March 2023

Public assessment summary report

Name of the Finished Pharmaceutical Product	Magnesium sulfate-Kalceks 500 mg/ml solution for injection
Manufacturer of the Finished Product	MSD International GmbH Ballydine, Kilsheelan, Clonmel, Country Tipperary Ireland
License holder	MAS KALCEKS Krustpils iela 53, Rīga, LV-1057, Latvia
Active Pharmaceutical Ingredient (API)	magnesium sulfate heptahydrate

1. Introduction

Based on review of quality, safety and efficacy data through the Abbreviated approval procedure, the authority granted a marketing authorization for Magnesium sulfate-Kalceks 500 mg/ml solution for injection.

Magnesium sulfate-Kalceks is indicated for: treatment of women with eclampsia; prevention of eclampsia in women with severe pre-eclampsia; prevention of cerebral palsy in the infant in women at risk of imminent preterm birth before 32 weeks of gestation

2. Assessment of quality

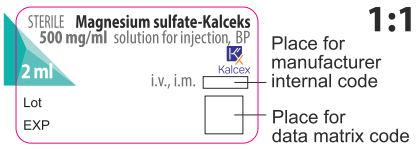
GMP compliance of the API manufacture was demonstrated by document review. The necessary waiver for cGMP of the finished pharmaceutical product has been carried out. Marketing authorization was granted by the stringent regulatory authority (SRA) and appropriate verification of marketing authorization was performed.

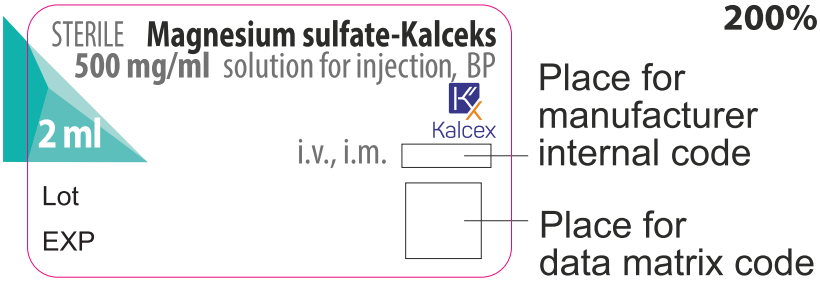
Stability testing:
It is confirmed that the finished product stability studies were conducted in the container closure system proposed for the marketing of the product in accordance with the current medicine registration guideline of Ethiopia. The packaged product was stored at the long term condition of 30ºC/75% RH and at the accelerated condition of 40°C/75%RH. The batches were packaged in 100 cc HDPE bottle with 6 g desiccant. The packaging components used are the same as those for proposed commercial package for the marketed product. Based on the data presented, a shelf life of 36 months was proposed.

