

## Summary of Investigation Results

### Sulfamethoxazole/trimethoprim

|                        |   |   |
|------------------------|---|---|
| Non-proprietary name   | Non-proprietary name  | Brand name<br>(marketing authorization holder)  |
| Brand name             | Sulfamethoxazole/trimethoprim   | (1) Baktar Combination Tablets, Baktar mini Combination Tablets, Baktar Combination Granules (Shionogi Pharma Co., Ltd.), Bactramin Combination Tablets, Bactramin Combination Granules (TAIYO Pharma Co., Ltd.), and the others.<br>(2) Bactramin for Injection (TAIYO Pharma Co., Ltd.) |
| Japanese market launch | Baktar Combination Tablets, Bactramin Combination Tablets: June 1976<br>Baktar Combination Granules, Bactramin Combination Granules: September 1981<br>Bactramin for Injection: December 1993<br>Baktar mini Combination Tablets: December 2021   |   |
| Indications            | <p>(1) &lt; Baktar Combination Tablets, Baktar mini Combination Tablets, Baktar Combination Granules, Bactramin Combination Tablets, Bactramin Combination Granules &gt;</p> <p>○ Common infection</p> <p>&lt; Applicable microorganisms &gt;</p> <p>Sulfamethoxazole/trimethoprim-sensitive <i>Enterococcus</i> spp., <i>Escherichia coli</i>, <i>Shigella</i>, <i>Salmonella typhi</i>, <i>Salmonella paratyphi</i>, <i>Citrobacter</i> spp., <i>Klebsiella</i> spp., <i>Enterobacter</i> spp., <i>Proteus</i> spp., <i>Morganella morganii</i>, <i>Providencia rettgeri</i>, <i>Haemophilus influenzae</i></p> <p>&lt; Applicable conditions &gt;</p> <p>Pneumonia, secondary infection of chronic respiratory lesions, complicated cystitis, pyelonephritis, infectious enteritis, typhoid, paratyphoid</p> <p>○ Treatment and prophylaxis of pneumocystis pneumonia</p> <p>&lt; Applicable microorganisms &gt;</p> <p><i>Pneumocystis jirovecii</i></p> <p>&lt; Applicable conditions &gt;</p> <p>Pneumocystis pneumonia, prophylaxis of pneumocystis pneumonia</p> <p>(2) &lt; Bactramin for Injection &gt;</p> |   |

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|---|---|
|   | <p>&lt; Applicable microorganisms &gt;<br/> <i>Pneumocystis carinii</i><br/>         &lt; Applicable conditions &gt;<br/>         Carinii pneumonia</p>   |
| Summary of revisions  | "Acute generalised exanthematous pustulosis" should be added to the 11.1 Clinically Significant Adverse Reactions section in the 11. ADVERSE REACTIONS.   |
| Investigation results and background of the revision  | Cases involving acute generalised exanthematous pustulosis were evaluated. Cases in which a causal relationship between sulfamethoxazole/trimethoprim and acute generalised exanthematous pustulosis was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary. |
| Reference:<br>Number of cases* involving acute generalised exanthematous pustulosis reported in Japan | A total of 12 cases have been reported to date (including 4 cases in which a causal relationship between the drug and the event was reasonably possible).<br>No deaths have been reported to date.  |

\*: Among cases collected in the PMDA's safety database for drugs, cases describing pustule observation were extracted from cases reported with "PT: "Acute generalised exanthematous pustulosis" (MedDRA ver. 28.1).

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).