Patient package insert according to Pharmacists' Regulation (Preparations)-1986

This medicine can be sold with a physician's prescription only

Cerebonin® 120 mg

Film-coated tablets

Name of the medicine, its form and strength:
Name of the medicine: Cerebonin® 120 mg
Form: Film-coated tablets

The active ingredient and its quantity in dosage unit:
Each film-coated tablet of Cerebonin® 120 mg contains: 120 mg dry extract from Ginkgo biloba leaves (35-67:1) (EGb 761®).
The 120 mg dry extract contains: Flavone glycosides 26.4 - 32.4 mg, Terpene lactones 6.48 - 7.92 mg, **Comprising of:** ginkgolides A,B,C (3.36 - 4.08 mg) and of bilobalide (3.12-3.84 mg). Ginkgolic acids less than 0.6 µg per film-coated tablet.

For list of excipients and allergens in the medicine- see section 6.

Read this entire leaflet carefully before using this medicine.
This leaflet contains concise information about the medicine. If you have any further questions, ask the physician or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar. The medicine is intended for adults above 18 years of age.

1. What is the medicine intended for?

The medicine Cerebonin® 120 mg is intended:

- For the symptomatic treatment of mental losses due to organic brain syndrome within the framework of a general therapeutic concept for dementia syndromes, having as major symptoms: Deficient memory, disturbances of concentration, depressive mood, dizziness, tinnitus and headache.
- For the treatment of vertigo and dizziness of vascular origin (due to disturbance in blood flow) or age related.
- For the supportive treatment of tinnitus of vascular origin (due to disturbance in blood flow) or age related.

Therapeutic group: other anti-dementia drugs, peripheral vasodilators

2. Before using this medicine:

X Do not use the medicine:

- If you are hypersensitive (allergic) to the plant Ginkgo biloba or to any of the additional ingredients that the medicine contains.
- During pregnancy.

! Special warnings regarding the use of this medicine:

- Prior to starting treatment with preparations containing Ginkgo biloba extract, clarification should be obtained as to whether the pathological symptoms encountered are not based on an underlying disease requiring a specific treatment.
- Before treatment with Cerebonin® 120 mg, tell your physician if you suffer from frequently occurring dizziness or tinnitus. In any case of sudden decrease in hearing or hearing loss, refer to your doctor immediately.
- Before treatment with Cerebonin® 120 mg tell your doctor if you suffer from a disease or disorder that is characterized by an increased tendency to bleeding (haemorrhagic diathesis) or if you are taking anticoagulants or blood thinners.
- Single reports indicate the possibility that using preparations containing Ginkgo biloba may increase bleeding tendency. Therefore, treatment with Cerebonin® 120 mg should be discontinued before a surgery or surgical interventions.
- Before treatment with Cerebonin® 120 mg, inform your doctor if you suffer from epileptic seizures.

! If you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements, tell your physician or pharmacist.

- Inform your doctor or pharmacist especially if you are taking anticoagulants and blood thinners such as: phenprocoumon, warfarin, clopidogrel, acetyl salicylic acid (aspirin) and other nonsteroidal antirheumatics (anti-inflammatory) drugs, as it cannot be excluded that the effect of these medicines is enhanced.
- As for other medicines, it cannot be excluded that taking Cerebonin® 120 mg acts on the metabolism of other medicines which may influence their potency and duration of activity. There are no sufficient investigations available on this effect. Tell your doctor or pharmacist if you are taking or have recently taken other medicines.

! Use of the medicine and food: The medicine Cerebonin® 120 mg can be taken with or without food.

! Children and adolescents: Do not use Cerebonin® 120 mg in children and adolescents under 18 years of age since there is no sufficient investigations available regarding use of this medicine in this age group.

! Pregnancy and breastfeeding: Since single reports indicate that using preparations containing Ginkgo biloba may increase the tendency to bleeding, do not use the medicine Cerebonin® 120 mg if you are pregnant.
There is no sufficient investigations available regarding the safety of the medicine during breastfeeding. Therefore, do not use Cerebonin® 120 mg if you are breastfeeding. It is unknown whether the extract components in Cerebonin® 120 mg are excreted in breast milk.

! Important information about some of the ingredients of the medicine: The medicine contains lactose. Consult your physician before using Cerebonin® 120 mg if you suffer from intolerance to sugars.

3. How to use this medicine:

Always use according to your physician‘s instructions. Check with your physician or pharmacist if you are not sure. The dosage and administration will be determined by your physician only. Tell your physician or pharmacist if the effect of the medicine is too weak or too strong. The individual response to treatment with Cerebonin® 120 mg cannot be predicted.

The usual recommended dosage is:

For the symptomatic treatment of mental losses due to organic brain syndrome within the framework of a general therapeutic concept for dementia syndromes: one film-coated tablet twice daily.

