

PACKAGE LEAFLET: INFORMATION FOR THE USER

OMNITUS

20 mg Film-coated tablet with modified release (OMNITUS)

50 mg Film-coated tablet with modified release (OMNITUS FORTE)

BUTAMIRATE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What OMNITUS is and what it is used for
2. Before you take OMNITUS
3. How to take OMNITUS
4. Possible side effects
5. How to store OMNITUS
6. Further information

1. WHAT OMNITUS IS AND WHAT IS IT USED FOR

OMNITUS is a medicine that prevents and soothes dry, chronic coughing. In addition, it relaxes muscle spasm of the bronchi making it easier to breathe.

OMNITUS is used to treat attacks of dry (non-productive) coughing of various causes.

2. BEFORE YOU TAKE OMNITUS

Do not take OMNITUS

- If you are allergic to the active substance or to any of the excipients in the medicine (see section 6)
- If you have a productive cough (cough with expectoration)
- If you are in the first trimester of pregnancy.

Take special care with OMNITUS

If after 7 days of treatment there is no improvement of the situation, that is, there is a deterioration of cough, it is necessary to consult a doctor about continuing the treatment.

If the cough is productive, ie followed by expectoration of thick mucus and secretions, it is not recommended to use this medicine, due to the fact that prevention of cough reflex may lead to building of secretions and mucus in the bronchi, which increases the risk of respiratory infections and the occurrence of muscle spasm of the bronchi (bronchospasm).

Concomitant administration of medicine OMNITUS which is an antiitussive, with medicines that make expectoration easier and break down thick secretions (expectorants and mucolytics), may also cause harm. OMNITUS 50 mg modified release tablets should only be taken by children over 12 years.

Taking other medicines

Please tell your doctor if you are taking or recently have taken any other medicines, including those obtained without a prescription.

There are no specific clinical studies which have investigated the interaction with other medicines; however, there is a theoretical interaction with medicines that have effect on the central nervous system, as well as the interaction with alcohol.

Taking OMNITUS with food and drink

Food and non-alcoholic beverages do not affect the effect of a medicine OMNITUS.

While taking the medicine OMNITUS, consumption of alcohol is not recommended.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Conducted studies on animals have shown that there are no harmful effects of the medicine on the fetus. Given that controlled clinical studies are not conducted in pregnant women, the administration of the medicine in pregnant women should be avoided in the first trimester of pregnancy, and during pregnancy medicine administration is justified only if the expected benefit to the pregnant woman outweighs the potential risk to the fetus.

It is not known whether the medicine OMNITUS excreted into human milk and the use of the medicine is not recommended during breast-feeding.

Driving and using machines

OMNITUS may cause drowsiness and thus affects the ability to drive and use machines.

Important information about certain ingredients of OMNITUS

OMNITUS tablets with modified release contain azo dyes that may cause allergic reactions.

OMNITUS medicine contains lactose. In case of intolerance to some sugars, contact your doctor before using this medicine.

3. HOW TO TAKE OMNITUS

OMNITUS is intended for oral administration.

Always take the medicine exactly as you doctor has recommended. If you are unsure, consult your doctor or pharmacist.

The maximum duration of therapy is 7 days. If your symptoms get worse or if the cough lasts longer than 7 days it is necessary to consult a doctor.

Film tablets with modified release 20 mg

Children from 6-12 years: 1 tablet 2 times a day

over 12 years: 1 tablet 2-3 times a day

Adults: 2 tablets 2-3 times a day

Film tablets with modified release 50 mg

Children over 12 years: 1-2 tablets a day.

Adults: 1 tablet every 8 to 12 hours.

If you take more OMNITUS than you should

If you have taken a higher dose of OMNITUS than you should, you should talk to your doctor or pharmacist!

Symptoms of an acute overdose of butamiratum are drowsiness, nausea, vomiting, diarrhea, loss of balance and lowering of blood pressure.

If you forget to take OMNITUS

If you have missed a dose of the medicine, you should take the next prescribed dose at the scheduled time. Do not take a double dose to make up for a forgotten one.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, OMNITUS can cause side effects, although not all patients experience them.

Uncommon side effects (may affect 1 in 10 out of 1,000 patients taking the medicine): dizziness, drowsiness, nausea and diarrhea.

These symptoms usually disappear after reducing the dose or stopping the treatment.

Rare side effects (may affect 1 in 10 out of 1,000 patients taking the medicine): rash and hives.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 OMNITUS

Keep out of the reach and sight of children.

Do not store above 25 °C.

Shelf life: 2 years.

Do not use OMNITUS after the expiration date shown on the packaging after the symbol “EXP”. The expiration date refers to the last day of the month indicated.

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.

6. FURTHER INFORMATION

What OMNITUS contains

OMNITUS, 20 mg of, film-coated tablets with modified release

The active substance is butamirate (as butamirate citrate).

1 tablet contains 20 mg of butamirate citrate.

The other ingredients are:

core:

Lactose monohydrate;

Hypromellose 4000 cp;

Magnesium stearate;

talc;

Silica, colloidal anhydrous;

Povidone.

Film:

Hypromellose 3 cp;

talc;

Ethyl cellulose;

Macrogol 6000;

Titanium dioxide E171 C.I. 77891;
FDC Yellow N 6 lack C.I. 15985: 1 (11%).
OMNITUS forte, 50 mg, film-coated tablets with modified release

The active substance is butamirate (as butamirate citrate).
1 tablet contains 50 mg of butamirate citrate.

The other ingredients are:

Core:

Lactose monohydrate;

Hypromellose 4000 cp;

talc;

Magnesium stearate;

Silica, colloidal anhydrous;

Povidone.

Film:

Hypromellose 3 cp;

talc;

ethylcellulose;

Macrogol 6000;

Titanium dioxide E 171 C.I. 77891;

Braun lack C.I. 15985: 1 / (E 110)

C.I. 14720: 1 / (E 122)

C.I. 28440: 1 / (E 151);

Cochineal Red lack E 124 C.I. 16,255.

What OMNITUS looks like and contents of the pack

OMNITUS, 20 mg, film-coated tablets with modified release

Round, biconvex tablets, yellow to orange, with white break line.

In a cardboard box with 1 blister of Al-foil and PVC / PVDC film with 10 tablets of 20 mg.

OMNITUS forte, 50 mg, film-coated tablets with modified release

Round, biconvex tablets, brick-red, with white break line.

In a cardboard box with 1 blister of PVC / PVDC / Al foil with 10 film-coated tablets of 50 mg.

Regime of dispensing

The medicine is issued without doctor`s prescription.

Manufacturer

Hemofarm d.o.o. Banja Luka, Novakovići bb, Banja Luka, BiH