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

1 What Levetiracetam Milpharm is and what it is used for
Levetiracetam is an antiepileptic medicine (a medicine used to treat seizures in epilepsy).
Levetiracetam Milpharm 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. 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 therefore extend to larger areas on both sides of the brain (partial onset seizures with or without secondary generalisation). Levetiracetam 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 generalisation in adults, adolescents, children and infants from one month 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 12 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 Levetiracetam Milpharm
Do not take Levetiracetam Milpharm:
- If you are allergic to levetiracetam pyrrolidone derivatives or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Levetiracetam Milpharm:
- 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.
- A small number of people being treated with anti-epileptics such as Levetiracetam Milpharm have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

Children and adolescents
Levetiracetam Milpharm is not indicated in children and adolescents below 16 years on its own (monotherapy).
Other medicines and Levetiracetam Milpharm
Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.
Do not take meazopil (a drug used as leseva) for one hour before and one hour after taking levetiracetam as this may result in a loss of its effect.

Pregnancy, breast-feeding and fertility
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.
Levetiracetam Milpharm should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot 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
Levetiracetam Milpharm may impair your ability to drive or operate any tools or machinery, as it 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.

Levetiracetam Milpharm contains Sunset Yellow FCF (E110);
Levetiracetam Milpharm 750 mg contains Sunset Yellow FCF (E110). It may cause allergic reactions.

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

Monotherapy
Dose in adults and adolescents (from 18 years of age):
- General dose: between 1000 mg and 3,000 mg each day.
- When you will first start taking Levetiracetam Milpharm, your doctor will prescribe you a lower dose during 2 weeks before giving you the lowest general dose.
- Example: if your daily dose is 1000 mg, your reduced starting dose is 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 2,000 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 (1 month 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 pharmacological form of Levetiracetam according to the age, weight and dose.
Levetiracetam 100 mg/ml oral solution is a formulation more appropriate to infants and children under the age of 6 years and to children and adolescent (from 6 to 17 years) weighing less than 50kg and when tablets don’t allow accurate dosage.

Method of administration:
Swallow Levetiracetam Milpharm tablets with a sufficient quantity of liquid (e.g. a glass of water). You may take Levetiracetam Milpharm with or without food.

Duration of treatment:
- Levetiracetam Milpharm is used as a chronic treatment. You should continue Levetiracetam Milpharm 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.
- If you take more Levetiracetam Milpharm than you should:
  - The possible side effects of an overdose of Levetiracetam Milpharm 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 Levetiracetam Milpharm:
  - 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 Levetiracetam Milpharm:
- Levetiracetam Milpharm should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Levetiracetam Milpharm treatment, he/she will instruct you about the gradual withdrawal of Levetiracetam Milpharm.
- If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.
-Driving and using machines:
  - Levetiracetam Milpharm may impair your ability to drive or operate any tools or machinery, as it 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.
  - Levetiracetam Milpharm contains Sunset Yellow FCF (E110);
  - Levetiracetam Milpharm 750 mg contains Sunset Yellow FCF (E110). It may cause allergic reactions.

5 Possible side effects
month.

which is stated on the label, carton & bottle after

Do not use this medicine after the expiry date

children.

By reporting side effects you can help provide more

Website:

Reporting of side effects
directly via

Rare: may affect up to 1 in 1,000 people

Very common: may affect more than 1 in

10 people

anxiety, increased nervousness or irritability;

convulsion, balance disorder (equilibrium

disorder), dizziness (sensation of unsteadiness),

lack of energy and enthusiasm, tremor (involuntary
trembling), vertigo (sensation of rotation);

cough;

abdominal pain, diarrhoea, dyspepsia

(indigestion), vomiting, nausea;

asthenia (fatigue, tiredness).

Uncommon: may affect up to 1 in 100 people

decreased number of blood platelets;

weight decrease, weight increase;

suicide attempt and suicidal ideation;

anxiety, increased nervousness or irritability;

convulsion, balance disorder (equilibrium

disorder), dizziness (sensation of unsteadiness),

lack of energy and enthusiasm, tremor (involuntary
trembling), vertigo (sensation of rotation);

cough;

abdominal pain, diarrhoea, dyspepsia

(indigestion), vomiting, nausea;

asthenia (fatigue, tiredness).

