

**PACKAGE LEAFLET: INFORMATION FOR THE USER**

**NERVIUS<sup>®</sup> 0.18 mg tablets**  
**NERVIUS<sup>®</sup> 0.7 mg tablets**  
**NERVIUS<sup>®</sup> 1.1 mg tablets**  
**Pramipexole**

**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 of the 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 **Nervius<sup>®</sup>** is and what is used for
2. What you need to know before you take **Nervius<sup>®</sup>**
3. How to take **Nervius<sup>®</sup>**
4. Possible side effects
5. How to store **Nervius<sup>®</sup>**
6. Other information

**1. WHAT NERVIUS<sup>®</sup> IS AND WHAT IS USED FOR**

**Nervius<sup>®</sup>** belongs to a group of medicines known as dopamine agonists, which stimulate dopamine receptors in the brain. Stimulation of the dopamine receptors triggers nerve impulses in the brain that help to control body movements.

**Nervius<sup>®</sup>** is used to:

- treat the symptoms of primary Parkinson's disease in adults. It can be used alone or in combination with levodopa.

**2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NERVIUS<sup>®</sup>****Do not take Nervius<sup>®</sup>**

- if you allergic to pramipexole (hypersensitive) or to any of the other ingredients of this medicine (listed in section 6)

**Take special care with Nervius<sup>®</sup>**

Talk to your doctor if you have (had) or develop any medicinal conditions or symptoms, especially any of the following:

- kidney disease.
- hallucinations (seeing, hearing or feeling things that are not there). Most hallucinations are visual.
- dyskinesia (e.g. abnormal, uncontrolled movements of the limbs). If you have advanced Parkinson's disease and are also taking levodopa, you might develop dyskinesia during the up titration of **Nervius<sup>®</sup>**.
- Sleepiness and episodes of suddenly falling asleep.

- behavioral changes (e.g. pathological gambling, compulsive shopping), increased libido (e.g. hypersexuality), binge eating – hyperphagia.
- psychosis (e.g. comparable with symptoms of schizophrenia).
- vision impairment. You should have regular eye examination during treatment with **Nervius**<sup>®</sup>.
- severe heart or blood vessels disease. You will need to have your blood pressure checked regularly, especially at the beginning of treatment. This is to avoid postural hypotension ( a fall in blood pressure on standing up)
- symptoms augmentation

You may experience that symptoms start earlier than usual, be more intense and involve other limbs.

### **Children and adolescents**

**Nervius**<sup>®</sup> is not recommended for use in children or adolescents under 18 years.

### **Taking other medicines**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines, herbal remedies, health foods or supplements that you have obtained without a prescription.

You should avoid taking **Nervius**<sup>®</sup> together with antipsychotic medicines.

Take care if you are taking the following medicines:

- cimetidine (to treat excess stomach acid and stomach ulcers)
- amantadine (which can be used to treat Parkinson's disease)
- mexitiline (to treat irregular heartbeats, a condition known as ventricular arrhythmia)
- zidovudine (which can be used to treat the acquired immune deficiency syndrome [AIDS]. a disease of the human immune system)
- cisplatin (to treat various types of cancers)
- quinine (which can be used for the prevention of painful night-time leg cramps and for the treatment of a type of malaria known as falciparum malaria [malignant malaria]).
- procainamide (to treat irregular heart beat).

If you are taking levodopa, the dose of levodopa is recommended to be reduced when you start treatment with **Nervius**<sup>®</sup>.

Take care if you are using any medicines that calm you down (have a sedative effect) or if you drink alcohol. The additive effect of **Nervius**<sup>®</sup> may affect your ability to drive and operate machinery.

### **Nervius**<sup>®</sup> with food, drink and alcohol

You should be cautious while drinking alcohol during treatment with **Nervius**<sup>®</sup>.

**Nervius**<sup>®</sup> can be taken with or without food. Swallow the tablet with a drink of water.

### **Pregnancy and breast-feeding**

#### *Pregnancy*

Tell your doctor if you are pregnant or if you are planning to have a baby. Your doctor will discuss with you if you should continue to take **Nervius**<sup>®</sup>.