For the treatment of vertigo and dizziness of vascular origin (due to disturbance in blood flow) or age related and for the supportive treatment of tinnitus of vascular origin (due to disturbance in blood flow) or age related: one film-coated tablet 1 to 2 times per day.

If your doctor has instructed you to take the medicine twice daily, take the film-coated tablet every morning and evening.
If your doctor has instructed you to take the medicine once daily, take the film-coated tablet every morning.

Do not take the film-coated tablet in a lying position. Do not chew the film-coated tablet. There is no data concerning crushing or cutting the film-coated tablet. Swallow the medicine with sufficient amount of liquid (preferably a glass of water). Do not exceed the recommended dose.

The duration of treatment with the medicine:

Your physician will decide on the duration of treatment according to your condition. Consult your physician if you feel that the effect of the medicine is too strong or too weak.

For the symptomatic treatment of mental losses due to organic brain syndrome within the framework of a general therapeutic concept for dementia syndromes: the minimal duration of treatment is 8 weeks. Consult your physician after 3 months of treatment with the medicine.

For the treatment of vertigo and dizziness of vascular origin (due to disturbance in blood flow) or age related: Consult your physician if there is no improvement in your condition after 6 to 8 weeks of treatment with the medicine.

For supportive treatment of tinnitus of vascular origin (due to disturbance in blood flow) or age related: the minimal duration of treatment is 12 weeks. Consult your physician if there is no improvement in your condition after 6 months of treatment with the medicine.

If you have accidently taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a physician or a hospital emergency room and bring the package of the medicine with you. If you have taken an overdose, the side effects as a result of using the medicine may be increased. No cases of overdose have been reported so far.

If you forgot to take the medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult your physician.

Continue with the treatment as recommended by your physician.
Even if there is an improvement in your health condition, do not discontinue treatment with this medicine without consulting your physician.

How can you assist in the success of the treatment?

Do not take medicines in the dark! Check the label and dose each time you take a medicine. Wear glasses if you need them. If you have any further questions regarding the use of this medicine**,** consult your physician or pharmacist.

4. Side effects:

Like any other medicine, the use of Cerebonin® 120 mg may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.
The following list of side effects includes all of the side effects reported as a result of using dry extract from Ginkgo biloba leaves (not only EGb 761®), including cases of long term treatment or high dosage.

Since only single cases of side effects have been reported by patients, physicians and pharmacists, the exact frequency of side effects resulting from the use of preparations containing Ginkgo biloba cannot be determined.
Based on single cases, the following side effects may appear during treatment with Cerebonin® 120 mg:

- Bleeding from single organs may occur, particularly in cases of concomitant treatment with anticoagulants and blood thinners such as: phenprocoumon, warfarin, clopidogrel, acetylsalicylic acid (aspirin) and other nonsteroidal antirheumatics (anti-inflammatory) drugs.
- Severe hypersensitivity reactions (anaphylactic shock) are possible in hypersensitive people.
- Allergic skin reactions (reddening, swelling, itching) may occur.
- Mild gastrointestinal disturbances, headache, dizziness or enhancement of existing dizziness may occur.

If one of the side effects appears, worsens, or when you suffer from a side effect not mentioned in the leaflet, consult your physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that can be found on the home page of the Ministry of Health's website (www.health.gov.il), which refers to the online form reporting side effects, or via the following link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine:

Avoid poisoning! This medicine and any other medicine must be stored in a safe place out of the reach of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
Do not use the medicine after the expiry date (Exp. Date) stated on the carton package or blister. The expiry date refers to the last day of that month.

Storing conditions: Store below 30ºC.

6. Additional information:

In addition to the active ingredient, the medicine also contains the following excipients:

Sodium croscarmellose; dimeticone; hypromellose; lactose monohydrate; macrogol 1500; magnesium stearate; maize starch; highly dispersed silicon dioxide; microcrystalline cellulose; alpha-octadecyl-omega-hydroxypoly (oxyethylene)-5; sorbic acid; talc; titanium dioxide (E171); iron oxide hydrate (E172), antifoam emulsion SE2 dry substance.

What the medicine looks like and contents of the package: The medicine Cerebonin® 120 mg is an oval, yellow colored tablet, with no score line. The tablets are packed in blisters, packaged in carton boxes.

Size of package: The medicine Cerebonin® 120 mg is supplied in carton packages containing blister/s with 15 film-coated tablets. The number of blisters in each carton package may vary according to the size of the package. Not all package sizes may be marketed.

Registration holder and importer: Dr. Samuelov Importing & Marketing Ltd. Company ID 512260944 P.O.B 2486, Ra'anana 4365007

Manufacturer: Dr. Willmar Schwabe GmbH & Co. KG, Karlsruhe, Germany.

The format of this leaflet was determined by the Ministry of Health and its content checked and approved in March 2016.

Drug registration number in the national medicine registry of the Ministry of Health: 155-61-34325-00