# JUMEX® TABLET

Selegiline Hydrochloride (5mg)

#### What is in this leaflet

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

#### What Jumex is used for

Jumex is used in the treatment of Parkinson's disease. Jumex may be taken alone in the early stages of your condition, delaying the need for the addition of Levodopa, may reduce the on-off symptoms or uncontrolled movements you may experience. Jumex, however, can also be used in conjunction with levodopa to enhance and prolong the effect of levodopa.

#### **How Jumex works**

Jumex is a monoamine oxidase-B inhibitor. It works by improving effects such as shakiness, muscle stiffness and loss of normal movement caused by Parkinson's disease.

# Before you use Jumex

- When you must not use it Do not take Jumex if
- You are allergic (hypersensitive) to Selegiline or any of the other ingredients of Jumex (listed in section 8 below)
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have active duodenal or gastric ulcer
- You are taking levodopa, the contraindication which apply to levodopa must be taken into account.
- You are taking opioid painkillers such as pethidine
- You are taking any sympathomimetics medicines used in treatment of asthma or relieve nasal congestion.

Do not use this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Jumex.

#### - Before you start to use it

Take special care and check with your doctor if:

- -You have labile hypertension (blood pressure that fluctuates abruptly and repeatedly)
- You have irregular heartbeats and severe chest pain
- You have delusions or hallucinations
- You have had ulcers in your stomach in the past
- You have severe liver or kidney dysfunction
- You are about to have an operation
- You have rare genetic problems such as galactose or lactose intolerance and glucose-galactose malabsorption (intestines lining unable to take in glucose and galactose).
- You are already taking levodopa. Your doctor may need to monitor you closely and alter your dose.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Jumex.

#### - Taking other medicines

Do not take this medicine and tell your doctor if you are taking:

- Pethidine used as pain killers
- Selective serotonin reuptake inhibitors (fluoxetine) and serotonin noradrenaline reuptake inhibitors (venlafaxine) – used as antidepressants
- Tricyclic antidepressants used to treat depressants.
- Sympathomimetics- used in treatment of asthma or relieve nasal congestion

Tell your doctor, if you are taking:

- Levodopa used for Parkinson's disease
- Monoamine oxidase inhibitors (such as antibiotic linezolide)
- Oral contraceptives.

Doctor need to monitor you more frequently if you are taking:

• Medicines used to treat heart problems (such as digitalis)

• Medicines used to thin the blood (such as anticoagulant)

#### How to use Jumex

Always take Jumex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### - How much to use

- •The usual initial daily dose is 5 to 10mg (1 to 2 tablets) in the morning or administered as divided doses in the morning and early afternoon (lunch time). The daily dose of Jumex must not exceed 10 mg.
- In combined treatments the earlier levodopa dose can generally be reduced.

#### - When to use it

Take Jumex at about the same time each day unless your doctor tells you otherwise.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the medicine.

If you are not sure when to use it, ask your doctor or pharmacist.

#### - How long to use it

Continue taking your medicine for as long as your doctor tells you.

# - If you forget to use it

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten tablet.

#### - If you use too much (overdose)

If you take too many tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. The following effects may happen: agitation, tremor, alternating low and high blood pressure, respiratory depression, severe muscle spasms, fever, coma and convulsions.

#### While you are using it

- Things you must do

Pregnancy and breast-feeding Tell your doctor immediately:

- If you are pregnant, planning to become pregnant or if you think you may be pregnant. (Preferable to avoid the use of selegiline in pregnancy)
- If you are breast-feeding. (Not recommended for use)
- Things you must not do
- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not stop taking Jumex, or change the dosage, without checking with your doctor.
- Limit the amount of alcohol you drink while taking this medicine.
- Do not consume food containing large amounts of tyramine such as aged cheese and yeast products.
- Things to be careful of

Driving and using machines

Jumex may make you feel dizzy,
drowsy or slow your reactions,
therefore your ability to drive or
operate machinery may be affected. If
you experience these side effects then
do not drive, use tools or operate
machinery.

#### Side Effect

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor immediately if you have any of the following side effects: Common side effects (affecting between 1 in 10 than 1 in 100 patients)

- Dizziness, headache
- Feeling sick
- Slow heart beat

Uncommon side effects (affecting between 1 in 100 and 1 in 1000 patients)

- Mild transient sleep disorder
- Dry mouth
- Fast heart beat
- Mood change

Rare side effects (affecting 1 in 1000 to 1 in 10000)

- Skin reaction
- Low blood pressure that happens when you stand up from sitting or lying down (postural hypotension)

The following side effects are more likely to happen when Jumex is administered in combination with Levodopa:

- Restlessness
- Extremely excess of movements
- Abnormal movements
- Agitation
- Confusion
- Hallucination
- Low blood pressure that happens when you stand up from sitting or lying down (postural hypotension)
- Irregular heartbeat

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <a href="mailto:npra.moh.gov.my">npra.moh.gov.my</a> (Public→Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

## Storage and Disposal of Jumex

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

#### - Storage

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Jumex after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in a cool place below 30°C.

### - <u>Disposal</u>

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### **Product Description**

- What it looks like

The tablets are white or near white, round, flat tablets with a bevelled edge and engraved with the code 'JU' on one side. They are available in 50 tablets in laminated Al/Al blister.

- Ingredients:
- Each tablet contains 5.0 mg selegiline hydrochloride.
- The other ingredients are lactose monohydrate, maize starch, talc, polvidone K-25 and magnesium stearate.

#### MAL Numbers:

Jumex Tablets 5mg: MAL19950723AZ

#### Manufacturer

Chinoin Pharmaceuticals and Chemical Works Private Co. Ltd, 5 Levai Utca, H-2112 Veresegyhaz, Hungary.

#### **Product Registration Holder**

Sanofi-aventis (Malaysia) Sdn. Bhd. Unit TB-18-1, Level 18-1, Tower B, Plaza 33 No.1 Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor Darul Ehsan, Malaysia.

## **Date of revision**

5/12/2017

# Serial number:

NPRA(R4/1)011117/00301