

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 more 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.

SMART® 800 mg tablets

Piracetam

What is in this leaflet:

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

1. What SMART is and what is it used for

SMART belongs to a group of medicines known as GABA analogues. **SMART** contains the active ingredient Piracetam. It acts on the brain and nervous system and is thought to protect it against a shortness of oxygen. **SMART** are used in combination with other medicines to treat myoclonus. This is a condition in which the nervous system causes muscles, particularly in the arms and legs, to start to jerk or twitch uncontrollably.

2. What you need to know before you take SMART Do not take SMART

- if you are allergic to piracetam or any of the other ingredients of this medicine (listed in section 6).
 - if you have ever had serious kidney problems
 - if you suffer from Huntington's Disease (also known as Huntington's Chorea)
 - if you have ever experienced a brain haemorrhage
- If any of the above applies to you, do not take **SMART** and talk to your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking **SMART**

- if you think your kidneys may not be working perfectly. (Your doctor may need to start you on a lower dose.)
- if you have ever had any kind of bleeding problem.

Other medicines and SMART

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Tell your doctor if you are taking any of the following medicines:

- Thyroid extract or thyroxine
- Anticoagulants such as warfarin or aceno-coumarol
- Low dose aspirin
- Any other medicines, including medicines obtained without a prescription.

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. If you are taking this medicine, use contraception to avoid becoming pregnant. If you are taking **SMART** and you think you may be pregnant,

consult your doctor immediately.

Driving and using machines

SMART may cause drowsiness and shakiness. If this happens to you, do not drive or use machinery.

3. How to take SMART

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Important: Your doctor will choose the dose that is right for you. Your dose will be shown clearly on the label that your pharmacist puts on your medicine. If it does not, or you are not sure, ask your doctor or pharmacist.

Adults

How much medicine to take and when to take it
The recommended starting dose is 7.2 g each day (nine). It is best to split the dose so that the are taken on two or three separate occasions during the day (3 in the morning, 3 at midday and 3 in the evening). When you start taking this medicine your doctor may tell you to gradually increase the dose to ensure that you receive the best dose to treat your condition. Follow your doctor's instructions carefully.

How to take your medicine

Swallow the whole with a glass of water. Elderly and patients with kidney problems
If you are elderly or have kidney problems your doctor may reduce your dose.

If you take more SMART than you should

If you accidentally take too much, immediately go to the nearest hospital casualty department or your doctor.

If you forget to take SMART

Do not take a double dose to make up for a forgotten dose. Simply take the next dose as planned.

If you stop taking SMART

Do not stop taking **SMART** without first talking to your doctor. Abruptly stopping your medicine may cause twitching and jerking. 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.

You may notice the following side effects:

- An allergic reaction and experience difficulty breathing, swelling, fever
- Spontaneous bleeding caused by defects in your blood clotting mechanism
- Worse fits
- Hallucinations
- Difficulty balancing and unsteadiness when standing
- Anxiety and agitation

- Confusion
- Restlessness
- Nervousness
- Sleepiness
- Depression
- Weakness
- Vertigo
- Weight increase
- Stomach pain
- Diarrhoea
- Feeling or being sick
- Headache
- Being unable to sleep
- Swelling of the skin, particularly around the face
- Skin rash and itching.

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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store SMART

Do not store above 25°C. Store in the original package. Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month

6. Contents of the pack and other information

What SMART contains

The active substance is piracetam. Each tablet contains 800 mg piracetam. The other ingredients are microcrystalline cellulose, croscarmellose sodium, copovidone, sodium stearyl fumarate.

What SMART look like and contents of the pack

Box of 60 tablets (elongated, biconvex, white with brake line on one side) of 800 mg piracetam in plastic bottle.

Marketing Authorisation Holder and Manufacturer

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75300 Lukavac
Bosnia and Herzegovina

Date and number of first authorisation/renewal of the authorization

SMART, 60 tablets of 800 mg in box:

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