).

Uncommon:

-decreased number of blood platelets, decreased number of white blood cells;

- weight decrease, weight increase;
- suicide attempt and suicidal ideation,mental disorder, abnormal behavior, hallucination, anger, confusion, panicattack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordination movements), paraesthesia(tingling), disturbance in attention (loss of concentration);
- diplopia (double vision), visionblurred;
- elevated/abnormal values in a liverfunction test;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (musclepain);
- injury.

Rare:

- infection;
- decreased number of all blood celltypes;
- severe allergic reactions (DRESS, anaphylactic reaction [severe andimportant allergic reaction]);
- decreased blood sodium concentration;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate); severe confusion (delirium);
- uncontrollable muscle spasms affecting the head, torso and
- limbs, difficulty in controlling movements,hyperkinesias (hyperactivity);
- encephalopathy (degenerative diseaseof the brain);
- seizures may become worse or happenmore often;
- disturbance in heart rhythm(electrocardiogram);
- pancreatitis (pancreas inflammation);
- liver failure, hepatitis;

-skin rash, which may form blisters and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythemamultiforme*), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*), and a more severe form causing skin peeling in more than 30% of the body surface (*toxic epidermal necrolysis*).

- rhabdomyolysis (breakdown of muscletissue) and associated blood creatine phosphokinase increase. Prevalence is significantly higher in Japanese patients when compared tonon-Japanese patients
- acute kidney injury
- limp or difficulty walking

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effectsnot yet known. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.
Ask your doctor or pharmacist if you do not understand anything in this list.

Tell your doctor immediately if you notice any of the following:

- Symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, may be a sign of sudden decrease of kidney function.
- Signs or symptoms including muscleache, feeling of weakness and dark urine may indicate the side effect of rhabdomyolysis (breakdown of muscle tissue).
- If someone around you notices signs of confusion, somnolence (sleepiness}, amnesia (loss of memory), memory impairment (forgetfulness),
  abnormal behaviour or other neurological signs including involuntary or uncontrolled movements, these could be symptoms of an encephalopathy (generally occur at the beginning of the treatment, from few days to a few months).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of INTIRACETAM

- *Storage*

Keep this medicine out of the sight andreach of children.
Store below 30°C.

- *Disposal*

Do not throw away any medicines via wastewater or household waste. Ask yourpharmacist how to throw away medicinesyou no longer use. These measures will help protect the environment.

Product Description

- *What it looks like*

- Intiracetam 250mg: Blue color, oval shaped film coated tablets with a break line on one side.

- Intiracetam 500mg: Yellow color, oval shaped film coated tablets with a break line on one side.

- Intiracetam 1000mg: White color, oval shaped film coated tablets with a break line on one side.

- *Ingredients*
  - Active ingredient(s)
  Levetiracetam (250mg, 500mg 1000mg per tablet)
  - Inactive ingredients

250mg: Hypromellose, Macrogol/PEG400, Titanium dioxide E171, Purified Talc, Indigo carmine lake E132, purified water.

500mg: Hypromellose, Macrogol/PEG400, Titanium dioxide E171, Purified Talc, Iron oxide yellow E172, purified water.

1000mg: Hypromellose, Macrogol/PEG400, Titanium dioxide E171, Purified Talc, purified water.

- *MAL number(s):*

INTIRACETAM 250mg: MAL22106004ACZ
INTIRACETAM 500mg: MAL22106005ACZ
INTIRACETAM 1000mg: MAL22106006ACZ

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Product Registration Holder
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