PATIENT INFORMATION LEAFLET

KAFESIT 20 mg/mL solution for infusion and oral solution
Sterile
Intravenous or oral route of administration.

• ***Active ingredient*:** Each ml contains 20 mg caffeine citrate (equivalent to 10 mg/ml caffeine).
Each vial contains 60 mg caffeine citrate (equivalent to 30 mg/3ml caffeine).

• ***Excipients:*** Citric acid monohydrate, sodium citrate dihiydrate and water for injection.

Read all of this leaflet carefully before treatment with this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have further questions, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher** or **lower** dose other than the recommended to you.*

In this leaflet:

1. What KAFESIT is and what is it used for?

KAFESIT is a stimulant of the central nervous system, belonging to a group of medicines called methylxanthines.

KAFESIT is used for the short-term treatment of premature apnea in infants with 28 to < 33 weeks gestational age.

These short periods when premature babies stop breathing are due to the baby's breathing centers not being fully developed.
Each box contains 1 or 10 vials of 3 ml.

2. Before you take KAFESIT

DO NOT take KAFESIT in the following cases:
If,
your newborn is allergic (hypersensitivity) to caffeine citrate or any of the other ingredients of this medicine,

Take special care with KAFESIT:
If:

- your newborn suffers from seizures
- your newborn suffers from any heart disease
- your infant has kidney or liver problems
- your infant has frequent regurgitation
- your infant produces more urine than usual
- your infant has a reduced weight gain or food intake
- your infant has been previously treated theophylline (used for breathing difficulties)
- you (the mother) consumed caffeine prior to delivery

Prior to starting treatment for apnea of prematurity with KAFESIT other causes of apnea should have been excluded or properly treated by your baby's doctor.

Please consult your doctor, even if these statements were applicable to you at any time in the past

Taking KAFESIT with food and drink
No data are available.

Pregnancy
Ask your doctor or pharmacist for advice before taking the medicine.

If you (the mother) are pregnant, you should not drink coffee or take any other high caffeine product as caffeine passes into breast milk.

If you notice that you are pregnant during treatment, please consult your doctor immediately.

Breast-feeding
Ask your doctor or pharmacist for advice before taking the medicine.

If you are breast-feeding while your infant is treated with KAFESIT, you should not drink coffee or take any other high caffeine product as caffeine passes into breast milk.

Driving and using machines
No data are available.

Important information about some of the excipients of KAFESIT
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. is essentially 'sodium-free'.

Taking with other medicines
Do not use the following medicines during the treatment with KAFESIT without talking to your doctor. The doctor may need to adjust the dose or change one of the medicines to something else:

- theophylline (used to treat breathing difficulties)
- doxapram (used to treat breathing difficulties)
- cimetidine (used to treat gastric disease)
- ketoconazole (used to treat fungi infections)
- phenobarbital (used to treat epilepsy)
- phenytoin (used to treat epilepsy)

This medicine may increase the risk for serious intestinal disease with bloody stools (necrotizing enterocolitis) when administered with medicines used to treat gastric disease (such as antihistamine H2 receptor blockers or proton-pump inhibitors that reduces gastric acid secretion)

If you (the mother) are taking medicines containing phenobarbitone or phenytoin used to treat epilepsy, your baby may react to caffeine treatment.

Kafesit should not be used with non-steroidal anti-inflammatory ketoprofen, acyclovir used in the treatment of infections caused by viruses, diuretic furosemide, nonsteroidal anti-inflammatory ibuprofen lysine, lorazepam used in the treatment of mental illness, nitroglycerin as a heart drug, and oxacillin as an antibiotic.

If you have taken any medicines used to treat epilepsy during pregnancy, please tell your doctor.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to take KAFESIT?
KAFESIT should only be used in a neonatal intensive care unit in which adequate facilities are available for patient surveillance and monitoring. Treatment should be initiated under supervision of a physician experienced in neonatal intensive care.

Instructions for proper use and dose/ administration frequency:
Your baby's doctor will prescribe the right amount of KAFESIT based on your baby's weight.

The starting dose is 20 mg per kg body weight (equivalent to 1 ml per kg body weight).

