SPECIALIST INFORMATION LEAFLET

SERSENCA

TRADE NAME
Sersenca

INTERNATIONAL NONPROPRIETARY NAME OR MODIFIED INTERNATIONAL NONPROPRIETARY NAME
Phospholipids

CHEMICAL NAME
1,2-diacyl-sn-glycero-3-phosphocholine

PHARMACEUTICAL FORM
Solution for intravenous administration.
Description: clear greenish-yellow coloured solution.

COMPOSITION
1 ampoule of the drug contains
Active substance: phosphatidylcholine (in the form of soybean phospholipids) 250 mg.
Excipients: sodium deoxycholate, 96% ethanol, all-rac-α-tocopheryl acetate, riboflavin (in the form of riboflavin sodium phosphate), benzyl alcohol, sodium chloride, sodium hydroxide and/or hydrochloric acid, water for injection.

ATC CODE OF THE DRUG A05BA

PHARMACOTHERAPEUTIC GROUP
Preparations for treatment of hepatobiliary diseases.
Hepatoprotective drug.

PHARMACOLOGICAL PROPERTIES

PHARMACODYNAMICS
Phospholipids in the composition of Sersenca are essential structural elements of cell membrane and organells; they are similar in their chemical structure to endogenous phospholipids, but are superior to these according to activity due to higher content of polyunsaturated fatty acids. Incorporation of these high-energy molecules into damaged sites of hepatocyte cell membranes restores integrity of liver cells and favours their regeneration. As cis-double links of their polyunsaturated fatty acids prevent parallel location of hydrocarbon chains in phospholipid membranes, density of phospholipid structures location is reduced, which increases metabolic rate. The formed functional units increase activity of enzymes fixed on membranes and favour normal, physiological pathway of essential metabolic processes. Phospholipids regulate lipoprotein metabolism, transferring neutral fats and cholesterol to oxidation sites, which is mainly performed due to an increase in the ability of high density lipoproteins to bind to cholesterol. Consequently, normalizing action towards lipid and protein metabolism is performed, as well as towards detoxification function of the liver, restoration and maintaining of the structure of liver cells and phospholipid-dependent enzyme systems, which finally prevents formation of connective tissue in the liver. Lithogenic index decreases and bile stabilizes in excretion of phospholipids in bile.

PHARMACOKINETICS
Binding mainly with high density lipoproteins, phosphatidylcholine enters particularly into liver cells.
Elimination half-life of the choline component is 66 hours; that of unsaturated fatty acids – 32 hours. About 5% of the drug are excreted in faeces.

**THERAPEUTIC INDICATIONS**
- liver steatosis (including in diabetes mellitus);
- acute and chronic hepatitis, liver cirrhosis, liver cell necrosis, hepatic encephalopathy, coma and precoma, toxic lesions of the liver (including in alcoholism);
- drug-induced liver injury;
- pronounced alterations of liver function tests in gestational toxicosis and gestosis; acute yellow atrophy of the liver (acute hepatitis, Sheehan’s disease); benign pregnancy cholestasis (hepatosis of pregnancy);
- pre- and postoperative treatment, especially in surgeries in the hepatobiliary area;
- cholestasis and prevention of recurrent gallstones formation;
- psoriasis (as adjuvant therapy);
- radiation disease.

**DOSAGE AND ADMINISTRATION**

**Sersenca** is designed for intravenous administration; it should not be administered subcutaneously and intramuscularly due to possible local irritation reactions.

**Adults and children aged 12 years and older**, unless recommended otherwise, are given a slow intravenous stream injection of 5-10 ml (1-2 ampoules) of the drug daily; in severe cases - 10 ml to 20 ml (2-4 ampoules) daily. A single acceptable dose of the drug is up to 10 ml (2 ampoules).

**Children aged 6 to 12 years** are given 2-5 ml of the drug daily.

**Children aged 3 to 6 years** are given 2 ml of the drug daily.

It is recommended to dilute the drug with the patient’s own blood in the ratio of 1:1. If using of the patient’s blood is impossible, dilute the drug with 5% or 10% dextrose (glucose) solution for infusion, free from electrolytes, in the ratio of 1:1. Duration of treatment is determined by the doctor individually with regard to clinico-laboratory indices and may vary from 2-5 days to 10-20 days.

According to doctor’s indications, the drug can be diluted in 250-300 ml of 5% dextrose (glucose) and administered dropwise at the rate of 40-50 drops per minute. Diluted solution should stay clear over the whole period of administration. It is recommended to substitute parenteral administration of the drug with oral administration within the shortest possible time.

Do not mix in one syringe with other drugs. Do not dilute with 0.9% sodium chloride solution and Ringer’s solution!

**CONTRAINDICATIONS**
- hypersensitivity to the components of the drug;
- children under 3 years old, including newborn and preterm children.

**SIDE EFFECTS**
The following terms are used in order to assess incidence of side effects: very common (≥ 1/10), common (≥ 1/100 - < 1/10), uncommon (≥ 1/1000 - < 1/100), rare (≥ 1/10000 - < 1/1000), very rare (< 1/10000), unknown incidence (cannot be assessed according to the available data).

**Gastrointestinal tract disorders:** administration in high doses may induce diarrhea.

**Immune system disorders:** in rare cases hypersensitivity reactions are possible due to the presence of benzyl alcohol in the composition of the drug; in very rare cases cutaneous allergic reactions (rash, exanthema or urticaria) are possible; unknown incidence - itching.

**SPECIAL INDICATIONS**
Use only clear solutions!
Do not use electrolyte solutions to dilute the solution for intravenous administration.
INFLUENCE ON ABILITY TO DRIVE AND OPERATE OTHER MECHANISMS
The drug does not influence the ability to drive and to perform activities requiring increased attention.

PREGNANCY AND LACTATION
Administration of the drug during pregnancy is possible only in cases when expected benefit for the mother outweighs potential risk for the fetus, due to the presence of benzyl alcohol, able to penetrate through the placental barrier, in the composition of Sersenca. If administration of Sersenca during lactation is necessary, terminate breast feeding due to the absence of the data on safety of the drug administration.

PEDIATRIC USE
The drug is contraindicated to children under 3 years old (due to the presence of benzyl alcohol in the composition of the drug).

DRUG INTERACTIONS
Interaction with anticoagulants is possible, thus anticoagulant dose adjustment is required in concomitant administration. Interaction with other drugs is unknown.

OVERDOSE
Not observed.

PRESENTATION
Solution for intravenous administration.
5 amber coloured glass ampoules of 5 ml capacity in a contour tray.
1 contour tray together with a leaflet in a carton box.

STORAGE CONDITIONS
Store at temperature of 2°C-8°C.
Keep out of reach of children!

SHELF LIFE
3 years from the date of manufacture.
Do not apply after the expiry date.

SALES TERMS
Sold under prescription.

MANUFACTURER
The holder of trade mark and marketing authorization is “DR SERTUS İLAÇ SANAYİ VE TİCARET LİMİTED ŞİRKETİ”, TURKEY.