**Nervius**<sup>®</sup> effect on the unborn child is not known. Therefore, you should not take **Nervius**<sup>®</sup> if you are pregnant, unless your doctor tells you to do so.

#### *Breast-feeding*

**Nervius**<sup>®</sup> should not be used during breast-feeding. **Nervius**<sup>®</sup> can reduce the production of breast milk. Also, it can pass into the breast milk and reach your baby.

If use of **Nervius**<sup>®</sup> is unavoidable, breast-feeding should be stopped.  
Ask your doctor or pharmacist for advice before taking any medicine.

### Driving and using of machines

**Nervius**<sup>®</sup> can cause hallucinations (seeing hearing or feeling things that are not there).

**Nervius**<sup>®</sup> has been associated with sleepiness and episodes of suddenly falling asleep, particularly in particularly in patients with Parkinson's disease.

If you experience these side effects, you must not drive or use machinery. You should tell your doctor if this occurs.

### Important information about some excipients of **Nervius**<sup>®</sup>

**Nervius**<sup>®</sup> tablets contains mannitol. It may have mild laxative (bowel emptying) action.

### 3. HOW TO TAKE NERVIUS<sup>®</sup>

Always take **Nervius**<sup>®</sup> exactly as your doctor has told you.  
The doctor will advise you on the right dosing.

You can take **Nervius**<sup>®</sup> with or without food. Swallow the tablets with water.

### Parkinson's disease

The daily dosage is to be taken divided into 3 equal doses.

During the first week, the usual dose is ½ tablet **Nervius**<sup>®</sup> 0.18 mg three times per day (equivalent to 0.27 mg daily):

	<b>1<sup>st</sup> week</b>
Number of tablets	½ tablet <b>Nervius</b> <sup>®</sup> 0.18 mg three times daily
Total daily dosage (mg)	0.27

This will be increased every 5-7 days as directed by your doctor until your symptoms are controlled (maintenance dosage).

	<b>2<sup>nd</sup> week</b>	<b>3<sup>rd</sup> week</b>
Number of tablets	1 tablet <b>Nervius</b> <sup>®</sup> 0.18 mg three times daily	½ tablet <b>Nervius</b> <sup>®</sup> 0.7 mg three times daily <b>ή</b> 2 tablets <b>Nervius</b> <sup>®</sup> 0.18 mg three times daily
Total daily dosage (mg)	0.54	1.1

The usual maintenance dose is 1.1 mg per day. However, your dose may have to be increased even further. If necessary, your doctor may increase your tablet dose up to a maximum of 3.2 mg of pramipexole a day.

	<b>Lowest maintenance dosage</b>	<b>Highest maintenance dosage</b>
Number of tablets	½ tablet <b>Nervius</b> <sup>®</sup> 0.18 mg three times daily	1 ½ tablet <b>Nervius</b> <sup>®</sup> 0.7 mg three times daily
Total daily dosage (mg)	0.27	3.2

#### *Patients with kidney disease*

If you have moderate or severe kidney disease, your doctor will prescribe a lower dosage. In this case, you will have to take the tablets only once or twice a day. If you have moderate kidney disease, the usual starting dose is ½ tablet **Nervius**<sup>®</sup> 0.18 mg twice a day. In severe kidney disease, the usual starting dose is just ½ tablet **Nervius**<sup>®</sup> 0.18 mg a day.

#### **If you take more Nervius<sup>®</sup> than you should**

If you accidentally take too many tablets,

- contact your doctor or nearest hospital casualty department immediately for advice.
- you may experience vomiting restlessness, or any of the side effects as described in section 4 (*Possible side effects*).

#### **If you forget to take Nervius<sup>®</sup>**

Do not worry. Simply leave out that dose completely and then take your next dose at the right time.

Do not try to make up for the missed dose.

#### **If you stop taking Nervius<sup>®</sup>**

Do not stop taking **Nervius**<sup>®</sup> without first talking to your doctor. If you have to stop taking this medicine, your doctor will reduce the dose gradually. This reduces the risk of worsening symptoms.

