



Summary of investigation results

Patch test products containing gold (I) sodium thiosulfate

July 4, 2017

Non-proprietary name

Patch test products containing gold (I) sodium thiosulfate

Ingredients

See Attachment

Brand name (Marketing authorization holder)

Patch Test Panel (S) (Sato Pharmaceutical Co., Ltd.)

Indications

Identification of allergens in allergic skin diseases

Summary of revision

Precaution against reactions to gold (I) sodium thiosulfate should be added to the Important Precautions section, along with a statement that patients should be instructed to visit a medical institution if they have sensitization or late positive reactions after the test results are determined.

Background of the revision and investigation results

Cases of sensitization to gold (I) sodium thiosulfate have been reported in patients treated with patch test products containing gold (I) sodium thiosulfate in Japan. Considering the data published in the literature, investigation results 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

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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.

Japan

A total of 7 cases associated with sensitization to gold (I) sodium thiosulfate have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.



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Attachment

Ingredients
Nickel sulphate, wool alcohols, fradiomycin sulfate, potassium dichromate, ethyl aminobenzoate, dibucaine hydrochloride, tetracaine hydrochloride, α -amyl cinnamaldehyde, isoeugenol, cinnamaldehyde, eugenol, cinnamyl alcohol, hydroxycitronellal, geraniol, oak moss, colophony, methyl parahydroxybenzoate, ethyl parahydroxybenzoate, propyl parahydroxybenzoate, butyl parahydroxybenzoate, benzyl parahydroxybenzoate, balsam of Peru, gold (I) sodium thiosulfate, cobalt chloride, <i>p-tert</i> -butylphenol formaldehyde resin, epoxy resin, diphenylguanidine, zinc diethyldithiocarbamate, zinc dibutyldithiocarbamate, <i>N</i> -isopropyl- <i>N</i> -phenyl paraphenylenediamine, <i>N</i> -cyclohexyl- <i>N</i> -phenyl paraphenylenediamine, <i>N,N</i> -diphenyl paraphenylenediamine, 5-chloro-2-methyl-4-isothiazolin-3-one, 2-methyl-4-isothiazolin-3-one, mercaptobenzothiazole, paraphenylenediamine, <i>N</i> -hydroxymethylsuccinimide, morpholinylmercaptobenzothiazole, <i>N</i> -cyclohexylbenzothiazylsulphenamide, dibenzothiazyl disulfide, thimerosal, tetramethylthiuram monosulfide, tetramethylthiuram disulfide, disulfiram, dipentamethylene thiuram disulfide