PATIENT INFORMATION LEAFLET FOR DYNA LEVETIRACETAM

Patient Information Leaflet

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

DYNA LEVETIRACETAM 250 mg film coated tablets

DYNA LEVETIRACETAM 500 mg film coated tablets

DYNA LEVETIRACETAM 750 mg film coated tablets

DYNA LEVETIRACETAM 1000 mg film coated tablets

1. WHAT DYNA LEVETIRACETAM CONTAINS:

Each **DYNA LEVETIRACETAM 250 mg** tablet contains 250 mg levetiracetam.

Each **DYNA LEVETIRACETAM 500 mg** tablet contains 500 mg levetiracetam.

Each **DYNA LEVETIRACETAM 750 mg** tablet contains 750 mg levetiracetam.

Each **DYNA LEVETIRACETAM 1000 mg** tablet contains 1000 mg levetiracetam.

Other ingredients are:

Croscarmellose sodium, magnesium stearate, maize starch, microcrystalline cellulose, povidone, purified talc, purified water, silica colloidal.

Additional ingredients are:

DYNA LEVETIRACETAM 250 mg contains Opadry blue

DYNA LEVETIRACETAM 500 mg contains Opadry yellow

DYNA LEVETIRACETAM 750 mg contains Opadry pink

DYNA LEVETIRACETAM 1000 mg contains Opadry white

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2. WHAT DYNA LEVETIRACETAM IS USED FOR:

DYNA LEVETIRACETAM is used as added therapy in the treatment of seizures (fits) in adults and children over 16 years of age with epilepsy.

3. BEFORE YOU TAKE DYNA LEVETIRACETAM:

Do not take DYNA LEVETIRACETAM:

- If you are allergic (hypersensitive) to levetiracetam, pyrrolidone-derived medicine or any of the other ingredients of **DYNA LEVETIRACETAM** (see **WHAT DYNA LEVETIRACETAM CONTAINS)**.
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

Take special care with DYNA LEVETIRACETAM:

- Do not stop taking **DYNA LEVETIRACETAM** or change to any other antiepileptic medicine as your doctor will need to gradually reduce your dose should this become necessary (see **Effects when treatment with DYNA LEVETIRACETAM is stopped**).
- If you have impaired kidney function (see **HOW TO TAKE DYNA LEVETIRACETAM**)
- If you have severe impaired liver function (see **HOW TO TAKE DYNA LEVETIRACETAM**)

Taking DYNA LEVETIRACETAM with food and drink

DYNA LEVETIRACETAM should be swallowed with liquid and may be taken with or without food.

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Pregnancy and breastfeeding:

If you are pregnant, suspect that you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or healthcare professional for advice before taking **DYNA LEVETIRACETAM**.

Do not take **DYNA LEVETIRACETAM** if you are pregnant or breastfeeding your baby.

Driving and using machines:

DYNA LEVITERACETAM can cause dizziness and sleepiness in certain individuals at the beginning of treatment or after a dosage increase and may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how **DYNA LEVETIRACETAM** affects you.

Taking other medicines with DYNA LEVETIRACETAM:

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

Please inform your doctor or pharmacist if you are taking or have taken any of the following:

- Probenecid (medicine used to treat gout)

Interactions with other antiepileptic medicine (phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin and primidone) have not been demonstrated.

4. HOW TO TAKE DYNA LEVETIRACETAM:

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

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Always take **DYNA LEVETIRACETAM** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Adults and children older than 16 years:

The usual dose of **DYNA LEVETIRACETAM** is 500 mg twice daily. Your doctor will monitor your response to treatment and adjust your dose if necessary.

Elderly:

Your doctor will determine the dose, especially if you have reduced kidney function.

Children under the age of 16 years:

DYNA LEVETIRACETAM should not be given to children under the age of 16 years.

Patients with reduced kidney function:

Your doctor will decide on the appropriate dosage depending on the level of impaired kidney function.

Patients with reduced liver function:

If you have severe liver function problems, your doctor will adjust your dose.

If you take more DYNA LEVETIRACETAM than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so the doctor knows what you have taken. Symptoms of overdose may include drowsiness, aggression, feeling agitated, appear less conscious, experiencing breathing problems, sleepiness and coma.

If you forget to take a dose of DYNA LEVETIRACETAM:

Take the missed dose as soon as you remember. If it is almost time for your next

dose, skip the missed dose and take the medicine at the next regularly scheduled time. **Do not** take a double dose to make up for forgotten individual doses.

Effects when treatment with DYNA LEVETIRACETAM is stopped:

Do not stop taking **DYNA LEVETIRACETAM** or change to other antiepileptic medicine. Your doctor will need to gradually reduce your dose over a period of time should this become necessary.

5. POSSIBLE SIDE EFFECTS:

DYNA LEVETIRACETAM can have side effects. Not all side effects reported for **DYNA LEVETIRACETAM** are included in this leaflet. Should your general health worsen while taking **DYNA LEVETIRACETAM** please consult your doctor, pharmacist or other health care professional for advice.

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

- swelling of the hands, feet ankles, lips, mouth or throat which may cause difficulty in breathing
- rash or itching

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

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

- Depression

- Convulsions
- Mood or mental changes
- Losing touch with reality, hallucinating (seeing things that are not there)
- Infections
- Pancreatitis (inflammation of the pancreas with symptoms such as stomach pain, fever, nausea, vomiting)
- Aggression, confusion

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

Tell your doctor if you notice any of the following:

- Blood disorders
- Anorexia (eating disorder), diarrhoea, indigestion, nausea
- Hair loss
- Sinusitis, coughing, throat infection, runny nose
- Double vision
- Feeling of “pins and needles”
- Loss of full control of bodily movements
- Nervousness, tremor, loss of balance
- Dizziness, headache, sleepiness
- Sleeplessness
- Feeling anxious, hostile
- Lack of interest

6. STORING AND DISPOSING OF DYNA LEVETIRACETAM:

Store at or below 30 °C.

KEEP OUT OF THE REACH OF CHILDREN.

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Do not use after the expiry date printed on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF DYNA LEVETIRACETAM:

Clear PVC/Aluminium blister strips containing 10 tablets. Six (6 x 10) or three (3 X 10) blister strips are packed in an outer cardboard box.

8. IDENTIFICATION OF DYNA LEVETIRACETAM:

DYNA LEVETIRACETAM 250 mg:

Blue, oblong-shaped, biconvex film coated tablets debossed with “250” on one side and a score line on the other side.

DYNA LEVETIRACETAM 500 mg:

Yellow, oblong-shaped, biconvex film coated tablets debossed with “500” on one side and a score line on the other side.

DYNA LEVETIRACETAM 750 mg:

Peach coloured, oblong-shaped, biconvex film coated tablets debossed with “750” on one side and a score line on the other side.

DYNA LEVETIRACETAM 1000 mg:

White to off white, oblong-shaped, biconvex film coated tablets debossed with “L” and “U” on either side of the score line on one side and “X04” on the other side.

9. REGISTRATION NUMBERS:

DYNA LEVETIRACETAM 250 mg: 44/2.5/0368

DYNA LEVETIRACETAM 500 mg: 44/2.5/0369

DYNA LEVETIRACETAM 750 mg: 44/2.5/0370

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DYNA LEVETIRACETAM 1000 mg: 44/2.5/0371

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION:

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