If you suffer from Parkinson's disease you should not stop treatment with **Nervius**<sup>®</sup> abruptly. A sudden stop could cause you to develop a medical condition called neuroleptic malignant syndrome which may represent a major health risk. The symptoms include:

- akinesia (loss of muscle movement)
- rigid muscles
- fever
- unstable blood pressure
- tachycardia (increased heart rate)
- confusion
- depressed level of consciousness (e.g. coma)

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, **Nervius**<sup>®</sup> can cause side effects, although not everybody gets them. Evaluation of these side effects is based on the following frequencies:

<b>Very Common</b>	may affect more than 1 in 10 people
<b>Common</b>	may affect 1 to 10 people in 100
<b>Uncommon</b>	may affect 1 to 10 people in 1.000
<b>Rare</b>	may affect 1 to 10 people in 10.000
<b>Very rare</b>	may affect up to 1 in 10.000 people
<b>Not known</b>	Frequency cannot be estimated from the available data

If you suffer from Parkinson's disease, you may experience the following side effects (regardless of indication):

Very Common:

- Dyskinesia (e.g. abnormal or uncontrolled movements of the limbs)
- Sleepiness
- Dizziness
- Nausea (sickness - tending to vomit)
- Hypotension (low blood pressure)

Common:

- Urge to behave in an unusual way
- Hallucinations (seeing, hearing or feeling things that are not there)
- Confusion
- Tiredness (fatigue)
- Sleeplessness (insomnia)
- Excess of fluid, usually in the legs (peripheral oedema)
- Headache
- Abnormal dreams
- Constipation
- Restlessness
- Amnesia (loss of memory)
- Visual impairment
- Vomiting (being sick - nausea)
- Weight loss

Uncommon:

- Paranoia (e.g. excessive fear for one's own well-being)
- Delusion
- Excessive daytime sleepiness and suddenly falling asleep
- Hyperkinesia (increased movements and inability to keep still)
- Weight increase
- Increased sexual interest and behaviour (e.g. increased libido)
- Allergic reactions (e.g. rash, itching, hypersensitivity)
- Fainting
- Pathological gambling especially when high dosages of **Nervius**<sup>®</sup> are taken.
- Hypersexuality
- Compulsive shopping
- Dyspnoea (difficulties to breathe)
- Pneumonia (infection of the lungs)

Not known:

- Increased eating (binge eating, hyperphagia)

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

## 5. HOW TO STORE NERVIUS®

Keep this medicine out the sight and reach of children.

Do not use **Nervius**® after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package to protect from light.

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. OTHER INFORMATION

### What **Nervius**® contains

The active substance is pramipexole.

0.18 mg tablets: each tablet contains 0.18 mg pramipexole base (as 0.25 mg pramipexole dihydrochloride monohydrate).

0.7 mg tablets: each tablet contains 0.7 mg pramipexole base (as 1.0 mg pramipexole dihydrochloride monohydrate).

1.1 mg tablets: each tablet contains 1.1 mg pramipexole base (as 1.5 mg pramipexole dihydrochloride monohydrate).

The other ingredients are: mannitol, maize starch, anhydrous colloidal silica, povidone K25 and magnesium stearate.

### What **Nervius**® looks like and contents of the pack

0.18 mg tablets: white, biconvex, oblong, scored on both sides tablets (dimensions: approximately 8mm×4mm).

0.7 mg tablets: white, round, flat, scored on one side tablets (diameter: about 9mm).

1.1 mg tablets: white, round, flat, scored on one side tablets (diameter: about 11mm).

**Nervius**® tablets are packed in blisters and in pack sizes of 30 or 100 tablets.

Not all pack sizes may be marketed.

### Marketing Authorization Holder

TARGET PHARMA Ltd.

54 Menandrou st., 10431, Athens Greece

Tel.: +30 210 52 24 830 Fax: +30 210 52 24 838

E-mail: [info@targetpharma.gr](mailto:info@targetpharma.gr), [www.targetpharma.gr](http://www.targetpharma.gr)

**Manufacturer**

Specifar ABEE,  
1, 28<sup>th</sup> October st. 123551 Agia Barbara, Athens Greece.  
Tel: +30 210 54 01 500  
E-mail: [info@specifar.gr](mailto:info@specifar.gr)

**Το παρόν φύλλο οδηγιών χρήσης εγκρίθηκε για τελευταία φορά στις 11/2016**

