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.

Summary of investigation results

Palivizumab (genetical recombination)

September 12, 2017

Non-proprietary name

Palivizumab (genetical recombination)

Brand name (Marketing authorization holder)

Synagis Liquid 50 mg, 100 mg for Intramuscular Injection (AbbVie G.K.)

Indications

Prevention of serious lower respiratory tract diseases caused by RSV (respiratory syncytial virus) infection in the following neonates and infants

At an early stage of the epidemic of RSV infection:

- Neonates and infants aged ≤12 months who were born prematurely at ≤28 weeks gestational age
- Neonates and infants aged ≤6 months who were born prematurely at 29-35 weeks gestational age
- Neonates and infants aged ≤24 months who were treated for bronchopulmonary dysplasia (BPD) within the past 6 months
- Neonates and infants aged ≤24 months who have congenital heart disease (CHD) with abnormality in hemodynamics
- Neonates and infants aged ≤24 months associated with immunodeficiency
- Neonates and infants aged ≤24 months who have Down's syndrome

Summary of revision

"Thrombocytopenia" should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of thrombocytopenia have been reported in patients treated with palivizumab

(genetical recombination) in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan (since FY 2014)

A total of 4 cases associated with thrombocytopenia have been reported (including 1 case for which a causal relationship to the product could not be ruled out). No fatality has been reported.