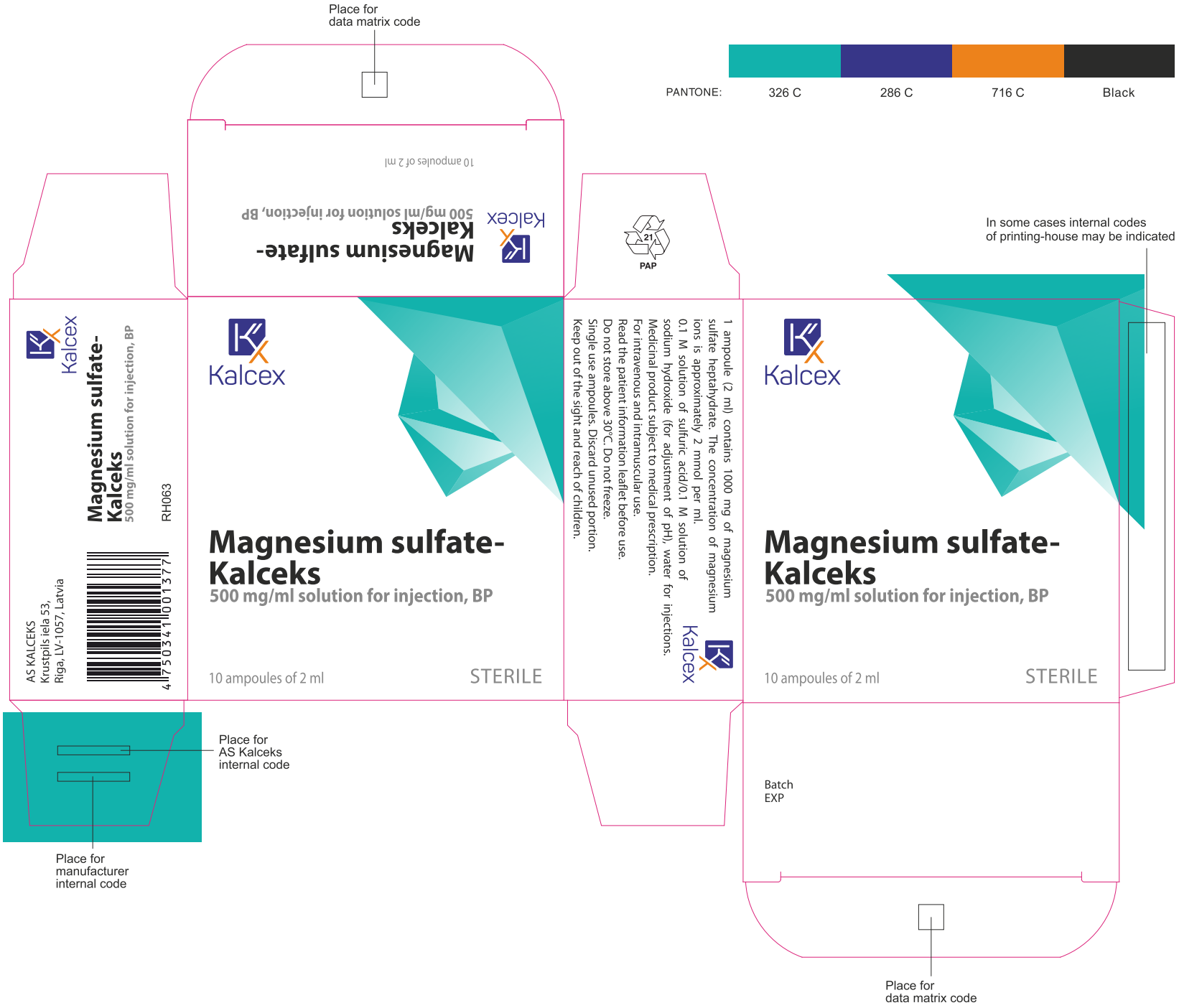
3. Conclusion

Based on assessment of administrative and technical document, it is considered that the benefit–risk profile of Magnesium sulfate-Kalecks , manufactured by HBM Pharma s.r.o Sklabinska 30,036 80 Martin is acceptable for the above mentioned indication.


PANTONE:
326 C
286 C
716 C
Black


STERILE Magnesium sulfate-Kalceks
500 mg/ml solution for injection, BP
2 ml
Kalcex
i.v., i.m.
Lot
EXP
1:1
Place for manufacturer internal code
Place for data matrix code


STERILE Magnesium sulfate-Kalceks
500 mg/ml solution for injection, BP
2 ml
Kalcex
i.v., i.m.
Lot
EXP
200%
Place for manufacturer internal code
Place for data matrix code


Place for
data matrix code
PANTONE:
326 C
286 C
716 C
Black
10 ampoules of 2 ml
Magnesium sulfate-
Kalceks
500 mg/ml solution for injection, BP
Kalcex
21
PAP
In some cases internal codes
of printing-house may be indicated
Kalcex
Magnesium sulfate-
Kalceks
500 mg/ml solution for injection, BP
RH063
AS KALCEKS
Krustpils iela 53,
Riga, LV-1057, Latvia
4750341001377
Kalcex
Magnesium sulfate-
Kalceks
500 mg/ml solution for injection, BP
10 ampoules of 2 ml
STERILE
1 ampoule (2 ml) contains 1000 mg of magnesium sulfate heptahydrate. The concentration of magnesium ions is approximately 2 mmol per ml.
0.1 M solution of sulfuric acid/0.1 M solution of sodium hydroxide (for adjustment of pH), water for injections.
Medicinal product subject to medical prescription.
For intravenous and intramuscular use.
Read the patient information leaflet before use.
Do not store above 30°C. Do not freeze.
Single use ampoules. Discard unused portion.
Keep out of the sight and reach of children.
Kalcex
Kalcex
Magnesium sulfate-
Kalceks
500 mg/ml solution for injection, BP
10 ampoules of 2 ml
STERILE
Batch
EXP
Place for
AS Kalceks
internal code
Place for
manufacturer
internal code
Place for
data matrix code