Rare: may affect up to 1 in 1,000 people

injection;

increased number of all blood cell types;

severe allergic reactions (DRESS, anaphylactic

reaction); severe and important allergic

reaction), Quincke’s oedema (swelling of the

face, lips, tongue and throat);

decreased blood sodium concentration;

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;

liver failure, hepatitis;

sudden decrease in kidney function;

skin rash, which may form blisters and

takes 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 (Steven-Johnson syndrome), and a

more severe form causing skin peeling in

more than 30% of the body surface (toxic

epidermal necrolysis);

rhabdomyolysis (breakdown of muscle tissue)

and associated blood creatine phosphokinase

increases. Provence is significantly higher in

Japanese patients when compared to non-

Japanese patients.

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

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more

information on the safety of this medicine.

How to store Levetiracetam

This medicine 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.

Contents of the pack and other information

What Levetiracetam Milpharm contains

The active substance is levetiracetam. Each

film-coated tablet contains 250 mg, 500 mg, 750 mg,

1000 mg levetiracetam.

The other ingredients are:

- Tablet core: Mezite starch, Silica colloidal

anhydrous (E550), Povidone (K-30) (E101), Talc

(E957), Magnesium stearate (E470).

Film-coating:

- 250 mg: Hypromellose 3cp & 6cp (E464), Titanium

dioxide (E171), macrogol 4000, indigo carmine

aluminium lake (E132).

- 500 mg: Hypromellose 3cp & 6cp (E464), Titanium

Dioxide (E171), macrogol 4000, iron oxide yellow

(E172).

- 750 mg: Hypromellose 3cp & 6cp (E464), Titanium

Dioxide (E171), macrogol 4000, indigo carmine

aluminium lake (E132), sunset yellow aluminium

lake (E110), iron oxide red (E172).

- 1000 mg: Hypromellose 3cp & 6cp (E464), Titanium

Dioxide (E171), macrogol 4000.

What Levetiracetam Milpharm looks like and

contains of the pack

Film-coated tablet.

Levetiracetam Milpharm 250 mg film-coated tablets

Blue oval shaped biconvex film-coated tablets

debossed with a deep break line separating ‘E’ and

‘13’ on one side and plain on the other side. The
tablet can be divided into equal doses.

Levetiracetam Milpharm 500 mg film-coated tablets

Yellow oval shaped biconvex film-coated tablets

debossed with a deep break line separating ‘E’ and

‘11’ on one side and plain on the other side. The
tablet can be divided into equal doses.

Levetiracetam Milpharm 750 mg film-coated tablets

Orange oval shaped biconvex film-coated tablets

debossed with a deep break line separating ‘E’ and

‘12’ on one side and plain on the other side. The
tablet can be divided into equal doses.

Levetiracetam Milpharm 1000 mg film-coated

tablets

White modified oval shaped, biconvex film-coated
tablets debossed with a deep break line separating ‘E’

and ‘13’ on one side and plain on the other side.
The tablet can be divided into equal doses.

Levetiracetam Milpharm film-coated tablets are

packaged in blister pack or HDPE bottle.

Pack sizes:

Blister pack: 20, 30, 50, 50, 100, 200 and 500

film-coated tablets

Bottle pack: 30, 100, 200 and 500 film-coated
tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Milpharm Limited

Ares, Odyssey Business Park

West End Road

South Ruislip, HA4 6QD

United Kingdom

Manufacturer

APL Swift Services (Malta) Limited

HP26, Hal Far Industrial Estate, Hal Far

Birzebbuga, BIBG 3000

Malta

This medicinal product is authorised in the Member

States of the EEA under the following names:

France: Levetiracetam Arrow Lab

250 mg/ 500 mg/ 1000 mg comprimé pelliculé

séparable

Germany: Levetiracetam Aurobindo

250 mg/ 500 mg/ 750 mg/ 1000 mg Filmtabletten

Ireland: Levetiracetam Aurobindo

250 mg/ 500 mg/ 750 mg/ 1000 mg film-coated tablets

Italy: Levetiracetam Aurobindo

500 mg 1000 mg compresse nesclite con film

Netherlands: Levetiracetam Aurobindo

250 mg/ 500 mg/ 750 mg/ 1000 mg film-coated tablets

Poland: Levetiracetam Aurobindo

Romania: Levetiracetam Aurobindo

250 mg/ 500 mg/ 1000 mg film-coated tablets

Spain: Levetiracetam Aurobindo

250 mg/ 500 mg/ 1000 mg comprimidos recubiertos con película EFC

United Kingdom: Levetiracetam Milpharm

250 mg/ 500 mg/ 750 mg/ 1000 mg film-coated tablets

This leaflet was last revised in 6/2018.