Package leaflet: information for the user

REMANTADIN 50 mg Tablets

Rimantadini hydrochloridum

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
This medicine is available without prescription. However, you still need to use *Remantadin* carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

In this leaflet:

1. What *Remantadin* is and what it is used for

This medicine contains rimantadine hydrochloride (referred to as rimantadine throughout this leaflet), which belongs to a group of medicines called antiviral agents. It is effective against influenza A virus and other A group viruses, as well as has an anti-toxic effect in case of intoxication caused by influenza B virus. *Remantadin* is effective against flaviviruses, which cause tick-borne encephalitis.

Remantadin is used for adults and children over 7 years of age for an early treatment of influenza, as well as for prophylaxis of the disease caused by influenza viruses during epidemic of influenza for adults and children over 7 years of age, and for prophylaxis of tick-borne encephalitis in adults.

2. What you need to know before you use *Remantadin*

Do not use *Remantadin*
- if you are allergic to rimantadine, compounds of the adamantane class or any of the other ingredients of this medicine (listed in section 6.)
- if you have acute hepatic disease
- if you have acute and/or chronic renal disease
- if you have thyrotoxicosis (an overactive thyroid gland)
- if you are pregnant or breast-feeding

Warnings and precautions
Before you use *Remantadin* consult your doctor:
- if you have gastrointestinal tract disorders
- if you have liver dysfunctions
- if you have serious heart disease and/or disorders of heart rhythm
- when you are elderly person

In these cases the decrease of *Remantadin* dose is recommended.

- If you have epilepsy and anticonvulsives are used, the concomitant use of *Remantadin* increases the risk of epilepsy attack. In this case it is recommended to reduce *Remantadin* dose to 100 mg daily. In case of attack, use of *Remantadin* must be discontinued.

Other medicines and *Remantadin*
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.
Paracetamol and acetylsalicylic acid decrease efficacy of *Remantadin*. Cimetidine may increase *Remantadin* efficacy.

***Remantadin* with food, drink and alcohol**
Food has no effect on *Remantadin* absorption. It is advisable to avoid alcohol, because unforeseen CNS reactions are possible.

Pregnancy, breast-feeding and fertility
Use of *Remantadin* is contraindicated.

Driving and using machines
Patients should be cautious if any signs of undesirable effects associated to CNS like dizziness, headache, occur during the course of treatment.

***Remantadin* contains lactose**
Remantadin tablets contain 74.5 lactose monohydrate. If your doctor has told you that you have some sugar intolerability, consult your doctor before use of this medicine.

3. How to use *Remantadin*

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Tablets are taken orally after meals, with liquid. *Remantadin* therapy should be initiated as soon as possible after onset of signs and symptoms of influenza. The pronounced therapeutic effect is achieved if the use of the preparation started within the first 48 hours.

Treatment of influenza.

Adults: in the first day use 100 mg (2 tablets) three times daily, in the second and third day – 100 mg twice a day, in the fourth and fifth day – 100 mg once a day. In the first day of illness 150 mg (3 tablets) twice a day or 300 mg (6 tablets) at once can be used.

Use in children and adolescents

Consult your doctor **obligatory** before use of *Remantadin* for children.
7-10 years – use 50 mg (1 tablet) twice a day, 11-14 years – 50 mg (1 tablet) three times a day, after 14 years – adult's doses. Course of treatment is 5 days.

Prophylaxis of influenza.

Adults – 50 mg (1 tablet) once a day, but not more than 30 days.

Use in children and adolescents

Children over 7 years – 50 mg once a day up to 15 days.

Prophylaxis of tick-born encephalitis after tick's bite.

Adults – 100 mg (2 tablets) twice a day during 3 days, in several cases (according to doctor's indication) – 5 days.

Prophylaxis using *Remantadin* should be started immediately after tick's bite, but not later than in 48 hours.

Prophylaxis of tick-born encephalitis without tick's bite

In separate cases (for risk groups, for hiking tours participants in wooded and overgrown countryside, for persons living in tents etc.) – only adults can use a tablet (50 mg) twice a day up to 15 days for prophylaxis.

If you use more *Remantadin* than you should
If you have used more *Remantadin* than you should, immediately call a doctor.

If you forget to use *Remantadin*
If you forget to take the medicine in the appropriate time, take it as soon as remember, and continue to use as usual.
Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Remantadin is usually well tolerated, but like all medicines it can cause side effects, although not everybody gets them.

Common (may affect up to 1 in 10 people): insomnia, nausea, vomiting.
Uncommon (may affect up to 1 in 100 people): palpitation, cardiac insufficiency, heart blockage, tachycardia, dizziness, headache, increased agitation, fatigue, attention disturbances, disturbances of movement coordination, somnolence, depression, euphoria, spontaneous movements, tremor, hallucination, confusion, crumps, decrease or loss of sense of smell, tinnitus, loss of appetite, dry mouth, stomach pain, diarrhea, gastrointestinal disorders, rash, hypertension, disturbances of brain blood circulation, syncope, weakness.

The frequency of side effects, especially of gastrointestinal tract and nervous system, is increased if the recommended doses are exceeded.
In separate cases when the dose is exceeded, increased lacrimation, increased frequency of micturition, fever, constipation, diaphoresis, stomatitis, increase of sensibility and eye pain are observed.
Usually side effects disappear after discontinuation of medicine administration.

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

5. How to store *Remantadin*

Do not store above 25°C. Store in the original package in order to protect from light and moisture.
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. The expiry date refers to the last day of that month.
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 *Remantadin* contains

- The active substance is rimantadine hydrochloride (Rimantadini hydrochloridum).

Each tablet contains 50 mg of rimantadine hydrochloride.

- Other ingredients are lactose monohydrate 74,5 mg, potato starch, stearic acid.

What *Remantadin* looks like and contents of the pack

White or almost white, round, flat tablets with bevelled edges.

10 tablets in blister, 2 blisters (20 tablets) and the patient leaflet in the carton box.

Marketing Authorisation Holder and Manufacturer
Joint-Stock Company “Olainfarm”
5, Rupnicu Street, Olaine,
LV-2114, Latvia

This leaflet was last revised in 10.2013.