PACKAGE LEAFLET:
Information for the patient

LANATOZID C

Solution for injection – 0.4 mg / 2 ml (0.02 %)
(Lanatoside C)

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT LANATOZID C IS AND WHAT IT IS USED FOR

Lanatozid C is a cardiac glycoside with positive inotropic effect. Its effects are similar with digoxin. It increases the myocardial contraction strength and decreases myocardial conductivity, especially the conductivity through the AV node.
Lanatozid C exerts positive inotropic effect and negative chronotropic effect.
Approximately 20% of the used dose is inactivated within 24 hours. Its effects disappear after 3 – 6 days. Digoxin is the metabolite of lanatoside C and it is eliminated through urine.

Lanatozid C is indicated in:
- the treatment of mild to moderately severe heart failure
- the treatment of paroxysmal supraventricular tachycardia.

Your doctor may have given Lanatozid C for a different purpose. Ask your doctor if you want to know why you have been given Lanatozid C.

2. BEFORE YOU TAKE LANATOZID C

Do not take Lanatozid C if:
- you are allergic to lanatoside C (rare), to other glycosides, or to any of the other ingredients of the formula;
- you suspect that you have a digitalics overdose (prior the injection of the drug, you must be sure that not only during the time but also 1-2 weeks before you have not been treated with digitalics, even in low doses);
- you have had a digitalics overdose;
- you have different conductive disorders;
- you suffer from sick sinus syndrome;
- you suffer from ventricular fibrillation;
- you suffer from hypertrophic obstructive cardiomyopathy;
- you have had acute myocardial infarction;
- you suffer from Wolff-Parkinson-White syndrome, especially if it is accompanied with atrial fibrillation.

Digitalis should be stopped in patients who are preparing to undergo electrical shock.

If you think you have any of the conditions mentioned above, consult your doctor first and follow the advice given.

Take special care with Lanatozid C
Lanatozid C should be used with caution in heart block. If lanatoside C and other cardiac glycosides are used in partial heart block, they may trigger a complete heart block.
Care should be done also in patients with rheumatic carditis.
Electrolytic disbalances can affect the sensibility to digitalics. Their effects are enhanced from: hypokalemia, hypomagnesemia, hypercalcemia, hypoxia, and hypothyroidism. In these cases, the digitalis dose should be reduced until these situations are corrected.
The dose and levels of Lanatozid C in plasma must be controlled in patients with impaired renal function, in elderly and in children.
During the use of digitalics, special attention should be paid to the appearance of symptoms of toxicity, because they are drugs with narrow therapeutic index.

Taking other medicines
Concomitant treatment with other medicines can affect or be affected by Lanatozid C. Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Remember to inform your doctor for the treatment with Lanatozid C if you get any other drug during treatment.
In patients treated with maintenance doses of one glycoside, injection into a vein of another glycoside with rapid action, causes severe toxicity.
In patients treated with Lanatozid C, injection into a vein of sympathomimetics or calcium preparation, is life - threatening because it can cause severe arrhythmias.
Drugs which cause electrolyte disbalance increase the toxicity risk of lanatoside C and cardiac glycosides in general.
Thiazide diuretics and loop diuretics cause hypokalemia and hypomagnesemia which can cause cardiac arrhythmia.
Other causes of hypokalemia are: treatment with corticosteroids, amphotericin, ion-exchanging resins, carbenoxolone and dialysis.
Serum concentrations of lanatoside C can be highly increased by quinidine, amiodarone and propafenone.
Calcium channel blockers can increase the concentrations of lanatoside C.
Propranolol, verapamil and reserpine have a synergistic effect with the chronotropic and dromotropic effect of lanatoside C.
Barbiturates, phenylbutazone, antihistamines, phenytoin, oral hypoglycemiants increase the metabolism of lanatoside C, reducing its effect.
Seek the advice of a doctor or pharmacist if simultaneously with Lanatozid C you also receive the above mentioned drugs.

Taking Lanatozid C with food and drinks
Not applicable.

