Package leaflet: Information for the user

Noepix 250 mg film-coated tablets.
Noepix 500 mg film-coated tablets.
Noepix 750 mg film-coated tablets.
Noepix 1,000 mg film-coated tablets.

Levetiracetam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Noepix is and what it is used for

Noepix is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Noepix is used:
- on its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat partial onset seizures with or without secondary generalisation.
- as an add-on to other antiepileptic medicines to treat:
  - partial onset seizures with or without generalisation in adults, adolescents, children and infants from one month of age
  - myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
  - primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with idiopathic generalised epilepsy

2. What you need to know before you take Noepix

Do not take Noepix
- if you are allergic to levetiracetam or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Noepix
- 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 slow down in the growth or unexpected puberty development of your child, please contact your doctor.
- If you notice an increase in seizure severity (e.g. increased number), please contact your doctor.
- A small number of people being treated with anti-epileptics such as Noepix have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

Other medicines and Noepix
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Noepix with food, drink and alcohol
You may take Noepix with or without food. As a safety precaution, do not take Noepix with alcohol.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Noepix should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child can not be completely excluded. Levetiracetam has shown unwanted reproductive effects in animal studies at dose levels higher than you would need to control your seizures.
Breast-feeding is not recommended during treatment.

Driving and using machines
Noepix may impair your ability to drive or operate any tools or machinery, as Noepix may make you feel 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.

Noepix 750 mg film-coated tablets contains sunset yellow
Sunset yellow (E110) colouring agent may cause allergic reactions.
The other strengths of /…/ do not contain this ingredient.

3. How to take Noepix

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Noepix must be taken twice a day, once in the morning and once in the evening, at about the same time each day.
Take the number of tablets following your doctor's instructions.

Monotherapy

Dose in adults and adolescents (from 16 years of age):
General dose: between 1,000 mg and 3,000 mg each day.
When you will first start taking /…/, your doctor will prescribe you a **lower dose** during 2 weeks before giving you the lowest general dose.
Example: if your daily dose is 1,000 mg, you might take 2 tablets of 250 mg in the morning and 2 tablets of 250 mg in the evening.

Add-on therapy

Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more:
General dose: between 1,000 mg and 3,000 mg each day.

Example: if your daily dose is 1,000 mg, you might take 2 tablets of 250 mg in the morning and 2 tablets of 250 mg in the evening.

Dose in infants (6 to 23 months), children (2 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg:
Your doctor will prescribe the most appropriate pharmaceutical form of levetiracetam according to the age, weight and dose. An oral solution is a presentation more appropriate to infants and children under the age of 6 years.

General dose: between 20 mg per kg bodyweight and 60 mg per kg bodyweight each day.
Example: a general dose of 20 mg per kg bodyweight each day, you might give your 25 kg child 1 tablet of 250 mg in the morning and 1 tablet of 250 mg in the evening.

Dose in infants (1 month to less than 6 months):
An oral solution is a presentation more appropriate to infants.

Method of administration
Swallow Noepix tablets with a sufficient quantity of liquid (*e.g.* a glass of water).

Duration of treatment
- Noepix is used as a chronic treatment. You should continue Noepix treatment for as long as your doctor has told you.
- Do not stop your treatment without your doctor's advice as this could increase your seizures. Should your doctor decide to stop your Noepix treatment, he/she will instruct you about the gradual withdrawal of Noepix.

If you take more Noepix than you should
The possible side effects of an overdose of Noepix 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 will establish the best possible treatment of overdose.

If you forget to take Noepix
Contact your doctor if you have missed one or more doses.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking Noepix
If stopping treatment, as with other antiepileptic medicines, Noepix should be discontinued gradually to avoid an increase of seizures.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of the side effects like sleepiness, tiredness and dizziness may be more common at the beginning of the treatment or at dose increase. These effects should however decrease over time.

Very common: may affect more than 1 user in 10
- nasopharyngitis;
- somnolence (sleepiness), headache.

Common: may affect 1 to 10 users in 100
- anorexia (loss of appetite);

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

Uncommon: may affect 1 to 10 users in 1,000
- decreased number of blood platelets, decreased number of white blood cells;
- weight decrease, weight increase;
- suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated movements), paraesthesia (tingling), disturbance in attention (loss of concentration);
- diplopia (double vision), vision blurred;
- liver function test abnormal;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- injury.

Rare: may affect 1 to 10 users in 10,000
- infection;
- decreased number of all blood cell types;
- severe hypersensitivity reactions (DRESS);
- decreased blood sodium concentrations;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- pancreatitis;
- hepatic failure, hepatitis;
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (*erythema multiforme*), 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*).

Reporting of side effects
If you get any 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 directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.
[To be completed nationally]

5. How to store Noepix

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, label or blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Noepix contains
The active substance is called levetiracetam.
One tablet of /…/ 250 mg contains 250 mg of levetiracetam
One tablet of /…/ 500 mg contains 500 mg of levetiracetam
One tablet of /…/ 750 mg contains 750 mg of levetiracetam
One tablet of /…/ 1,000 mg contains 1,000 mg of levetiracetam

The other ingredients are: Crospovidone, povidone, silica colloidal anhydrous, magnesium stearate, polyvinyl alcohol – part. hydrolysed, macrogol, talc, titanium dioxide (E171), colourants*.

* The colourants are:
250 mg tablet: Indigo carmine (E132)
500 mg tablet: Iron oxide yellow (E172), indigo carmine (E132)
750 mg tablet: Indigo carmine (E132), sunset yellow (E110), iron oxide red (E172)
1000 mg tablet: No additional colourant.

What Noepix looks like and contents of the pack
Noepix 250 mg film-coated tablets are oval, light blue, 13.6 x 6.4 mm marked with “L” on one side and “250” on the other side.
Noepix 500 mg film-coated tablets are oval, yellow, 17.1 x 8.1 mm marked with “L” on one side and “500” on the other side.
Noepix 750 mg film-coated tablets are oval, orange 19.0 x 9.3 mm marked with “L” on one side and “750” on the other side.
Noepix 1,000 mg film-coated tablets are oval, white, 19.0 x 10.0 mm marked with “L” on one side and “1000” on the other side.

Pack sizes
Blisters: 20, 30, 50, 60, 100, 120 and 200 film-coated tablets.
Tablet containers: 30, 100 and 200 film-coated tablets.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

{Name and address}
<{tel}>
<{fax}>
<{e-mail}>

<This medicinal product is authorised in the Member States of the EEA under the following names:>

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last approved in 2014-06-04