The maintenance dose is 5 mg per kg body weight (equivalent to 0.25 ml per kg body weight) every 24 hours.

Your baby's doctor will decide exactly how long your baby must continue therapy with KAFESIT.

If your baby has 5 to 7 days without apnea attacks, the doctor will stop the treatment.

Route and method of administration:
KAFESIT will be infused by controlled intravenous infusion (the infusion of medicine directly into a vein), using a syringe infusion pump or other metered infusion device. This method is also known as “a drip”.

It may be needed that your doctor decides to check the levels of caffeine in a blood test periodically throughout treatment to avoid toxicity.

Doses may be administered by oral administration.

If it will be administered orally, doses may be given orally or through a feeding tube every 24 hours.

Different age groups:
Use in children:
KAFESIT is intended for use in newborn infants.

Use in elderly:
No data are available.

Special usage condition
Renal/liver failure:
KAFESIT should be used with caution in renal/liver failure.

If you have the impression that the effect of KAFESIT is too strong or too weak, talk to your doctor or pharmacist.

If you have taken more KAFESIT than you should:
Your baby may experience fever, rapid breathing (tachypnea), jitteriness, muscular tremor, vomiting, high blood levels of sugar (hyperglycemia), low blood levels of potassium (hypokalemia), high blood levels of certain chemicals (urea), elevated number of certain cells (leukocyte) in blood and seizures if he/she receives more caffeine citrate than he/she should. In the event of this happening treatment with KAFESIT should be stopped immediately and your baby’s doctor should treat the overdose.

If you have any further questions on the use of this medicinal product, ask your baby’s doctor.

If you may have taken more KAFESIT than you should, talk to a doctor or pharmacist.

If you forget to take KAFESIT
Do not give double dose to your baby to balance the missed doses.

If you stop taking KAFESIT
As there is a risk for recurrence of apneas after cessation of caffeine citrate treatment monitoring of the patient should be continued for approximately one week.

4. Possible side effects?
Like all medicines, KAFESIT may cause side effects in some patients who are sensitive to the substances contained in KAFESIT.

However, it is difficult to distinguish them from frequent complications occurring in premature babies and complications due to the disease.

If any of the following occur stop using KAFESIT and IMMEDIATELY inform your doctor or go to the nearest emergency department:

Unknown
- Serious intestinal disease with bloody stools and regurgitation (necrotizing enterocolitis),

Side effects were listed as shown in the following categories:
Very common: may be seen at least 1 in 10 patients
Common: may be seen less than 1 in 10 patients but more than 1 in 100 patients
Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients
Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients
Very rare: may be seen less than 1 in 10.000 patients
Unknown: it cannot be estimated from the available data

While under treatment with KAFESIT, your newborn may experience some of the following reactions:

Common:
- Local inflammatory reactions at the infusion site
- Cardiac disorders such as rapid heartbeat (tachycardia)
- Changes of sugar in blood or serum (hyperglycemia)

Uncommon:
- Stimulation of central nervous system such as seizures
- Cardiac disorders such as irregular heartbeat (arrhythmia)

Rare:
- Allergic reactions

Unknown:
- Blood infections (sepsis),
- Changes of sugar in blood or serum (hypoglycemia), failure to grow, feeding intolerance,
- Stimulation of central nervous system irritability (hypersentivity to stimulus), nervousness and restlessness; brain injury,

- Deafness,
- Increase of urine flow, increase of urine sodium and calcium,
- Changes in blood tests (reduced levels of hemoglobin (oxygen carrying protein in the blood) after prolonged treatment and reduced thyroid hormone at the start of treatment)

These are very serious side effects. Emergency medical intervention may be required.
If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store KAFESIT
Keep in the original package and out of the reach and sight of children.

Store this medicine at room temperature under 25°C.

Vials of all parenteral solutions must be inspected visually for particulate matter prior to administration. After opening the vials, the medicinal product should be used immediately.

Use in accordance with expire date.

Do not use KAFESIT after the expiry date.

Do not use KAFESIT if you notice deterioration on product and/or packaging.

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