



# Summary of investigation results

## Infliximab

Aug 6, 2014

### Non-proprietary Name

Infliximab (genetical recombination) (including follow-on biologics/biosimilars)

### Brand Name (Marketing Authorization Holder)

REMICADE for intravenous infusion 100 (Mitsubishi Tanabe Pharma Corporation) and the others

### Indications

- The following diseases that are not adequately responsive to conventional therapies:
  - Rheumatoid arthritis (including prevention of structural joint damage)
  - Refractory Behcet's uveoretinitis
  - Psoriasis vulgaris, psoriatic arthropathy, pustular psoriasis, erythrodermic psoriasis
  - Ankylosing spondylitis
- Treatment or maintenance therapy of Crohn's disease in the following patients (limited to patients who have had an inadequate response to conventional therapy):
  - Patients with moderately to severely active Crohn's disease
  - Patients with external fistula
- Treatment of moderately to severely ulcerative colitis (limited to patients who have had an inadequate response to conventional therapy)

### Summary of revision

‘Rhabdomyolysis’ should be added in Clinically significant adverse reactions section.

### Background of the revision and investigation results

Cases of Rhabdomyolysis have been reported in patients treated with infliximab in Japan and foreign countries. Following an investigation result based on opinions of expert advisors and



**Pharmaceuticals and Medical Devices Agency**

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available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

**The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan**  
A Rhabdomyolysis-associated case, in which causality could not be ruled out, has been reported. No fatality has been reported.

**Pharmaceuticals and Medical Devices Agency**

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