Pregnancy and breast-feeding
Tell your doctor or pharmacist if you are pregnant or are planning to become pregnant or if you are feeding your baby with breast milk.
Use during this period should be avoided.

Driving and using machines
No data.

3. HOW TO TAKE LANATOZID C

Always take Lanatozid C exactly as your doctor has told you. If you are not sure, check with your doctor or pharmacist.
If you feel that the effects of Lanatozid C are very strong or too weak, talk to your doctor or pharmacist.

Before administration into the vein, the solution of the ampoule is diluted with physiologic solution or glucose and then administered slowly into the vein.
The slow saturation dose in severe heart failure is 0.4 - 0.8 mg (1 - 2 ampoules) injected into a vein for 7 - 10 days, while in moderately rapid saturation 0.8 - 1.2 mg (2 - 3 ampoules) for 3 - 5 days are injected into a vein.
After achieving the therapeutic effect, it is continued with maintenance doses.
This dose is 0.2 - 0.4 mg (1/2 - 1 ampoule) per day, injected into a vein.
The maximal single dose is 0.8 mg, while the maximal daily dose is 1.6 mg.
Children: the saturation dose is 0.008 - 0.016 mg/kg weight.
Your doctor may ask you to take Lanatozid C for a longer time. Ask your doctor for advice if you are not sure for how long you should take it.

If you take more Lanatozid C
Taking doses higher than those recommended may lead to toxicity from lanatoside C.
If you have taken more Lanatozid C than the amount that should be taken, or if the children have taken this drug by mistake, please contact your doctor, hospital, or call the emergency to get an opinion on the risk and advice on the actions to be taken.
Symptoms of overdose from Lanatozid C are: nausea, vomiting, anorexia, diarrhea, headache, tiredness, weakness, dizziness, drowsiness, mental confusion, nightmares and rarely delirium, acute psychosis and hallucinations.

If you forget to take Lanatozid C
If you forget a dose, take your next dose when it is time to take it usually.
Do not take a double dose to make up the missed dose.
If you have further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

All medicines may cause side effects. Sometimes they are serious, most of the time not.
Lanatoside C and other cardiac glycosides can cause side effects because the range between therapeutic and toxic doses is small and this may be a cause even for fatal outcomes.
Toxicity is the most common side effect, which is displayed with general signs, cardiac signs, gastrointestinal and neurological signs.
Cardiac signs can display with deterioration of heart failure, sinus bradycardia, atrioventricular block. Characteristic of digitalis toxicity is paroxysmal atrial tachycardia with block.
In the gastrointestinal tract are observed: nausea, vomiting, anorexia, diarrhea.
In CNS appear: headache, fatigue, weakness, vertigo, drowsiness, mental confusion, nightmares, rarely delirium, acute psychosis and hallucinations.
Hypersensitivity reactions may appear, expressed as thrombocytopenic purpura, maculopapular rash, gynecomastia.
Inform your doctor if you get any of the mentioned side effects. If you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LANATOZID C

Keep out of the reach and sight of children!
Do not use Lanatozid C after the expiry date stated on the package.
Do not store above 25 ºC!
Keep in the original packaging to protect it from light and humidity.

6. FURTHER INFORMATION

What Lanatozid C- Solution for injection contains
The active substance is lanatoside C.
Each 2 ml ampoule contains 0.4 mg lanatoside C.
The other ingredients are: ethyl alcohol, glycerin, hydrochloric acid may be added for pH adjustment, water for injection.

Content of the pack
Box with 10 ampoules and box with 100 ampoules (hospital use).

Explanatory of the illustration icons on the packaging:

Prescription only medicine.

Content. Warning.

Solution for injection.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a.
Rruga "Myslym Keta"
Tel.: 00355 4 23 89 602
Tirana - ALBANIA

This leaflet was last revised in November 2010.

SPECIFICATION CROPING AREA 12 x 19 cm

PAY ATENTION, all the layers are visible.
If you have to print this document please check or uncheck the specific layers.