



# Summary of Investigation Results

## Magnesium sulfate/glucose, magnesium sulfate (indicated for eclampsia)

July 20, 2021

### Non-proprietary name

- a., b. Magnesium sulfate hydrate/glucose
- c. Magnesium sulfate hydrate

### Branded name (Marketing authorization holder)

- a. Magsent Injection 100 mL, Magsent Injection Syringe 40 mL (Aska Pharmaceutical Co., Ltd.)
- b. Magnesol for Intravenous Injection 20 mL (Aska Pharmaceutical Co., Ltd.)
- c. Magnesium Sulfate Hydrate "NikP" (Nichi-Iko Pharmaceutical Co., Ltd.)

### Indications

- a.
  - Inhibition of uterine contractions in threatened premature labour
  - Prophylaxis and treatment of eclampsia in severe hypertensive disorders of pregnancy
- b. Prophylaxis and treatment of eclampsia in severe hypertensive disorders of pregnancy
- c. Constipation (oral dosage form)
  - Cholelithiasis (infusion via duodenal tube)
  - Hypomagnesaemia (injection)
  - Eclampsia (injection)
  - Tachyarrhythmia (injection)

### **Summary of revisions**

a.

A statement should be added to the Pregnant Women section that rickets-like bone lesion may be identified in neonates at birth with prolonged administration of this drug during pregnancy.

b.

A statement should be added to the Use during Pregnancy, Delivery or Lactation section that rickets-like bone lesion may be identified in neonates at birth with prolonged administration of this drug during pregnancy.

c.

A statement should be added to the Use during Pregnancy, Delivery or Lactation section that rickets-like bone lesion may be identified in neonates at birth with prolonged administration of this drug during pregnancy.

### **Investigation results and background of the revision**

Cases of rickets-like bone lesion have been reported in neonates born to patients treated with magnesium sulfate/glucose in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

In all the cases reported in Japan for which a causal relationship between the drug and event was reasonably possible, the mother was on prolonged (18 to 71 days) treatment with magnesium sulfate/glucose. It was decided that the shortest duration in these cases should be added for an example of prolonged administration.

### **Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years**

Cases involving rickets-like bone lesion

a.

1 case has been reported to date. (A causal relationship between the drug and event was reasonably possible for this case.)

No patient mortalities have been reported to date.

b.

No cases have been reported to date.

c.



*This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

No cases have been reported to date.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).